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Presidential Documents

Title 3—

The President

Memorandum of July 16, 1997

Implementation of Revised Air Quality Standards for Ozone and Particulate Matter

Memorandum for the Administrator of the Environmental Protection Agency

I have approved the issuance of new air quality standards to provide important new health protection for all Americans by further controlling pollution from ozone and particulate matter. These new standards promise to improve the lives of millions of Americans in coming years.

Consistent with my Administration's approach to regulatory decision making, I also want to ensure that these new standards are implemented in a common sense, cost-effective manner. It is critically important that these standards be implemented in the most flexible, reasonable, and least burdensome manner, and that the Federal Government work with State and local governments and other interested parties to this end.

I have determined that there are certain essential elements of an approach to implementation that will accomplish these goals. I direct you to use the following elements when implementing the new air quality standards:

1. Implementation of the air quality standards is to be carried out to maximize common sense, flexibility, and cost effectiveness;

2. Implementation shall ensure that the Nation continues its progress toward cleaner air by respecting the agreements already made by States, communities, and businesses to clean up the air, and by avoiding additional burdens with respect to the beneficial measures already underway in many areas. Implementation also shall be structured to reward State and local governments that take early action to provide clean air to their residents; and to respond to the fact that pollution travels hundreds of miles and crosses many State lines;

3. Implementation shall ensure that the Environmental Protection Agency (''Agency'') completes its next periodic review of particulate matter, including review by the Clean Air Scientific Advisory Committee, within 5 years of issuance of the new standards, as contemplated by the Clean Air Act. Thus, by July 2002, the Agency will have determined, based on data available from its review, whether to revise or maintain the standards. This determination will have been made before any areas have been designated as ''nonattainment'' under the $PM_{2.5}$ standards and before imposition of any new controls related to the $PM_{2.5}$ standards; and

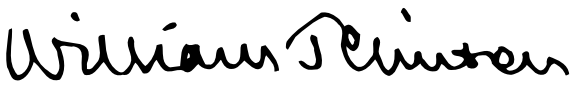
4. Implementation is to be accomplished with the minimum amount of paperwork and shall seek to reduce current paperwork requirements wherever possible.

Excellent preliminary work on the strategy for carrying out these implementation principles has been accomplished by an interagency Administration group and I commend that group for these important efforts. The group's work is set out in the attached plan, which is hereby incorporated by reference.

In order for the implementation of these standards to proceed in accordance with the goals I have established, I hereby direct you, in consultation with all affected agencies and parties, to undertake the steps appropriate under law to carry out the attached plan and to complete all necessary guidance and rulemaking no later than December 31, 1998.

This memorandum is for the purposes of internal Administration management only, and is not judicially reviewable.

You are authorized and directed to publish this determination and plan in the **Federal Register.**



THE WHITE HOUSE
Washington, July 16, 1997.

Implementation Plan for Revised Air Quality Standards

An interagency Administration group has discussed and evaluated approaches for the common sense, flexible, and cost effective implementation of the revised National Ambient Air Quality Standards (NAAQS) for ozone and particulate matter (PM). This document reflects the preliminary work by that group on a strategy for implementing these health-based standards consistent with the principles discussed by President Clinton in his announcement of the standards. The Environmental Protection Agency (EPA) will continue to work with other Federal agencies, State and local governments, small businesses, industry, and environmental and public health groups to fully develop and implement this strategy.

This implementation plan provides a road map for areas to attain the standards and protect public health without sacrificing economic growth. The goals of the plan are to: 1) maintain the progress currently being made toward cleaner air and respect the agreements and technological progress already made by communities and businesses to pursue clean air; 2) reward State and local governments and businesses that take early action to reduce air pollution levels through cost-effective approaches; 3) respond to the fact that pollution can travel hundreds of miles and cross many State lines; 4) work with the States to develop control programs which employ regulatory flexibility to minimize economic impacts on businesses large and small to the greatest possible degree consistent with public health protection; 5) minimize planning and regulatory burdens for State and local governments and businesses where air quality problems are regional, not local, in nature; 6) ensure that air quality planning and related Federal, State, and local planning are coordinated; and 7) recognize the substantial lead time necessary for State and local governments and businesses to plan for and meet standards for a new indicator of PM.

The Clean Air Act (CAA) requires the EPA to set air quality standards to protect the public health and the environment without consideration of costs. The 1997 revisions to the NAAQS for ground level ozone and PM fulfill this requirement. However, the Act recognizes that the EPA and the States must work together to develop cost-effective, flexible, and fair implementation plans if the standards are to be met as expeditiously as practicable.

There are a number of important linkages between these pollutants. There is also a linkage between these pollutants and their precursors and regional haze problems. Promulgation of the two standards simultaneously provides a more complete description of the health and environmental effects associated with two of the major components of air pollution. It can help States and local areas better manage their air quality by focusing on the common precursors of both pollutants and provides the opportunity to work jointly with industry to address common sources of multiple air pollutants in a comprehensive manner. This will lead to more effective and efficient protection of public health and the environment.

In addition to the interagency process, the EPA has been soliciting other input. While the review of the ozone and PM NAAQS was underway, the EPA convened a group of air quality experts representing industry, environmental, and public health groups; State and local governments; other Federal agencies; and academia under the Federal Advisory Committee Act (FACA). This group was charged by the Administrator of the EPA to develop innovative, flexible, and cost-effective implementation strategies that utilize a mix of control measures to address ozone, PM, and regional haze. This group will continue working with the EPA to further develop this strategy.

In addition, all Federal agencies will continue to do their part in carrying out the Federal responsibilities in the State/Federal partnership that has been so successful in improving air quality in the United States. In addition, the EPA, in partnership with the other Federal agencies, has developed

an interagency research program that is described in Appendix 1 for the coordination of future research on both ground level ozone and PM.

IMPLEMENTATION OF OZONE STANDARD

Phase-out of 1-hour standard

The revised ozone standard is intended to replace the current 1-hour standard with an 8-hour standard. However, the 1-hour standard will continue to apply to areas not attaining it for an interim period to ensure an effective transition to the new 8-hour standard.

Subpart 2 of part D of Title I of the CAA addresses the requirements for different classifications of nonattainment areas that do not meet the current 1-hour standard (i.e., marginal, moderate, serious, and severe). These requirements include such items as mandatory control measures, annual rate of progress requirements for emission reductions, and offset ratios for the emissions from new or modified stationary sources. These requirements have contributed significantly to the improvements in air quality since 1990. Although the EPA initially offered an interpretation of the CAA in the proposed Interim Implementation Policy (IIP) (61 FR 65764, December 13, 1996) under which the provisions of Subpart 2 would not apply to existing ozone nonattainment areas once a new ozone NAAQS is promulgated, the EPA has reconsidered that interpretation after receiving comments on the proposed IIP. Based on EPA's legal review, the Agency has concluded that Subpart 2 should continue to apply as a matter of law for the purpose of achieving attainment of the current 1-hour standard. Once an area attains the 1-hour standard, those provisions will no longer apply and the area's implementation of the new 8-hour standard would be governed only by the provisions of Subpart 1 of Part D of Title I.

To streamline the process and minimize the burden on existing nonattainment areas, the 1-hour standard will cease to apply to an area upon a determination by the EPA that an area has attained air quality that meets the 1-hour standard. In light of the implementation of the new 8-hour standard, which is more stringent than the existing 1-hour standard, States will not have to prepare maintenance plans for those areas that attain the 1-hour standard. Within 90 days, the EPA will publish an action identifying existing nonattainment areas and maintenance areas to which the 1-hour standard will cease to apply because they have attained the 1-hour standard.

For areas where the air quality does not currently attain the 1-hour standard, the 1-hour standard will continue in effect. The provisions of Subpart 2 would also apply to designated nonattainment areas until such time as each area has air quality meeting the 1-hour standard. At that time, the EPA will take action so that the 1-hour standard no longer applies to such areas. In any event, the ''bump-up'' provisions of Subpart 2, which require areas not attaining the standard by the applicable attainment date to be reclassified to the next higher classification, will not be triggered by the failure of any area to meet the new 8-hour standard. The purpose of retaining the current standard is to ensure a smooth legal and practical transition to the new standard.

Implementation of New 8-hour Ozone standard

This section discusses the general timeline for implementing the 8-hour standard, the importance of regional approaches to address ozone and options for classifying and designating areas relative to the 8-hour ozone NAAQS.

General Timeline

Following promulgation of a revised NAAQS, the Clean Air Act provides up to 3 years for State governors to recommend and the EPA to designate areas according to their most recent air quality. In addition, States will have up to 3 years from designation to develop and submit State Implementation Plans (SIPs) to provide for attainment of the new standard. Under

this approach, areas would be designated as nonattainment for the 8-hour standard by 2000 and would submit their nonattainment SIPs by 2003. The Act allows up to 10 years plus two 1-year extensions from the date of designation for areas to attain the revised NAAQS.

Regional Strategy

Ozone is a pollutant that travels great distances and it is increasingly clear that it must be addressed as a regional problem. For the past 2 years the EPA has been working with the 37 most eastern States through the Ozone Transport Assessment Group (OTAG) in the belief that reducing interstate pollution will help all areas in the OTAG region attain the NAAQS. A regional approach can reduce compliance costs and allow many areas to avoid most traditional nonattainment planning requirements. The OTAG was sponsored by the Environmental Council of States, with the objective of evaluating ozone transport and recommending strategies for mitigating interstate pollution. The OTAG completed its work in June 1997 and forwarded recommendations to the EPA. Based on these recommendations, in September 1997, the EPA will propose a rule requiring States in the OTAG region that are significantly contributing to nonattainment or interfering with maintenance of attainment in downwind States to submit SIPs to reduce their interstate pollution. The EPA will issue the final rule by September 1998.

If the States choose to establish a regional emission cap-and-trade system, modeled on the current acid rain program, reductions can be obtained at a lower cost. The EPA will encourage and assist the States to develop and implement such a program. Most important, based on the EPA's review of the latest modeling, a regional approach, coupled with the implementation of other already existing State and Federal Clean Air Act requirements, will allow the vast majority of areas that currently meet the 1-hour standard but would not otherwise meet the new 8-hour standard to achieve healthful air quality without additional local controls.

Areas in the OTAG region that would exceed the new standard after the adoption of the regional strategy, including areas that do not meet the current 1-hour standard, will benefit as well because the regional NO_X program will reduce the extent of additional local measures needed to achieve the 8-hour standard. In many cases these regional reductions may be adequate to meet CAA progress requirements for a number of years, allowing areas to defer additional local controls.

Transitional Classification

For areas that attain the 1-hour standard but not the new 8-hour standard, the EPA will follow a flexible implementation approach that encourages cleaner air sooner, responds to the fact that ozone is a regional as well as local problem, and eliminates unnecessary planning and regulatory burdens for State and local governments. A primary element of the plan will be the establishment under Section 172(a)(1) of the CAA of a special ''transitional'' classification for areas that participate in a regional strategy and/or that opt to submit early plans addressing the new 8-hour standard. Because many areas will need little or no additional new local emission reductions to reach attainment, beyond those reductions that will be achieved through the regional control strategy, and will come into attainment earlier than otherwise required, the EPA will exercise its discretion under the law to eliminate unnecessary local planning requirements for such areas. The EPA will revise its rules for new source review (NSR) and conformity so that States will be able to comply with only minor revisions to their existing programs in areas classified as transitional. During this rulemaking, the EPA will also reexamine the NSR requirements applicable to existing nonattainment areas, in order to deal with issues of fairness among existing and new nonattainment areas. The transitional classification will be available for any area attaining the 1-hour standard but not attaining the 8-hour standard as of the time the EPA promulgates designations for the 8-hour

standard. Areas will follow the approaches described below based on their status.

(1) Areas attaining the 1-hour standard, but not attaining the 8-hour standard, that would attain the 8-hour standard through the implementation of the regional NO_X transport strategy for the East.

Based on the OTAG analyses, areas in the OTAG region that can reach attainment through implementation of the regional transport strategy would not be required to adopt and implement additional local measures. When the EPA designates these areas under section 107(d), it will place them in the new transitional classification if they would attain the standard through implementation of the regional transport strategy and are in a State that by 2000 submits an implementation plan that includes control measures to achieve the emission reductions required by the EPA's rule for States in the OTAG region. This is 3 years earlier than an attainment SIP would otherwise be required. The EPA anticipates that it will be able to determine whether such areas will attain based on the OTAG and other regional modeling and that no additional local modeling would be required.

(2) Areas attaining the 1-hour standard but not attaining the 8-hour standard for which a regional transport strategy is not sufficient for attainment of the 8-hour standard.

To encourage early planning and attainment for the 8-hour standard, the EPA will make the transitional classification available to areas not attaining the 8-hour standard that will need additional local measures beyond the regional transport strategy, as well as to areas that are not affected by the regional transport strategy, provided they meet certain criteria. To receive the transitional classification, these areas must submit an attainment SIP prior to the designation and classification process in 2000. The SIP must demonstrate attainment of the 8-hour standard and provide for the implementation of the necessary emissions reductions on the same time schedule as the regional transport reductions. The EPA will work with affected areas to develop a streamlined attainment demonstration. By submitting these attainment plans earlier than would have otherwise been required, these areas would be eligible for the transitional classification and its benefits and would achieve cleaner air much sooner than otherwise required.

(3) Areas not attaining the 1-hour standard and not attaining the 8-hour standard

The majority of areas not attaining the 1-hour standard have made substantial progress in evaluating their air quality problems and developing plans to reduce emissions of ozone-causing pollutants. These areas will be eligible for the transitional classification provided that they attain the 1-hour standard by the year 2000 and comply with the appropriate provisions of section (1) or (2) above depending upon which conditions they meet.

Areas not Eligible for the Transitional Classification

For these areas, their work on planning and control programs to meet the 1-hour standard by their current attainment date (e.g., 2005 for Philadelphia and 2007 for Chicago) will take them a long way toward meeting the 8-hour standard. While the additional local reductions that they will need to achieve the 8-hour standard must occur prior to their 8-hour attainment date (e.g., 2010), for virtually all areas the additional reductions needed to achieve the 8-hour standard can occur after the 1-hour attainment date. This approach allows them to make continued progress toward attaining the 8-hour standard throughout the entire period without requiring new additional local controls for attaining the 8-hour standard until the 1-hour standard is attained. These areas, however, will need to submit an implementation plan within 3 years of designation as nonattainment for the new standard for achieving the 8-hour standard. Such a plan can rely in large part on measures needed to attain the 1-hour standard. For virtually all of these areas, no additional local control measures beyond those needed to meet the requirements of Subpart 2 and needed in response to the regional

transport strategy would be required to be implemented prior to their applicable attainment date for the 1-hour standard. Nonattainment areas that do not attain the 1-hour standard by their attainment date would continue to make progress in accordance with the requirements of Subpart 2; the control measures needed to meet the progress requirements under Subpart 2 would generally be sufficient for meeting the control measure and progress requirements of Subpart 1 as well.

IMPLEMENTATION OF PARTICULATE MATTER STANDARDS

As required under the Act, within the next 5 years the EPA will complete the next periodic review of the PM criteria and standards, including review by the CASAC. As with all NAAQS reviews, the purpose is to update the pertinent scientific and technical information and to determine whether it is appropriate to revise the standards in order to protect the public health with an adequate margin of safety or to protect the public welfare. Although the EPA has concluded that the current scientific knowledge provides a strong basis for the revised PM_{10} and new $PM_{2.5}$ standards, there remain scientific uncertainties associated with the health and environmental effects of PM and the means of reducing them.

The following steps discussed below and in Appendix 1, Interagency Research Program, will address these concerns. First, recognizing the importance of developing a better understanding of the effects of fine particles on human health, including their causes and mechanisms, as well as the species and sources of $PM_{2.5}$, the EPA will continue to sponsor research, particularly in these areas. Second, the Administrator of the EPA will promptly initiate a new review of the scientific criteria on the effects of airborne particles on human health and the environment. Within 90 days, the EPA will develop and provide to CASAC a plan and proposed schedule for this review to assure that the review is completed within 5 years. The plan and schedule will be published in the **Federal Register**. Thus, by July 2002, the Agency will have determined, based on data available from its review, whether to revise or maintain the standards. This determination will have been made before any areas have been designated nonattainment under the $PM_{2.5}$ standards and before imposition of any new controls related to the $PM_{2.5}$ standards.

Implementation of New $PM_{2.5}$ NAAQS

As set forth in the EPA's final action regarding PM, the EPA is establishing a new indicator for fine particles (i.e., $PM_{2.5}$) and promulgating new $PM_{2.5}$ standards. Monitoring and planning will be required before control measures to address these standards would be required. Therefore, the first priority for implementing them is establishment of a comprehensive monitoring network to determine ambient fine particle concentrations across the country. The monitoring network will help the EPA and the States determine which areas do not meet the new air quality standards, what are the major sources of $PM_{2.5}$ in various regions, and what action is needed to clean up the air. The EPA and the States will consult with affected stakeholders on the design of the network and will then establish the network, which will consist of approximately 1,500 monitors. All monitors will provide for limited speciation, or analysis of the chemical composition, of the particles measured. At least 50 of the monitors will provide for a more comprehensive speciation of the particles. The EPA will work with states to deploy the $PM_{2.5}$ monitoring network. Based on the ambient monitoring data we have seen to date, these would generally not include agricultural areas. The EPA will fund the cost of purchasing the monitors, as well as the cost of analyzing particles collected at the monitors to determine their chemical composition.

Because the EPA is establishing standards for a new indicator for PM (i.e., $PM_{2.5}$), it is critical to develop the best information possible before attainment and nonattainment designation decisions are made. Three calendar years of Federal reference method monitoring data will be used to determine

whether areas meet or do not meet the $PM_{2.5}$ standards. Three years of data will be available from the earliest monitors in the spring of 2001, and 3 years of data will be available from all monitors in 2004. Following this monitoring schedule and allowing time for data analysis, Governors and the EPA will not be able to make the first determinations as to which areas should be designated nonattainment until at least 2002, 5 years from now. The Clean Air Act, however, requires that the EPA make designation determinations (i.e., attainment, nonattainment, or unclassifiable) within 2 to 3 years of revising a NAAQS. To fulfill this requirement, in 1999 the EPA will issue ''unclassifiable'' designations for $PM_{2.5}$. These designations will not trigger the planning or control requirements of part D of Title I of the Act.

When the EPA designates $PM_{2.5}$ nonattainment areas pursuant to the Governors' recommendations beginning in 2002, areas will be allowed 3 years to develop and submit to the EPA pollution control plans showing how they will meet the new standards. Areas will then have up to 10 years from their redesignation to nonattainment to attain the $PM_{2.5}$ standards with the possibility of two 1-year extensions.

In developing strategies for attaining the $PM_{2.5}$ standards, it is important to focus on measures that decrease emissions that contribute to regional pollution. Available information indicates that nearly one-third of the areas projected not to meet the new $PM_{2.5}$ standards, primarily in the Eastern United States, could come into compliance as a result of the regional SO_2 emission reductions already mandated under the Clean Air Act's acid rain program, which will be fully implemented between 2000 and 2010. Similarly, the Grand Canyon Visibility Transport Commission, consisting of Western States and tribes, committed to reducing regional emissions of $PM_{2.5}$ precursors (sulfates, nitrates, and organics) to improve visibility across the Colorado Plateau.

As detailed $PM_{2.5}$ air quality data and data on the chemical composition of $PM_{2.5}$ in different areas become available, the EPA will work with the States to analyze regional strategies that could reduce $PM_{2.5}$ levels. If further cost-effective regional reductions will help areas meet the new standard, the EPA will encourage States to work together to use a cap-and-trade approach similar to that used to curb acid rain. This acid rain program delivered environmental benefits at a greatly reduced cost.

Given the regional dimensions of the $PM_{2.5}$ problem, local governments and local businesses should not be required to undertake unnecessary planning and local regulatory measures when the problem requires action on a regional basis. Therefore, as long as the States are doing their part to carry out regional reduction programs, the areas that would attain the $PM_{2.5}$ standards based on full implementation of the acid rain program would not face new local requirements. Early identification of other regional strategies could also assist local areas in completing their programs to attain the $PM_{2.5}$ standards after those areas have been designated nonattainment.

The EPA will also encourage States to coordinate their $PM_{2.5}$ control strategy development and efforts to protect regional visibility. Visibility monitoring and data analysis will support both $PM_{2.5}$ implementation and the visibility program.

Implementation of Revised PM_{10} NAAQS

In its rule, the EPA is revising the current set of PM_{10} standards. Given that health effects from coarse particles are still of concern, the overall goal during this transition period is to ensure that PM_{10} control measures remain in place to maintain the progress that has been achieved toward attainment of the current PM_{10} NAAQS (and which provides benefits for $PM_{2.5}$) and protection of public health.

To ensure that this goal is met, the existing PM_{10} NAAQS will continue to apply until certain critical actions by the EPA, and by States and local agencies, have been taken to sustain the progress already made. For areas

not attaining the existing PM_{10} NAAQS when the revised standards go into effect, those standards remain in effect until the EPA has completed a section 172(e) rulemaking to prevent backsliding. The EPA will propose this rulemaking in the Fall of 1997. For areas attaining the existing PM_{10} NAAQS, the EPA will retain the existing PM_{10} NAAQS until the State submits and the EPA approves the section 110 SIP which States are required to submit within 3 years of a NAAQS revision. Once those areas have an approved SIP, the EPA will take action so the standard no longer applies. In addition, the EPA will take action within 3 years to designate areas for the revised PM_{10} standards.

COST-EFFECTIVE IMPLEMENTATION STRATEGIES

There is a strong desire to drive the development of new technologies with the potential of greater emission reduction at less cost. It was agreed that $10,000 per ton of emission reduction is the high end of the range of reasonable cost to impose on sources. Consistent with the State's ultimate responsibility to attain the standards, the EPA will encourage the States to design strategies for attaining the PM and ozone standards that focus on getting low cost reductions and limiting the cost of control to under $10,000 per ton for all sources. Market-based strategies can be used to reduce compliance costs. The EPA will encourage the use of concepts such as a Clean Air Investment Fund, which would allow sources facing control costs higher than $10,000 a ton for any of these pollutants to pay a set annual amount per ton to fund cost-effective emissions reductions from non-traditional and small sources. Compliance strategies like this will likely lower the costs of attaining the standards through more efficient allocation, minimize the regulatory burden for small and large pollution sources, and serve to stimulate technology innovation as well.

ADDITIONAL FUTURE ACTIVITIES AND COORDINATION WITH OTHER FEDERAL DEPARTMENTS AND AGENCIES

The approaches outlined above for implementation of the current and new ozone standards will be developed in the future in much greater detail. In order to ensure that the final details are practical, incorporate common sense, and provide the appropriate steps toward cleaning the air, input is needed from many stakeholders such as representatives of State and local governments, industry, environmental groups, and Federal agencies. The EPA will continue seeking such advice from a range of stakeholders and, after evaluating their input, propose the necessary guidance to make these approaches work. Moreover, the EPA will continue to work with a number of Federal agencies to ensure that those agencies comply with these new standards in cost-effective, common sense ways. The guidance and rules (e.g., revisions to NSR and conformity) will be completed by the end of 1998.

The EPA will continue to work with the Small Business Administration (SBA) because small businesses are particularly concerned about the potential impact resulting from future control measures to meet the revised PM and ozone standards. The EPA, in partnership with SBA, will work with the States to include in their SIPs flexible regulatory alternatives that minimize the economic impact and paperwork burden on small businesses to the greatest possible degree consistent with public health protection.

The EPA and the Department of Defense will continue to work towards assuring that the CAA's general conformity provisions are applied appropriately so as to maintain the air quality benefits of this requirement consistent with the Department's goals for cost-saving consolidation of the defense infrastructure and the economic viability for civilian use of former military bases, in support of base realignment and closure activities.

In addition, understanding that critical training using smoke and obscurants must continue to ensure the training and readiness of the military, the EPA will work with the Department of Defense to develop a policy that ensures that a local area will not be redesignated to nonattainment solely on the basis of the use of obscurants or smoke for such purposes. While there is a need to keep the public informed of violations of air quality standards, if any were to occur, there is no need to curtail the training or limit it to certain weather conditions.

The EPA will also work closely with the Department of Agriculture and the Agriculture Air Quality Task Force on any agricultural issues associated with the ozone and PM standards. By establishing new standards for particulate matter smaller than 2.5 micrometers in diameter ($PM_{2.5}$), as opposed to tightening the existing standards for particles smaller than 10 micrometers (PM_{10}), the EPA is actually focusing regulatory attention away from farming and tilling issues. Indeed, soils and agriculture comprise a much smaller portion of the $PM_{2.5}$ problem than they do of the PM_{10} problem. The EPA will issue guidance to the States to ensure that in meeting the $PM_{2.5}$ standards they focus their control strategies on sources of fine particles, rather than coarse particles (those particles larger than $PM_{2.5}$).

Finally, the EPA will continue to work with the interagency group addressing fire and air quality issues. The EPA recognizes the inevitability of fire, and the important role of fire in natural systems. The interagency group will develop policies and practices to assure compatibility between fire and air quality programs consistent with public health, safety, and environmental protection.

Appendix 1

Interagency Research Program

The EPA has concluded that the current scientific knowledge provides a strong basis for the revised ozone and PM_{10} standards and the new $PM_{2.5}$ standards. However, for both pollutants there exist uncertainties about the health effects and their causes that can benefit from further study. The complex chemistry of their formation and the potential for the regional transport of their precursor pollutants and ozone and PM also needs to be better understood to design effective control strategies to reduce their concentrations in the ambient air. The research program is structured to prioritize those projects that ensure research activities are focused on high-priority topics and that the research carried out by various agencies is both complementary and timely. The EPA will reach out to form partnerships with the private sector and State and local governments in performing the research wherever possible.

Particulate Matter Research

As discussed elsewhere, the EPA will complete another full scientific and technical review of the PM standards by 2002. Simultaneous with the planning for the current criteria review in 1993, the EPA began a process of increasing emphasis on PM research. As discussed above, commenters on the proposed PM NAAQS also expressed significant concerns about the science. The steps discussed below are intended to address the concerns raised by the commenters.

Based on the recently completed comprehensive scientific review, the EPA is again reassessing its research priorities to address the most recent understanding of these uncertainties with the development of two documents, entitled PM Research Needs for Human Health Risk Assessment and ORD PM Research Program Strategy. These documents are designed to highlight significant health research needs and EPA/ORD's strategy to address a subset of those needs as well as research needs for implementing the standards. Both documents were reviewed by the Clean Air Scientific Advisory Committee (CASAC) in a November 1996 meeting, and are currently undergoing revisions to address CASAC comments.

These documents, in turn, will help to guide an expansion of an ongoing government-wide effort to target and coordinate Federal research on particulate matter. The EPA, in partnership with other Federal agencies, will develop a greatly expanded coordinated interagency PM research program. The program will contribute to expanding the science associated with particulate matter health effects, as well as developing improved monitoring methods and cost-effective mitigation strategies. For example, the Department of Health and Human Services is conducting research on respiratory disease and could undertake surveillance of PM-related health effects. Significant emphasis will be placed on coordinating research on health effects, biological mechanism causing effects, monitoring, source-receptor relationships, speciation of PM, identification of sources, control technologies and regional transport for particulate matter with corresponding research on ozone and other related pollutants including regional haze. To assist State and local efforts in completing planning requirements and reducing PM, the EPA will work cooperatively with the Department of Agriculture, Department of Defense, Department of Energy, Department of Transportation, and other affected Federal agencies to refine existing, limited analytical models for PM_{10} and to develop new reliable predictive models for $PM_{2.5}$.

Tropospheric (Ground Level) Ozone Research

To ensure that the ozone NAAQS and their implementation continue to be based on the best available science, the EPA will continue its research efforts on tropospheric or ground level ozone. As with the setting and implementation of virtually all health-based environmental standards, there remain scientific uncertainties associated with the effects of ozone and the means of reducing them. The EPA has participated in an intergovernmental

public/private partnership called the North American Research Strategy for Tropospheric Ozone (NARSTO) that involves a coordinated effort to identify and address key issues in the emissions, transport, and mitigation of photochemical pollutants. Further, with the completion of the ozone Criteria Document, the EPA has reassessed the uncertainties and research needs on the health and ecological effects of ozone at workshops held in March and May 1997, respectively. The EPA is currently developing a health and ecological effects research needs document for ozone, which will be submitted for review by CASAC.

In addition, the EPA will continue broader efforts to coordinate Federal research on tropospheric ozone. The public/private NARSTO partnership is a model cooperative effort already begun in the area of atmospheric processes and risk management. NARSTO's membership spans government, utilities and other industries, and the academic community—all following a single national research agenda. The EPA will also work in partnership with other Federal agencies to address research needs on ozone health and ecological effects. For example, the Department of Health and Human Services is conducting research on respiratory disease and could undertake surveillance of ozone-related health effects. These research efforts will be coordinated to ensure research activities are focused on high-priority topics and that the research carried out by various agencies is complementary. Significant emphasis will be placed on coordinating both health effects, monitoring, source-receptor, and control technologies for ozone with corresponding research on particulate matter and other related pollutants subject to significant regional transport.

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Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

RIN 3206–AH46

Federal Employees Health Benefits Program: Opportunities to Enroll and Change Enrollment

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is issuing final regulations to simplify and clarify the existing Federal Employees Health Benefits (FEHB) Program regulations concerning opportunities to enroll and change enrollment. These regulations will make it easier for employing offices to determine whether circumstances permit individuals to enroll or change enrollment, and will result in a reduced potential for error and improved customer service.

EFFECTIVE DATE: August 18, 1997.

FOR FURTHER INFORMATION CONTACT: Barbara Myers (202) 606–0004.

SUPPLEMENTARY INFORMATION: On July 9, 1996, OPM issued proposed regulations in the **Federal Register** (61 FR 35973) that would amend Part 890 to (1) organize the opportunities to enroll and change enrollment into separate sections for each category of enrollee, (2) group enrollment opportunities within each category by similar characteristics, such as change in employment status, or loss of health benefits coverage, (3) standardize timeframes for individuals to enroll or change enrollment, (4) locate effective date information within the paragraph that describes the enrollment or change opportunity, (5) clarify some opportunities by removing certain hard to define requirements that individuals must meet to become eligible to enroll or change, and (6) permit insurance carriers to determine incapacity of self-support for children over age 22 under certain conditions.

OPM received comments from six Government agencies, two insurance carriers, and one retired employees' association. While all of the commenters were in favor of the proposed regulations, some had specific areas of concern that we will address below. We have tried to list these issues in the same order as the regulations that they pertain to.

Two commenters recommended expanding the definition of ''appropriate request'' to include elections not to enroll, and to add the term ''processing office.'' We have expanded the definition of ''appropriate request'' to include elections not to enroll. We have also defined ''election not to enroll'' in the definitions section. We do not believe that adding the term ''processing office'' to the definition of ''appropriate request'' is necessary because the term ''employing office'' as defined in § 890.101 means the office with jurisdiction and responsibility for health benefits actions. This would include the processing office.

We are removing the definition of ''regular tour of duty'' because it no longer reflects the definition as set forth in § 610.102 of this chapter.

Several commenters had concerns with the new paragraph (c) that we are adding to § 890.103 that will give the employing office authority to retroactively correct enrollee enrollment code errors. This paragraph applies only to enrollment code errors made by the employee and therefore should not be combined with paragraphs (a) and (b) which concern administrative errors. In the past, agencies had no authority to correct enrollee enrollment code errors. The intent of the new paragraph is to give enrollees who discover that they made an enrollment code error an opportunity to have it corrected; we did not intend to give them the opportunity to change their election should they find that they are dissatisfied with their election. An enrollee who reports an enrollment code error beyond the specified time frame must wait until the next open season to correct the error. If an error was made by the employing office, then it would be an administrative error and would be subject to paragraphs (a) and (b) rather than this new paragraph (c).

One commenter believes that these regulations should require employees to furnish evidence of their eligibility to enroll or change enrollment. Employing offices have always been responsible for determining eligibility, and they may require whatever evidence they need to verify that an event actually occurred. In some cases, such as changes in employment status, the employing office has the information readily available; in others, such as documentation of a marriage, a move, or the loss of other group health insurance coverage, they can require additional evidence. Special regulatory language is not needed.

One commenter expressed concern about the reenrollment of an employee whose enrollment was terminated after 365 days of leave without pay status. When this employee returns to pay status, he or she may reenroll and the enrollment would normally take effect on the first day of the next pay period. However, if the employee is not in pay status in the pay period after the one in which he or she submitted the enrollment request, the enrollment could not take effect. If an employee's enrollment terminated after 365 days leave without pay, and the employee is not entitled to any further continuation of coverage because he or she has not had 4 consecutive months of pay status since exhausting the 365 days continuation of coverage in leave without pay, coverage terminates on the last day of his or her last pay period in pay status. There is no need for special regulatory language as this principle is reflected in § 890.304(a)(1)(v).

On July 22, 1996, OPM published interim regulations that require Federal agencies to provide employees entering leave without pay status, or whose pay is insufficient to cover their FEHB premium payments, written notice of their opportunity to continue their FEHB coverage (61 FR 37807). These employees have the option of continuing or terminating their FEHB coverage. Employees who elect to terminate their coverage may enroll upon their return to duty in a pay status in a position which provides eligibility for FEHB coverage. We have added a provision to paragraph 890.301(h)(1) of these final regulations that would reflect this enrollment opportunity.

One commenter expressed concern about our requirement that the effective date of an open season enrollment must follow a pay period during any part of which the employee is in pay status. This is not a new provision and we have made no change to the existing regulation. If an employee is in leave without pay status when an open season enrollment would normally take effect, the enrollment could not take effect until the employee returns to pay status.

One commenter suggested that we define changes in family status in the definitions section. We are concerned that it would be unnecessarily restrictive to specify in regulation the situations that we believe are changes in family status. We believe it is sufficient to continue to provide this information in our guidance in the FEHB Handbook for Personnel and Payroll Offices (formerly FPM Supplement 890–1). For the convenience of the reader, we will restate the examples of changes in family status given in the supplementary information of the proposed regulations, as follows: (1) Birth or acquisition of a child; (2) issuance of a court order specifically requiring an employee to enroll for his or her children or provide health benefits protection for them; (3) issuance or termination of a court order granting interlocutory divorce, limited divorce, legal separation, or separate maintenance to the enrollee or spouse; (4) entry into or discharge from military service of a spouse or of a child under age 22.

Two commenters suggest that we consider further changing the regulations to give the employing office discretion in determining effective dates of enrollment changes in certain situations. We do not favor making this change. We believe that specifying effective dates of coverage in regulation is easier to administer and assures that all enrollees and their family members are treated in a uniform manner. For example, when an enrollee changes from self only to self and family coverage because of the birth of a child, the regulations specify that the effective date of the change is the first day of the pay period in which the child is born.

One commenter expressed concern about the events based upon a loss of other FEHB coverage (paragraph 890.301(i)) and our extension of the enrollment timeframe from 31 to 60 days. We are extending the timeframe for uniformity and to try to reduce the number of requests for belated enrollment. We realized that some individuals may enroll after the expiration of the 31-day temporary extension of coverage, but within the 60 day timeframe and that this will cause a gap in coverage. However, as long as the individuals enrolls with the time limit required by regulation, he or she will not be penalized for purposes of meeting the requirements for continuing the FEHB enrollment into retirement (coverage for 5 years of service immediately before retirement, or, if less than 5 years, for all service since the first opportunity to enroll).

One commenter asked if OPM could treat employees and former spouses whose plan is discontinued and who do not select another plan the same as annuitants and deem them to have enrolled in the Blue Cross and Blue Shield (BCBS) Service Benefit Plan. The provision for annuitants was originally written when the Aetna plan left the FEHB Program and there were many annuitants who did not respond to our request that they change plans. It was intended to assure that no annuitant would be without FEHB coverage, especially since those who did not select another plan were deemed to have cancelled their enrollment and, generally, annuitants who cancel their enrollment may not reenroll. This provision is not difficult to administer since annuitants have one employing office. We do not favor extending this provision to employees or former spouses since they may make a belated change of enrollment if their employing office permits, or they can reenroll during the next open season. We believe that giving agencies the authority to place employees and former spouses who do not change plans in the BCBS Plan would be difficult for agencies to administer, since these enrollees might object to being placed in BCBS without their consent.

Several comments are concerned about our proposal to permit carriers to determine whether an enrollee's child over age 22 is incapable of self-support when the child's disability appears on a list of specific medical conditions provided by OPM. We agree that carriers and employing offices will need to communicate their determinations to each other and we plan to issue additional guidance and procedures on this issue. The purpose of our revision to the current regulation is to provide uninterrupted coverage when the child's condition is so severe that there would be no question that the child is incapable of self-support and that the condition would not abate. In cases where the child's condition does not appear on the OPM list, the enrollee would have to contact their employing office and follow the procedures currently required for approval.

We also are simplifying and clarifying the current regulations regarding the effective date of cancellation so that all cancellations take effect on the last day of the pay period in which the appropriate request cancelling the enrollment is received by the employing office.

Another commenter had several concerns about our section pertaining to former spouses. Former spouses may change to family status only if the child to be covered is a child of the former spouse and the employee or annuitant. In addition, former spouses who establish eligibility for a former spouse enrollment but postpone enrolling (e.g. because they are on active military service or are covered by CHAMPUS) may enroll at a later date. Therefore, there is no need for special regulatory language for former spouses who are discharged from the military. Finally, we deleted the first sentence of § 890.806(j) because it is redundant with § 890.806(a).

One commenter asked why these regulations allow annuitants and former spouses who cancel their enrollment for the purpose of enrolling in a Medicare-sponsored Coordinated Care Plan (also referred to as a Medicare HMO) or Medicaid (or similar State-sponsored program of medical assistance for the needy) to reenroll in FEHB, but do not extend this same opportunity to individuals enrolled under the Temporary Continuation of Coverage (TCC) provisions. FEHB law (5 U.S.C. 8905a) is very specific about the events that qualify individuals to continue their FEHB coverage under the TCC provisions, as follows: (1) Employees who lose coverage upon separation from service; (2) children who cease to meet the requirements for being unmarried dependent children, and (3) former spouses who lose coverage under a self and family enrollment because of termination of marriage, and who do not qualify for coverage under the former spouse provisions of FEHB law. There is nothing in the TCC provisions of law that would permit us to allow an individual to cancel their TCC for the purpose of obtaining MCCP or Medicaid (or similar State-sponsored) coverage and later reenroll.

We also would like to point out that we plan to revise the Table of Permissible Changes in Enrollment on the back of the Health Benefits Registration Form (Standard Form 2809) to incorporate these changes.

In addition, there were several suggestions to correct real or perceived technical or typographical errors in the proposed regulations. We have made

changes and clarifications where appropriate.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they primarily affect Federal employees, annuitants, and former spouses.

List of Subjects in 5 CFR Part 890

Administrative practice and procedure, Government employees, Health facilities, Health insurance, Health professions, Hostages, Iraq, Kuwait, Lebanon, Reporting and recordkeeping requirements, and Retirement.

Office of Personnel Management.

James B. King,

Director.

Accordingly, OPM is amending 5 CFR part 890 as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

1. The authority citation for part 890 continues to read as follows:

Authority: 5 U.S.C. 8913; § 890.803 also issued under 50 U.S.C. 403p, 22 U.S.C. 4069c and 4069c–1; subpart L also issued under sec. 599C of Pub. L. 101–513, 104 Stat. 2064, as amended.

2. In § 890.101, paragraph (a), the definitions for *Enrolled* and *Enrollee* are revised, the definitions for *Cancellation, Change of enrollment, Register, Register to enroll,* and *Regular tour of duty* are removed, and the definitions for *Appropriate request, Cancel, Change the enrollment, Election not to enroll,* and *Enroll* are added in alphabetical order to read as follows:

§ 890.101 Definitions; time computations.

(a) * * *

Appropriate request means a properly completed health benefits registration form or an alternative method acceptable to both the employing office and OPM. Alternative methods must be capable of transmitting to the health benefits plans the information they require before accepting an enrollment, change of enrollment, or cancellation. Electronic signatures, including the use of Personal Identification Numbers (PIN), have the same validity as a written signature.

* * * * *

Cancel means to submit to the employing office an appropriate request electing not to be enrolled by an enrollee who is eligible to continue enrollment.

Change the enrollment means to submit to the employing office an appropriate request electing a change of enrollment to a different plan or option, or to a different type of coverage (self only or self and family).

* * * * *

Election not to enroll means to submit to the employing office an appropriate request electing not to be enrolled by an employee who is eligible to enroll.

* * * * *

Enroll means to submit to the employing office an appropriate request electing to be enrolled in a health benefits plan.

Enrolled means an appropriate request has been accepted by the employing office and the enrollment in a health benefits plan approved by OPM under this part has not been terminated or cancelled.

Enrollee means the individual in whose name the enrollment is carried. The term includes employees, annuitants, former employees, former spouses, or children who are enrolled after completing an appropriate request under the provisions of §§ 890.301, 890.306, 890.601, 890.803, or 890.1103 or have continued an enrollment as an annuitant or survivor annuitant under 5 U.S.C. 8905(b) or § 890.303.

* * * * *

3. In § 890.103, paragraphs (c) and (d) are redesignated as (d) and (e), and a new paragraph (c) is added to read as follows:

§ 890.103 Correction of errors.

* * * * *

(c) The employing office may make retroactive correction of enrollee enrollment code errors if the enrollee reports the error by the end of the pay period following the one in which he or she received the first written documentation (i.e. pay statement or enrollment change confirmation) indicating the error.

* * * * *

4. The title of Subpart C is received to read as follows:

Subpart C—Enrollment

5. Section 890.301 is revised to read as follows:

§ 890.301 Opportunities for employees to enroll or change enrollment; effective dates.

(a) *Initial opportunity to enroll.* An employee who becomes eligible may elect to enroll or not to enroll within 60 days after becoming eligible.

(b) *Effective date—generally.* Except as otherwise provided, an enrollment or change of enrollment takes effect on the first pay of the first pay period that begins after the date the employing office receives an appropriate request to enroll or change the enrollment and that follows a pay period during any part of which the employee is in pay status.

(c) *Belated enrollment.* When an employing office determines that an employee was unable, for cause beyond his or her control, to enroll or change the enrollment within the time limits prescribed by this section, the employee may enroll or change the enrollment within 60 days after the employee office advises the employment of its determination.

(d) *Enrollment by proxy.* Subject to the discretion of the employing office, an employee's representative, having written authorization to do so, may enroll or change the enrollment for the employee.

(e) *Change to self only.* (1) An employee may change the enrollment from self and family to self only at any time.

(2) A change of enrollment to self only takes effect on the first day of the first pay period that begins after the date the employing office receives an appropriate request to change the enrollment, except that at the request of the employee and upon a showing satisfactory to the employing office that there was no family member eligible for coverage by the family enrollment, the employing office may make the change effective on the first day of the pay period following the one in which there was no family member.

(f) *Open season.* (1) An open season will be held each year from the Monday of the second full workweek in November through the Monday of the second full workweek in December.

(2) The Director of the Office of Personnel Management may modify the dates specified in paragraph (f)(1) of this section or hold additional open seasons.

(3) During an open season, an eligible employee may enroll and an enrolled employee may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes.

(4)(i) An open season new enrollment takes effect on the first day of the first pay period that begins in the next following year and which follows a pay period during any part of which the employee is in a pay status.

(ii) An open season change of enrollment takes effect on the first day of the first pay period which begins in January of the next following year.

(5) When a belated open season enrollment or change of enrollment is accepted by the employing office under paragraph (c) of this section, it takes effect as required by paragraph (f)(4) of this section.

(g) *Change in family status.* (1) An eligible employee may enroll and an enrolled employee may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the employee's family status changes, including a change in marital status or any other change in family status. The employee must enroll or change the enrollment within the period beginning 31 days before the date of the change in family status, and ending 60 days after the date of the change in family status.

(2) An enrollment or change of enrollment made in conjunction with the birth of a child, or the addition of a child as a new family member in some other manner, takes effect on the first day of the pay period in which the child is born or becomes an eligible family member.

(h) *Change in employment status.* An eligible employee may enroll and an enrolled employee may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the employee's employment status changes. Except as otherwise provided, an employee must enroll or change the enrollment within 60 days after the change in employment status. Employment status changes include, but are not limited to—

(1) A return to pay status following loss of coverage under either—

(i) Section 890.304(a)(1)(v) due to the expiration of 365 days in leave without pay (LWOP) status, or

(ii) Section 890.502(b)(5) due to the termination of coverage during LWOP status.

(2) Reemployment after a break in service of more than 3 days.

(3) Restoration to a civilian position after serving in the uniformed services under conditions that entitle him or her to benefits under part 353 of this chapter, or similar authority.

(4) A change from a temporary appointment in which the employee is eligible to enroll under 5 U.S.C. 8906a, which requires payment of the full premium with no Government contribution, to an appointment that entitles the employee to receive the Government contribution.

(5) Separation from Federal employment when the employee or the employee's spouse is pregnant and the employee supplies medical documentation of the pregnancy. An employee who enrolls or changes the enrollment under this paragraph (h)(5) must do so during his or her final pay period. The effective date of an enrollment or a change of enrollment under this paragraph (h)(5) is the first day of the pay period which the employing office receives an appropriate request to enroll or change the enrollment.

(6) A transfer from a post of duty within a State of the United States or the District of Columbia to a post of duty outside a State of the United States or the District of Columbia, or the reverse. An employee who enrolls or changes the enrollment under this paragraph (h)(6) must do so within the period beginning 31 days before leaving the old post of duty and ending 60 days after arriving at the new post of duty.

(7) A change, without a break in service or after a separation of 3 days or less, to part-time career employment as defined in 5 U.S.C. 3401(2) and 5 CFR part 340, subpart B, or a change from such part-time career employment to full-time employment that entitles the employee to the full Government contribution.

(i) *Loss of coverage under this part or under another group insurance plan.* An eligible employee may enroll and an enrolled employee may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the employee or an eligible family member of the employee loses coverage under this part or another group health benefits plan. Except as otherwise provided, an employee must enroll or change the enrollment within the period beginning 31 days before the date of loss of coverage, and ending 60 days after the date of loss of coverage. Losses of coverage include, but are not limited to—

(1) Loss of coverage under another FEHB enrollment due to the termination, cancellation, or a change to self only, of the covering enrollment.

(2) Loss of coverage under another federally-sponsored health benefits program.

(3) Loss of coverage due to the termination of membership in an employee organization sponsoring or underwriting an FEHB plan.

(4) Loss of coverage due to the discontinuance of an FEHB plan in whole or in part. For an employee who loses coverage under this paragraph (i)(4):

(i) If the discontinuance is at the end of a contract year, the employee must change the enrollment during the open season, unless OPM establishes a different time. If the discontinuance is at a time other than the end of the contract year, OPM must establish a time and effective date for the employee to change the enrollment.

(ii) If the whole plan is discontinued, an employee who does not change the enrollment within the time set is considered to have canceled the plan in which enrolled.

(iii) If one option of a plan that has two options is discontinued, an employee who does not change the enrollment is considered to be enrolled in the remaining option of the plan.

(5) Loss of coverage under the Medicaid program or similar State-sponsored program of medical assistance for the needy.

(6) Loss of coverage under a non-Federal health plan because an employee moves out of the commuting area to accept another position and the employee's non-federally employed spouse terminates employment to accompany the employee. An employee may enroll or change the enrollment within the period beginning 31 days before the date the employee leaves employment in the old commuting area and ending 180 days after entry on duty at place of employment in the new commuting area.

(7) Loss of coverage under a non-Federal health plan.

(j) *Move from comprehensive medical plan's area.* An employee in a comprehensive medical plan who moves or becomes employed outside the geographic area from which the plan accepts enrollments, or if already outside this area, moves or becomes employed further from this area, may change the enrollment upon notifying the employing office of the move or change of place of employment. Similarly, an employee whose covered family member moves outside the geographic area from which the plan accepts enrollments, or if already outside this area, moves further from this area, may change the enrollment upon notifying the employing office of the family member's move. The change of enrollment takes effect on the first day of the pay period that begins after the employing office receives an appropriate request.

(k) *On becoming eligible for Medicare.* An employee may change the enrollment from one plan or option to another at any time beginning on the 30th day before becoming eligible for coverage under title XVIII of the Social Security Act (Medicare). A change of enrollment based on becoming eligible for Medicare may be made only once.

(1) *Salary of temporary employee insufficient to pay withholdings.* If the salary of a temporary employee eligible under 5 U.S.C. 8906a is not sufficient to pay the withholdings for the plan in which the employee is enrolled, the employing office shall notify the

employee of the plans available at a cost that does not exceed the employee's salary. The employee may enroll in another plan whose cost is no greater than his or her salary within 60 days after receiving such notification from the employing office. The change of enrollment takes effect immediately upon termination of the prior enrollment.

6. In § 890.302, paragraph (f) is revised to read as follows:

§ 890.302 Coverage of family members.

* * * * *

(f) *Determiniation of incapacity.* (1) Except as provided in paragraph (f)(2) of this section, the employing office shall make determinations of incapacity.

(2) Either the employing office or the carrier may make a determination of incapacity if a medical condition, as specified by OPM, exists that would cause a child to be incapable of self-support during adulthood.

* * * * *

7. In § 890.303, paragraph (a)(1) is amended by removing ''registration'' and adding in its place ''enrollment'', and paragraph (a)(3) is revised to read as follows:

§ 890.303 continuation of enrollment.

(a) * * *

(3) For the purpose of this part, an employee is considered to have enrolled at his or her first opportunity if the employee enrolled during the first of the periods set forth in § 890.301 in which he or she was eligible to enroll or was covered at that time by the enrollment of another employee or annuitant, or whose enrollment was effective not later than December 31, 1964.

* * * * *

8. In § 890.304, paragraph (a)(2) is amended by removing ''§ 890.301(ee)'' and adding in its place ''§ 890.301(1)'', paragraph (b)(1) is amended by removing ''§ 890.301(q)'' and adding in its place ''§ 890.306(q)'', and paragraph (d) is revised to read as follows:

§ 890.304 Termination of enrollment.

* * * * *

(d) *Cancellation.* (1) Except as provided in § 890.807(e), an enrollee may cancel his or her enrollment at any time by filing an appropriate request with the employing office. The cancellation takes effect on the last day of the pay period in which the appropriate request cancelling the enrollment is received by the employing office.

(2) If an annuitant submits documentation that the cancellation is for the purpose of enrolling in a prepaid health plan under section 1833 or 1876 of the Social Security Act, the cancellation becomes effective on the day before the enrollment under the prepaid health plan takes effect. Such documentation must be submitted to the employing office within the period beginning 31 days before and ending 31 days after the prepaid health plan enrollment takes effect.

(3) The enrollee and covered family members are not entitled to the temporary extension of coverage for conversion or to convert to an individual contract for health benefits.

* * * * *

9. Section 890.306 is revised to read as follows:

§ 890.306 Opportunities for annuitants to change enrollment or to reenroll; effective dates.

(a) *Requirements to continue coverage.* (1) To be eligible to continue coverage in a plan under this part, a former employee in receipt of an annuity must meet the statutory requirements under 5 U.S.C. 8905(b) of having retired on an immediate annuity and having been covered by a plan under this part for the 5 years of service immediately before retirement, or if less than 5 years, for all service since his or her first opportunity to enroll, unless OPM waives the requirement under § 890.108.

(2) To be eligible to continue coverage in a plan under this part, a survivor annuitant must be covered as a family member when the employee or annuitant dies.

(b) *Effective date—generally.* Except as otherwise provided, an annuitant's change of enrollment takes effect on the first day of the first pay period that begins after the date the employing office receives an appropriate request to change the enrollment.

(c) *Belated enrollment.* When an employing office determines that an annuitant was unable, for cause beyond his or her control, to continue coverage by enrolling in his or her own name or change the enrollment within the time limits prescribed by this section, the annuitant may do so within 60 days after the employing office advises the annuitant of its determination.

(d) *Enrollment by proxy.* Subject to the discretion of the employing office, an annuitant's representative, having written authorization to do so, may continue the annuitant's coverage by enrolling in the annuitant's own name, or change the enrollment for the annuitant.

(e) *Change to self only.* (1) An annuitant may change the enrollment from self and family to self only at any time.

(2) A change of enrollment to self only takes effect on the first day of the first pay period that begins after the date the employing office receives an appropriate request to change the enrollment, except that at the request of the annuitant and upon a showing satisfactory to the employing office that there was no family member eligible for coverage under the family enrollment, the employing office may make the change effective on the first day of the pay period following the one in which there was no family member.

(f) *Open season.* (1) During an open season as provided by § 890.301(f)—

(i) An enrolled annuitant may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes.

(ii) An annuitant who cancelled the enrollment under this part for the purpose of enrolling in a prepaid health plan under section 1833 or 1876 of the Social Security Act, and who subsequently voluntarily disenrolls from the prepaid health plan, may reenroll.

(iii) An annuitant who cancelled the enrollment under this part because he or she furnished proof of eligibility for coverage under the Medicaid program or similar State-sponsored program of medical assistance for the needy, and who wishes to reenroll in a plan under this part for reasons other than an involuntary loss of that coverage, may do so.

(2) An open season reenrollment or change of enrollment takes effect on the first day of the first pay period that begins in January of the next following year.

(3) When a belated open season reenrollment or change of enrollment is accepted by the employing office under paragraph (c) of this section, it takes effect as required by paragraph (f)(2) of this section.

(g) *Change in family status.* (1) An enrolled former employee in receipt of an annuity may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the annuitant's family status changes, including a change in martial status or any other change in family status. In the case of an enrolled survivor annuitant, a change in family status based on additional family members occurs only if the additional family members are family members of the deceased employee or annuitant. The annuitant must change the enrollment within the period beginning 31 days before the date of the change in family status, and

ending 60 days after the date of the change in family status.

(2) A change of enrollment made in conjunction with the birth of a child, or the addition of a child as a new family member in some other manner, takes effect on the first day of the pay period in which the child is born or becomes an eligible family member.

(h) *Reenrollment of annuitants who cancelled enrollment to enroll in a Medicare-sponsored Coordinated Care Plan.* (1) An annuitant who had been enrolled (or was otherwise eligible to enroll) for coverage under this part and cancelled the enrollment for the purpose of enrolling in a prepaid health plan under section 1833 or 1876 of the Social Security Act (as provided by § 890.304(d)), and who is subsequently involuntarily disenrolled from the prepaid health plan, may immediately reenroll in any available plan under this part at any time beginning 31 days before and ending 60 days after the disenrollment. A reenrollment under this paragraph (h) takes effect on the date following the effective date of the disenrollment as shown on the documentation from the prepaid health plan.

(2) An annuitant who voluntarily disenrolls from the prepaid health plan must do so in conjunction with reenrolling in a plan under this part during the next available open season (as provided by paragraph (f) of this section) to assure continuing uninterrupted health plan coverage.

(i) *Reenrollment of annuitants who cancelled enrollment because of eligibility under Medicaid or similar State-sponsored program of medical assistance for the needy.* (1) An annuitant who had been enrolled (or was otherwise eligible to enroll) for coverage under this part and cancelled the enrollment because he or she furnished proof of eligibility for coverage under the Medicaid program or a similar State-sponsored program of medical assistance for the needy, and who involuntarily loses that coverage, may reenroll in any available plan under this part at any time beginning 31 days before and ending 60 days after the loss of Medicaid or similar State-sponsored coverage. A reenrollment under this paragraph (i)(1) takes effect on the date following the date of loss of Medicaid or similar State-sponsored coverage.

(2) An annuitant who cancelled his or her enrollment because he or she furnished proof of eligibility for coverage under the Medicaid program or a similar State-sponsored program of medical assistance for the needy, and who wishes to reenroll in a plan under this part for reasons other than an involuntary loss of that coverage, may do so during the next available open season as provided by paragraph (f) of this section.

(j) *Annuitants who apply for postponed minimum retirement age plus 10 years of service (MRA plus 10) annuity.* (1) A former employee who meets the requirements for an immediate annuity under 5 U.S.C. 8412(g) and for continuation of coverage under 5 U.S.C. 8905(b) at the time of separation, and whose enrollment is terminated under § 890.304(a)(1)(ii) may enroll in a health benefits plan under this part within 60 days after OPM mails the former employee a notice of eligibility. If such former employee dies before the end of this 60-day election period, a survivor who is entitled to a survivor annuity may enroll in a health benefits plan under this part within 60 days after OPM mails the survivor a notice of eligibility.

(2) The former employee's enrollment takes effect on the first day of the month following the month in which OPM receives the appropriate request or on the commencing date of annuity, whichever is later. A survivor's enrollment takes effect on the first day of the month following the month in which OPM receives the appropriate request.

(k) *Restoration of annuity or compensation payments.* (1) A disability annuitant who was enrolled in a health benefits plan under this part immediately before his or her disability annuity was terminated because of restoration to earning capacity or recovery from disability, and whose disability annuity is restored under 5 U.S.C. 8337(e) after December 31, 1983, or 8455(b), may enroll in a health benefits plan under this part within 60 days after OPM mails a notice of insurance eligibility. The enrollment takes effect on the first day of the month after the date OPM receives the appropriate request.

(2) An annuitant who was enrolled in a health benefits plan under this part immediately before his or her compensation was terminated because OWCP determined that he or she had recovered from the job-related injury or disease, and whose compensation is restored due to a recurrence of disability, may enroll in a health benefits plan under this part within 60 days after OWCP mails a notice of insurance eligibility. The enrollment takes effect on the first day of the pay period after the date OWCP receives the appropriate request.

(3) A surviving spouse who was covered by a health benefits enrollment under this part immediately before his or her survivor annuity was terminated because of remarriage, and whose survivor annuity is later restored, may enroll in a health benefits plan under this part within 60 days after OPM mails a notice of eligibility. The enrollment takes effect on either—

(i) The first day of the month after the date OPM receives the appropriate request; or

(ii) The date of restoration of the survivor annuity or October 1, 1976, whichever is later.

(4) A surviving child who was covered by a health benefits enrollment under this part immediately before his or her survivor annuity was terminated because he or she ceased being a student, and whose survivor annuity is later restored, may enroll in a health benefits plan under this part within 60 days after OPM mails a notice of eligibility. The enrollment takes effect on the first day of the month after the date OPM receives the appropriate request or the date of restoration of the survivor annuity, whichever is later.

(5) A surviving child who was covered by a health benefits enrollment under this part immediately before his or her survivor annuity was terminated because he or she married, and whose survivor annuity is later restored because the marriage ended, may enroll in a health benefits plan under this part within 60 days after OPM mails a notice of eligibility. The enrollment takes effect on the first day of the month after the date OPM receives the appropriate request or the date of restoration of the survivor annuity, whichever is later.

(6) A surviving spouse who received a basic employee death benefit under 5 U.S.C. 8442(b)(1)(A) and who was covered by a health benefits enrollment under this part immediately before remarriage prior to age 55, may enroll in a health benefits plan under this part upon termination of the remarriage. The survivor must provide OPM with a certified copy of the notice of death or the court order terminating the marriage. The surviving spouse must enroll within 60 days after OPM mails a notice of eligibility. The enrollment takes effect on the first day of the month after the date OPM receives the appropriate request and the notice of death or court order terminating the remarriage.

(l) *Loss of coverage under this part or under another group insurance plan.* An annuitant who meets the requirements of paragraph (a) of this section, and who is not enrolled but is covered by another enrollment under this part may continue coverage by enrolling in his or her own name when the annuitant loses

coverage under the other enrollment under this part. An enrolled annuitant may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the annuitant or an eligible family member of the annuitant loses coverage under this part or under another group health benefits plan. Except as otherwise provided, an annuitant must enroll or change the enrollment within the period beginning 31 days before the date of loss of coverage and ending 60 days after the date of loss of coverage. Losses of coverage include, but are not limited to—

(1) Loss of coverage under another FEHB enrollment due to the termination, cancellation, or a change to self only, of the covering enrollment;

(2) Loss of coverage under another federally-sponsored health benefits program;

(3) Loss of coverage due to the termination of membership in an employee organization sponsoring or underwriting an FEHB plan;

(4) Loss of coverage due to the discontinuance of an FEHB plan in whole or in part. For an annuitant who loses coverage under this paragraph (l)(4)—

(i) If the discontinuance is at the end of a contract year, the annuitant must change the enrollment during the open season, unless OPM establishes a different time. If the discontinuance is at a time other than the end of the contract year, OPM must establish a time and effective date for the annuitant to change the enrollment;

(ii) If a plan has only one option and is discontinued, an annuitant who does not change the enrollment is deemed to have enrolled in the standard option of the Blue Cross and Blue Shield Service Benefit Plan.

(iii) If a plan has two options, and one option of the plan is discontinued, an annuitant who does not change the enrollment is considered to be enrolled in the remaining option of the plan.

(iv) If a plan has two options and both options are discontinued, an annuitant who does not change the enrollment is deemed to have enrolled in the corresponding option of the Blue Cross and Blue Shield Service Benefit Plan. If the annuitant is enrolled in a high option and his or her annuity is insufficient to pay the withholding for the high option, the annuitant is deemed to have enrolled in the standard option of the Blue Cross and Blue Shield Service Benefit Plan. The exemptions from debt collection procedures that are provided under §§ 831.1305(d)(2) and 845.205(d)(2) of this chapter apply to elections under this paragraph (1)(4)(iv);

(5) Loss of coverage under the Medicaid program or similar State-sponsored program of medical assistance for the needy.

(6) Loss of coverage under a non-Federal health plan.

(m) *Move from comprehensive medical plan's area.* An annuitant in a comprehensive medical plan who moves or becomes employed outside the geographic area from which the plan accepts enrollments, or, if already outside this area, moves or becomes employed further from this area, may change the enrollment upon notifying the employing office of the move or change of place of employment. Similarly, an annuitant whose covered family member moves outside the geographic area from which the plan accepts enrollments, or if already outside this area, moves further from this area, may change the enrollment upon notifying the employing office of the family member's move. The change of enrollment takes effect on the first day of the pay period that begins after the employing office receives an appropriate request.

(n) *Overseas post of duty.* An annuitant may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes within 60 days after the retirement or death of the employee on whose service title to annuity is based, if the employee was stationed at a post of duty outside a State of the United States or the District of Columbia at the time of retirement or death.

(o) *On return from a uniformed service.* An enrolled annuitant who enters on duty in a uniformed service for 31 days or more may change the enrollment within 60 days after separation from the uniformed service.

(p) *On becoming eligible for Medicare.* An annuitant may change the enrollment from one plan or option to another at any time beginning on the 30th day before becoming eligible for coverage under title XVIII of the Social Security Act (Medicare). A change of enrollment based on becoming eligible for Medicare may be made only once.

(q) *Annuity insufficient to pay withholdings.* (1) If an annuity is insufficient to pay the withholdings for the plan that the annuitant is enrolled in, the retirement system must provide the annuitant with information regarding the available plans and written notification of the opportunity to either—

(i) Pay the premium directly to the retirement system in accordance with § 890.502(d); or

(ii) Enroll in any plan in which the annuitant's share of the premium is less than the amount of annuity. If the annuitant elects to change to a lower cost enrollment, the change takes effect immediately upon loss of coverage under the prior enrollment.

(2) If the annuitant is enrolled in the high option of a plan that has two options, and does not change the enrollment to a plan in which the annuitant's share of the premium is less than the amount of annuity or does not elect to pay premiums directly, the annuitant is deemed to have enrolled in the standard option of the same plan, unless the annuity is insufficient to pay the withholdings for the standard option.

(3) An annuitant whose enrollment was terminated because the amount of annuity was insufficient to cover the enrollee's share of the premium may apply to be reinstated in any available plan or option.

(4) An annuitant who can show evidence that he or she previously changed to a lower cost option, plan, or to a self-only enrollment prior to May 29, 1990, because the annuity was insufficient to cover the withholdings for the plan in which he or she was enrolled, may apply to change the enrollment to any available plan or option in which the enrollee's share of the total premium exceeds his or her monthly annuity.

(5) The effective date of the reinstatement of enrollment of an annuitant whose enrollment was terminated, or the change of enrollment of an annuitant who previously changed enrollment because his or her annuity was insufficient to cover the annuitant's share of the total premium, and who elects to pay premiums directly to the retirement system in accordance with § 890.502(f) is either—

(i) The first day of the first pay period that begins after the appropriate request is received by the retirement system; or,

(ii) The later of the date the enrollment was terminated or changed, or May 29, 1990.

(6) Retroactive reinstatement or change of enrollment is contingent upon payment of appropriate contributions retroactive to the effective date of the reinstatement or the change of enrollment. For the purpose of this paragraph (q)(6), a previous cancellation of enrollment because of insufficient annuity to cover the full amount of the withholdings is deemed to be a termination of enrollment.

(r) *Sole survivor.* When an employee or annuitant enrolled for self and family dies, leaving a survivor annuitant who is entitled to continue the enrollment, and it is apparent from available records that the survivor annuitant is the sole survivor entitled to continue the enrollment, the office of the retirement system which is acting as employing office must change the enrollment from self and family to self only, effective on the commencing date of the survivor annuity. On request of the survivor annuitant made within 31 days after the first installment of annuity is paid, the office of the retirement system which is acting as employing office must rescind the action retroactive to the effective date of the change to self only, with corresponding adjustment in withholdings and contributions.

(s) *Election between survivor annuities.* A surviving spouse, irrespective of whether his or her survivor annuity continued or was terminated upon remarriage, who was covered by an enrollment under this part immediately before the remarriage, may elect to continue an enrollment under this part acquired as a dependent by virtue of the remarriage or to enroll in his or her own right (by virtue of entitlement to the original survivor annuity) in any plan or option under this part within 60 days after the termination of the remarriage and entitlement to a survivor annuity.

§ 890.602 [Amended]

10. Section 890.602 is amended by removing ''register'' and adding in its place ''elect to enroll''.

§ 890.803 [Amended]

11. In § 890.803, paragraph (a)(3)(i) is amended by removing ''5'' CFR 831.606 (a) and (b) and 842.605 (a) and (b)'' and adding in its place §§ 831.613 (a) and (b) and 842.605 (a) and (b) of this chapter''.

§ 890.805 [Amended]

12. In § 890.805, paragraph (a)(2)(v) is amended by removing ''appointment'' and adding in its place ''apportionment''.

13. Section 890.806 is revised to read as follows:

§ 890.806 Opportunities for former spouses to enroll and change enrollment; effective dates of enrollment.

(a) *Initial opportunity to enroll.* A former spouse who has met the eligibility requirements of § 890.803 and the application time limitation requirements of § 890.805 may enroll at any time after the employing office establishes that these requirements have been met.

(b) *Effective date—generally.* (1) Except as otherwise provided, an enrollment takes effect on the first day of the first pay period that begins after the date the employing office receives an appropriate request and satisfactory proof of eligibility as required by paragraph (a) of this section. If a former spouse requests immediate coverage, and the employing office receives an appropriate request and satisfactory proof of eligibility within 60 days after the date of divorce, the enrollment may be made effective on the same day that temporary continuation of coverage under subpart K of this part would otherwise take effect.

(2) A change of enrollment takes effect on the first day of the first pay period that begins after the date the employing office receives the appropriate request.

(c) *Belated enrollment.* When an employing office determines that a former spouse was unable, for cause beyond his or her control, to enroll or change the enrollment within the time limits prescribed by this section, the former spouse may do so within 60 days after the employing office advises the former spouse of its determination.

(d) *Enrollment by proxy.* Subject to the discretion of the employing office, a former spouse's representative, having written authorization to do so, may enroll or change the enrollment for the former spouse.

(e) *Change to self only.* (1) A former spouse may change the enrollment from self and family to self only at any time.

(2) A change of enrollment to self only takes effect on the first day of the first pay period that begins after the date the employing office receives an appropriate request to change the enrollment, except that at the request of the former spouse and upon a showing satisfactory to the employing office that there was no family member eligible for coverage under the family enrollment, the employing office may make the change take effect on the first day of the pay period following the one in which there was no family member.

(f) *Open season.* (1) During an open season as provided by § 890.301(f)—

(i) An enrolled former spouse may change the enrollment from self only to self and family provided the family member(s) is eligible for coverage under § 890.804, from one plan or option to another, or make any combination of these changes.

(ii) A former spouse who cancelled the enrollment under this part for the purpose of enrolling in a prepaid health plan under section 1833 or 1876 of the Social Security Act, and who subsequently voluntarily disenrolls from the prepaid health plan, may reenroll.

(iii) A former spouse who cancelled the enrollment under this part because he or she furnished proof of eligibility for coverage under the Medicaid program or a similar State-sponsored program of medical assistance for the needy, and who wishes to reenroll in a plan under that part for reasons other than an involuntary loss of that coverage, may do so.

(2) An open season reenrollment or change of enrollment takes effect on the first day of the first pay period that begins in January of the next following year.

(3) When a belated open season reenrollment or change of enrollment is accepted by the employing office under paragraph (c) of this section, it takes effect as required by paragraph (f)(2) of this section.

(g) *Change in family status.* (1) An enrolled former spouse may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes within the period beginning 31 days before and ending 60 days after the birth or acquisition of a child who meets the eligibility requirements of § 890.804.

(2) A change in enrollment under paragraph (g)(1) of this section takes effect on the first day of the pay period in which the child is born or becomes an eligible family member.

(h) *Reenrollment of former spouses who cancelled enrollment to enroll in a Medicare-sponsored Coordinated Care Plan.* (1) A former spouse who had been enrolled for coverage under this part and cancelled enrollment for the purpose of enrolling in a prepaid health plan under section 1833 or 1876 of the Social Security Act, or who meets the eligibility requirements of § 890.803 and the application time limitation requirements of § 890.805, but postponed enrollment for this purpose, and who is subsequently involuntarily disenrolled from the prepaid health plan, may immediately reenroll in any available plan under this part at any time beginning 31 days before and ending 60 days after the disenrollment. A reenrollment under this paragraph (h) takes effect on the date following the effective date of the disenrollment as shown on the documentation from the prepaid health plan.

(2) A former spouse who voluntarily disenrolls from the prepaid health plan must do so in conjunction with reenrolling in a plan under this part during the next available open season (as provided by paragraph (f) of this

section) to assure continuing uninterrupted health plan coverage.

(i) *Reenrollment of former spouses who cancelled enrollment because of eligibility under Medicaid or similar State-sponsored program of medical assistance for the needy.* (1) A former spouse who had been enrolled for coverage under this part and cancelled the enrollment because he or she furnished proof of eligibility for coverage under the Medicaid program or a similar State-sponsored program of medical assistance for the needy, or who meets the eligibility requirements of § 890.803 and the application time limitation requirements of § 890.805, but postponed enrollment for this reason, and who involuntarily loses that coverage, may reenroll in any available plan under this part at any time beginning 31 days before and ending 60 days after the loss of Medicaid or similar State-sponsored coverage. A reenrollment under this paragraph (i)(1) takes effect on the date following the date of loss of Medicaid or similar State-sponsored coverage.

(2) A former spouse who cancelled his or her enrollment because he or she furnished proof of eligibility for coverage under the Medicaid program or a similar State-sponsored program of medical assistance for the needy, and who wishes to reenroll in a plan under this part for reasons other than an involuntary loss of that coverage, may do so during the next available open season as provided by paragraph (f) of this section.

(j) *Loss of coverage under this part or under another group insurance plan.* An enrolled former spouse may change the enrollment from self only to self and family, from one plan or option to another or make any combination of these changes when the former spouse or a child who meets the eligibility requirements under § 890.804 loses coverage under another enrollment under this part or under another group health benefits plan. Except as otherwise provided, the former spouse must change the enrollment within the period beginning 31 days before the date of loss of coverage and ending 60 days after the date of loss of coverage, provided he or she continues to meet the eligibility requirements under § 890.803. Losses of coverage include but are not limited to—

(1) Loss of coverage under another FEHB enrollment due to the termination, cancellation, or a change to self only, of the covering enrollment;

(2) Loss of coverage under another federally-sponsored health benefits program;

(3) Loss of coverage due to the termination of membership in an employee organization sponsoring or underwriting an FEHB plan;

(4) Loss of coverage due to the discontinuance of an FEHB plan in whole or in part. For a former spouse who loses coverage under this paragraph (j)(4)—

(i) If the discontinuance is at the end of a contract year, the former spouse must change the enrollment during the open season, unless OPM establishes a different time. If the discontinuance is at a time other than the end of the contract year, OPM must establish a time and effective date for the former spouse to change the enrollment;

(ii) If the whole plan is discontinued, a former spouse who does not change the enrollment within the time set is considered to have cancelled the plan in which enrolled.

(iii) If one option of a plan that has two options is discontinued, a former spouse who does not change the enrollment is considered to be enrolled in the remaining option of the plan.

(5) Loss of coverage under the Medicaid program or similar State-sponsored program of Medical assistance for the needy.

(6) Loss of coverage under a non-Federal health plan.

(k) *Move from comprehensive medical plan's area.* A former spouse in a comprehensive medical plan who moves or becomes employed outside the geographic area from which the plan accepts enrollments, or, if already outside this area, moves or becomes employed further from this area, may change the enrollment upon notifying the employing office of the move or change of place of employment. Similarly, a former spouse whose covered family member moves outside the geographic area from which the plan accepts enrollments, or if already outside this area, moves further from this area, may change the enrollment upon notifying the employing office of the family member's move. The change of enrollment takes effect on the first day of the pay period that begins after the employing office receives an appropriate request.

(1) *On becoming eligible for Medicare.* A former spouse may change the enrollment from one plan or option to another at any time beginning on the 30th day before becoming eligible for coverage under title XVIII of the Social Security Act (Medicare). A change of enrollment based on becoming eligible for Medicare may be made only once.

(m) *Annuity insufficient to pay withholdings.* (1) If the annuity of a former spouse is insufficient to pay the full subscription charge for the plan in which he or she is enrolled, the retirement system must provide the former spouse with information regarding the available plans and written notification of the opportunity to either—

(i) Pay the premium directly to the retirement system in accordance with § 890.808(d); or

(ii) Enroll in any plan with a full premium that is less than the amount of annuity. If the former spouse elects to change to a lower cost enrollment, the change takes effect immediately upon loss of coverage under the prior enrollment.

(2) If the former spouse is enrolled in the high option of a plan that has two options, and does not elect a plan with a full premium that is less than the annuity or does not elect to pay premiums directly, he or she is deemed to have enrolled in the standard option of the same plan unless the annuity is insufficient to pay the full subscription charge for the standard option.

(3) A former spouse who is enrolled in a plan with only one option, who fails to make the election required by this paragraph (m)(3) will be subject to the provisions of § 890.807(c).

14. Section 890.807 is amended by revising the heading for paragraph (c), and revising paragraphs (c) (1) and (e) to read as follows:

§ 890.807 Termination of enrollment.

* * * * *

(c) *Failure to make an election under § 890.806(1).* (1) If the annuity is insufficient to pay the full subscription charge due for the plan in which the former spouse is enrolled, the former spouse may elect one of the two opportunities offered under § 890.806(1) (electing a plan with a full subscription charge that is less than the annuity; or paying premiums directly to the retirement system in accordance with § 890.808(d)). Except as provided in paragraph (c)(3) of this section the enrollment of a former spouse who fails to make an election within the specified time frame will be terminated.

* * * * *

(e) *Cancellation.* (1) A former spouse may cancel his or her enrollment at any time by filing an appropriate request with the employing office. The cancellation takes effect on the last day of the pay period in which the appropriate request cancelling the enrollment is received by the employing office.

(2) If a former spouse submits documentation that the cancellation is for the purpose of enrolling in a prepaid health plan under section 1833 or 1876

of the Social Security Act, the cancellation becomes effective on the day before the enrollment under the prepaid health plan takes effect. Such documentation must be submitted to the employing office within the period beginning 31 days before and ending 31 days after the prepaid health plan enrollment takes effect.

(3) The former spouse and family members, if any, are not entitled to the temporary extension of coverage for conversion or to convert to an individual contract for health benefits.

(4) Except for a former spouse who provides documentation that he or she is canceling for the purpose of enrolling in a prepaid health plan under section 1833 or 1876 of the Social Security Act, or for coverage under the Medicaid program or a similar State-sponsored program of medical assistance for the needy, a former spouse who cancels his or her enrollment may not later reenroll.

15. In section 890.808, paragraph (e) is revised to read as follows:

§ 890.808 Employing office responsibilities.

* * * * *

(e) *Withholding from annuity.* The retirement system acting as employing office for a former spouse will establish a method for withholding the full subscription charge from the former spouse's annuity check. When the annuity is insufficient to cover the full subscription charge, the retirement system will follow the procedures specified in § 890.806(1).

16. Section 890.1105 is amended by revising the section heading, by revising paragraphs (b), (c), (d), and (f), and by adding a new paragraph (g) to read as follows:

§ 890.1105 Initial election of temporary continuation of coverage; application time limitations and effective dates.

* * * * *

(b) *Former employees.* A former employee's election under this subpart must be submitted to the employing office within 60 days after the later of—

(1) The date of separation; or

(2) The date the former employee received the notice from the employing office.

(c) *Children.* A child's election under this subpart must be submitted to the employing office within 60 days after the later of—

(1) The date of the qualifying event; or

(2) If the employee notified the employing office within the 60-day time period specified under § 890.1104(b)(1) of this part, the date the child received the notice from the employing office. If the employee did not notify the employing office within the specified time period, the child's opportunity to elect continued coverage ends 60 days after the qualifying event.

(d) *Former spouses.* (1) A former spouse's election must be received by the employing office within 60 days after the later of—

(i) The date of the qualifying event; or

(ii) The date coverage under subpart H of this part was lost because of remarriage or loss of qualifying court order, if the loss of coverage under subpart H occurred before the expiration of the 36-month period specified in § 890.1107(c); or

(iii) If the employee, annuitant, or former spouse notified the employing office of the termination of the marriage within the time period specified in § 890.1104(c)(1), the date the former spouse received the notice from the employing office described in § 890.1104(c)(2). If the employee, annuitant, or former spouse did not notify the employing office within the specified time period, the former spouse's opportunity to elect continued coverage ends 60 days after the qualifying event.

(2) The effective date of former spouse coverage is the later of—

(i) The date determined under paragraph (g) of this section; or

(ii) The date of the divorce or annulment.

* * * * *

(f) *Belated elections.* Except as provided in paragraphs (c)(2) and (d)(1)(iii) of this section, when an employing office determines that an eligible individual was unable, for cause beyond his or her control, to elect temporary continuation of coverage within the time limits prescribed by this section, that office must accept the election within 60 days after it advises the individual of that determination.

(g) *Effective date of coverage.* Except as provided in paragraph (d)(2)(ii) of this section, the effective date of temporary continuation of coverage is the day after other coverage under this part expires, including the 31-day temporary extension of coverage under § 890.401. If an individual elects temporary continuation of coverage after the 31-day temporary extension of coverage expires, but before the expiration of the applicable election period specified in this section, coverage is restored retroactively, with appropriate contributions and claims, to the same extent and effect as though no break in coverage occurred.

17. Section 890.1108 is revised to read as follows:

§ 890.1108 Opportunities to change enrollment; effective dates.

(a) *Effective date—generally.* Except as otherwise provided, a change of enrollment takes effect on the first day of the first pay period that begins after the date the employing office receives an appropriate request to change the enrollment.

(b) *Belated change of enrollment.* When an employing office determines that an enrollee was unable, for cause beyond his or her control, to change the enrollment within the time limits prescribed by this section, the enrollee may do so within 60 days after the employing office advises the enrollee of its determination.

(c) *Change of enrollment by proxy.* Subject to the discretion of the employing office, an enrollee's representative, having written authorization to do so, may change the enrollment for the enrollee.

(d) *Change to self only.* (1) An enrollee may change the enrollment from self and family to self only at any time.

(2) A change of enrollment to self only takes effect on the first day of the first pay period that begins after the date the employing office receives an appropriate request to change the enrollment, except that at the request of the enrollee and upon a showing satisfactory to the employing office that there was no family member eligible for coverage under the family enrollment, the employing office may make the change effective on the first day of the pay period following the one in which there was no family member.

(e) *Open season.* (1) During an open season as provided by § 890.301(f), an enrollee (except for a former spouse who is eligible for continued coverage under § 890.1103(a)(3)) may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes. A former spouse who is eligible for continued coverage under § 890.1103(a)(3) may change from one plan or option to another, but may not change from self only to self and family unless the individual to be covered under the family enrollment qualifies as a family member under § 890.1106(a)(2).

(2) An open season change of enrollment takes effect on the first day of the first pay period that begins in January of the next following year.

(3) When a belated open season change of enrollment is accepted by the employing office under paragraph (b) of this section, it takes effect as required by paragraph (e)(2) of this section.

(f) *Change in family status.* (1) Except for a former spouse, an enrollee may

change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the enrollee's family status changes, including a change in marital status or any other change in family status. The enrollee must change the enrollment within the period beginning 31 days before the date of the change in family status, and ending 60 days after the date of the change in family status.

(2) A former spouse who is covered under this section may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes within the period beginning 31 days before and ending 60 days after the birth or acquisition of a child who qualifies as a covered family member under § 890.1106(a)(2).

(3) A change of enrollment made in conjunction with the birth of a child, or the addition of a child as a new family member in some other manner, takes effect on the first day of the pay period in which the child is born or becomes an eligible family member.

(g) *Reenrollment of individuals who lose other coverage under this part.* An individual whose continued coverage under this section terminates because of the provisions of § 890.1110(a)(3) (termination due to other coverage under another provision of this part) may reenroll if the coverage that terminated the enrollment under this part ends, but not later than the expiration of the period described in § 890.1107. Coverage does not extend beyond the expiration of the period described in § 890.1107. The effective date of the reenrollment is the day following the termination of the coverage described in § 890.1110(a)(3).

(h) *Loss of coverage under this part or under another group insurance plan.* An enrollee may change the enrollment from self only to self and family, from one plan or option to another, or make any combination of these changes when the enrollee loses coverage under this part or a qualified family member of the enrollee loses coverage under this part or under another group health benefits plan. Except as otherwise provided, an enrollee must change the enrollment within the period beginning 31 days before the date of loss of coverage and ending 60 days after the date of loss of coverage. Losses of coverage include, but are not limited to—

(1) Loss of coverage under another FEHB enrollment due to the termination, cancellation, or change to self only, of the covering enrollment.

(2) Loss of coverage under another federally-sponsored health benefits program.

(3) Loss of coverage due to the termination of membership in an employee organization sponsoring or underwriting an FEHB plan.

(4) Loss of coverage due to the discontinuance of an FEHB plan, in whole or in part. For an enrollee who loses coverage under this paragraph (h)(4)—

(i) If the discontinuance is at the end of a contract year, the enrollee must change the enrollment during the open season, unless OPM establishes a different time. If the discontinuance is at a time other than the end of the contract year, OPM must establish a time and effective date for the enrollee to change the enrollment.

(ii) If the whole plan is discontinued, an enrollee who does not change the enrollment within the time set is considered to have cancelled the plan in which enrolled.

(iii) If a plan has two options, and one option of the plan is discontinued, an enrollee who does not change the enrollment is considered to be enrolled in the remaining option of the plan.

(5) Loss of coverage under the Medicaid program or similar State-sponsored program of medical assistance for the needy.

(6) Loss of coverage under a non-Federal health plan.

(i) *Move from comprehensive medical plan's area.* An enrollee in a comprehensive medical plan who moves or becomes employed outside the geographic area from which the plan accepts enrollments, or, if already outside this area, moves or becomes employed further from this area, may change the enrollment upon notifying the employing office of the move or change of place of employment. Similarly, an enrollee whose covered family member moves outside the geographic area from which the plan accepts enrollments, or if already outside this area, moves further from this area, may change the enrollment upon notifying the employing office of the family member's move. The change of enrollment takes effect on the first day of the pay period that begins after the employing office receives an appropriate request.

(j) *On becoming eligible for Medicare.* An enrollee may change the enrollment from one plan or option to another at any time beginning on the 30th day before becoming eligible for coverage under title XVIII of the Social Security Act (Medicare). A change of enrollment based on becoming eligible for Medicare may be made only once.

[FR Doc. 97–18958 Filed 7–17–97; 8:45 am]
BILLING CODE 6325–01–M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 78

[Docket No. 97–036–1]

Brucellosis in Cattle; State and Area Classifications; Iowa

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the brucellosis regulations concerning the interstate movement of cattle by changing the classification of Iowa from Class A to Class Free. We have determined that Iowa meets the standards for Class Free status. This action relieves certain restrictions on the interstate movement of cattle from Iowa.

DATES: Interim rule effective July 14, 1997. Consideration will be given only to comments received on or before September 16, 1997.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 97–036–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 97–036–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue, SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Michael J. Gilsdorf, Senior Staff Veterinarian, National Animal Health Programs, VS, APHIS, Suite 3B08, 4700 River Road, Unit 36, Riverdale, MD 20737–1231, (301) 734–7708; or e-mail: mgilsdorf@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Brucellosis is a contagious disease affecting animals and humans, caused by bacteria of the genus *Brucella.*

The brucellosis regulations, contained in 9 CFR part 78 (referred to below as

the regulations), provide a system for classifying States or portions of States according to the rate of *Brucella* infection present, and the general effectiveness of a brucellosis control and eradication program. The classifications are Class Free, Class A, Class B, and Class C. States or areas that do not meet the minimum standards for Class C are required to be placed under Federal quarantine.

The brucellosis Class Free classification is based on a finding of no known brucellosis in cattle for the 12 months preceding classification as Class Free. The Class C classification is for States or areas with the highest rate of brucellosis. Class B and Class A fall between these two extremes. Restrictions on moving cattle interstate become less stringent as a State approaches or achieves Class Free status.

The standards for the different classifications of States or areas entail (1) maintaining a cattle herd infection rate not to exceed a stated level during 12 consecutive months; (2) tracing back to the farm of origin and successfully closing a stated percent of all brucellosis reactors found in the course of Market Cattle Identification (MCI) testing; (3) maintaining a surveillance system that includes testing of dairy herds, participation of all recognized slaughtering establishments in the MCI program, identification and monitoring of herds at high risk of infection (including herds adjacent to infected herds and herds from which infected animals have been sold or received), and having an individual herd plan in effect within a stated number of days after the herd owner is notified of the finding of brucellosis in a herd he or she owns; and (4) maintaining minimum procedural standards for administering the program.

Before the effective date of this interim rule, Iowa was classified as a Class A State.

To attain and maintain Class Free status, a State or area must (1) remain free from field strain *Brucella abortus* infection for 12 consecutive months or longer; (2) trace back at least 90 percent of all brucellosis reactors found in the course of MCI testing to the farm of origin; (3) successfully close at least 95 percent of the MCI reactor cases traced to the farm of origin during the 12 consecutive month period immediately prior to the most recent anniversary of the date the State or area was classified Class Free; and (4) have a specified surveillance system, as described above, including an approved individual herd plan in effect within 15 days of locating the source herd or recipient herd.

After reviewing the brucellosis program records for Iowa, we have concluded that this State meets the standards for Class Free status. Therefore, we are removing Iowa from the list of Class A States in § 78.41(b) and adding it to the list of Class Free States in § 78.41(a). This action relieves certain restrictions on moving cattle interstate from Iowa.

Immediate Action

The Administrator of the Animal and Plant Health Inspection Service has determined that there is good cause for publishing this interim rule without prior opportunity for public comment. Immediate action is warranted to remove unnecessary restrictions on the interstate movement of cattle from Iowa.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553 to make it effective upon signature. We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. It will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

Cattle moved interstate are moved for slaughter, for use as breeding stock, or for feeding. Changing the brucellosis status of Iowa from Class A to Class Free will promote economic growth by reducing certain testing and other requirements governing the interstate movement of cattle from this State. Testing requirements for cattle moved interstate for immediate slaughter or to quarantined feedlots are not affected by this change. Cattle from certified brucellosis-free herds moving interstate are not affected by this change.

The groups affected by this action will be herd owners in Iowa, as well as buyers and importers of cattle from this State.

There are an estimated 45,000 cattle herds in Iowa that would be affected by this rule. All of these are owned by small entities. Test-eligible cattle offered for sale interstate from other than certified-free herds must have a negative test under present Class A status regulations, but not under regulations concerning Class Free status. If such testing were distributed equally among all herds affected by this rule, Class Free status would save approximately $5 per head.

Therefore, we believe that changing the brucellosis status of Iowa will not have a significant economic impact on the small entities affected by this interim rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This document contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 78

Animal diseases, Bison, Cattle, Hogs, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, 9 CFR part 78 is amended as follows:

PART 78—BRUCELLOSIS

1. The authority citation for part 78 continues to read as follows:

Authority: 21 U.S.C. 111–114a–1, 114g, 115, 117, 120, 121, 123–126, 134b, and 134f; 7 CFR 2.22, 2.80, and 371.2(d).

§ 78.41 [Amended]

2. In § 78.41, paragraph (a) is amended by adding ''Iowa,'' immediately after ''Indiana,''.

3. In § 78.41, paragraph (b) is amended by removing ''Iowa,''.

Done in Washington, DC, this 14th day of July 1997.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–18951 Filed 7–17–97; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 92

[Docket No. 96–094–2]

Limited Ports; Dayton, OH

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: On May 22, 1997, the Animal and Plant Health Inspection Service published a direct final rule. (See 62 FR 27937–27938, Docket No. 96–094–1.) The direct final rule notified the public of our intention to amend the animal importation regulations by adding Dayton, OH, to the list of limited ports of entry for horses and horse products, such as horse test specimens, that do not appear to require restraint and holding inspection facilities. We did not receive any written adverse comments or written notice of intent to submit adverse comments in response to the direct final rule.

EFFECTIVE DATE: The effective date of the direct final rule is confirmed as: July 21, 1997.

FOR FURTHER INFORMATION CONTACT: Dr. David Vogt, Senior Staff Veterinarian, Animal Products, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231, (301) 734–8423; or e-mail: dvogt@aphis.usda.gov.

Authority: 7 U.S.C. 1622, 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 114a, 134a, 134b, 134c, 134d, 134f, 135, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(d).

Done in Washington, DC, this 14th day of July 1997.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–18950 Filed 7–17–97; 8:45 am]

BILLING CODE 3410–34–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–CE–47–AD; Amendment 39–10063; AD 97–14–05]

RIN 2120–AA64

Airworthiness Directives; Air Tractor Incorporated Models AT–301, AT–302, AT–400, AT–400A, AT–401, AT–402, AT–501, and AT–502 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes Airworthiness Directive AD 95–20–06, which applies to certain Air Tractor Incorporated (Air Tractor) Models AT–301, AT–302, AT–400, AT–400A, AT–401, AT–402, AT–501, and AT–502 airplanes and currently requires repetitively inspecting the front spar attachment lugs and the rear spar for fatigue cracks, and modifying the vertical fin if cracks are found. The modification terminates the repetitive inspection requirement of AD 95–20–06 and may be incorporated at any time, if cracks are not found. The FAA has determined that the Air Tractor Models mentioned above with a ¼-inch fin front spar fitting installed should be exempt from the AD. The AD will retain the requirements of AD 95–20–06 for all Air Tractor airplanes that have a 3/16-inch fin front spar fitting. The actions specified by this AD are intended to prevent in-flight vertical fin cracking, which, if not detected and corrected, could result in structural failure of the front spar attachments and eventually the rear spar attachment and cause loss of directional control of the airplane.

DATES: Effective August 25, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 25, 1997.

ADDRESSES: Service information that applies to this AD may be obtained from Air Tractor Incorporated, P. O. Box 485, Olney, Texas 76374. This information may also be examined at the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket 96–CE–47–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Bob May, Aerospace Engineer, FAA, Fort Worth Airplane Certification Office, 2601 Meacham Boulevard, Fort Worth, Texas 76193–0150; telephone (817) 222–5156; facsimile (817) 222–5960.

SUPPLEMENTARY INFORMATION:

Events Leading to the Issuance of This AD

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to Air Tractor airplanes fitted with 3/16-inch thick front spar attachment fittings that do not have the modification in Snow Engineering Company Report No. 138, dated July 29, 1995, Revised August 7, 1996, included the following Models and serial numbers:

Models	Serial numbers
AT–301 and AT–401	301–0261 through 301–0736, and 401–0662 through 401–0736 that have been converted to turbine powerplants and equipped with the all metal rudder, part number (P/N) 30456–1.
AT–302	All aircraft equipped with the all metal rudder, P/N 30456–1.
AT–400 and AT–400A	All aircraft equipped with the all metal rudder, P/N 30456–1.
AT–402	402–0694, and 402–0695 through 402–0736.
AT–501	501–0002 through 501–0030 that have been converted to turbine powerplants and equipped with the all metal rudder, P/N 30456–1.
AT–502	502–0002 through 502–0030.

The notice of proposed rulemaking (NPRM) for this action was published in the **Federal Register** on February 19, 1997 (62 FR 7377). The proposed AD would supersede AD 95–20–06 with a new AD that would require inspecting the fin front spar attachment fittings of Models that have 3/16-inch thick fin front spar attachment fittings for cracks, and if cracks are found, prior to further flight, modifying the front spar attachment fittings. If no cracks are

found, the proposed AD would require repetitively inspecting the front spar attachment fittings until cracks are found. Accomplishing the modification upon finding cracks or at any time prior to finding cracks would terminate the repetitive inspections.

Accomplishment of the proposed action would be in accordance with Snow Engineering Report (SER) number (No.) 138, dated July 29, 1995, Revised August 7, 1996.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposed rule or the FAA's determination of the cost to the public.

The FAA's Determination

After careful review of all available information related to the subject presented above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. The FAA has determined that these minor corrections will not change the meaning of the AD and will not add any additional burden upon the public than was already proposed.

Cost Impact

The FAA estimates that 24 airplanes in the U.S. registry will be affected by this AD, that it will take approximately 16 workhours per airplane to accomplish this action, and that the average labor rate is approximately $60 an hour. Parts cost approximately $10 per airplane. Based on these figures, the total cost impact of this AD on U.S. operators is estimated to be $23,280 or $970 per airplane. This figure is based on the presumption that no owner/operator of the affected airplanes has accomplished the required actions.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 USC 106(g), 40113, 44701.

§39.13 [Amended]

2. Section 39.13 is amended by removing airworthiness directive (AD) 95–20–06, Amendment No. 39–9384 (60 FR 52620) and by adding a new AD to read as follows:

97–14–05. Air Tractor Incorporated: Amendment No. 39–10063; Docket No. 96–CE–47–AD; Supersedes AD 95–20–06, Amendment 39–9384. Applicability: The following airplane Models and serial numbers fitted with a 3/16-inch fin front spar fitting that do not have the modification in Snow Engineering Company Report No. 138, dated July 29, 1995, revised August 7, 1996, incorporated, certificated in any category:

Note 1: The modification in Snow Engineering Company Report No. 138, dated July 29, 1995, revised August 7, 1996, and AD 95–20–06 required the airplanes to replace 3/16-inch thick fin front spar attach fittings with ¼-inch thick fin front spar attach fittings.

Models	Serial numbers
AT–301 and AT–401	301–0261 through 301–0736, and 401–0662 through 401–0736 that have been converted to turbine powerplants and equipped with the all metal rudder, part number (P/N) 30456–1.
AT–302	All aircraft equipped with the all metal rudder, P/N 30456–1.
AT–400 and AT–400A	All aircraft equipped with the all metal rudder, P/N 30456–1.
AT–402	402–0694 and 402–0695 through 402–0736.
AT–501	501–0002 through 501–0030 that have been converted to turbine powerplants and equipped with the all metal rudder, P/N 30456–1.
AT–502	AT–502 502–0002 through 502–0030.

Note 2: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required initially within the next 25 hours time-in-service (TIS) after the effective date of this AD, unless already accomplished, and thereafter as indicated in the body of this AD.

To prevent in-flight vertical fin cracking, which, if not detected and corrected, could result in structural failure of the front spar attachments and eventually the rear spar attachment and cause loss of directional control of the airplane, accomplish the following:

(a) Inspect the fin front spar attachment fittings for fatigue cracks in accordance with the INSTRUCTIONS section of the Snow Engineering Report (SER) number (No.) 138, dated July 29, 1995, Revised August 7, 1996.

(b) If no cracks are found during the initial inspection, repeat the inspection required by paragraph (a) of this AD at intervals not to exceed 25 hours TIS thereafter in accordance with the INSTRUCTIONS section of the SER No. 138, Revised August 7, 1996.

(c) If cracks are found during any inspections required by this AD, prior to further flight, modify the fin front spar attachment fittings in accordance with the

INSTRUCTIONS section of the SER No. 138, dated July 29, 1995, Revised August 7, 1996.

(d) Incorporating the modification specified in paragraph (c) of this AD is considered terminating action for the repetitive inspection requirements of this AD.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(f) An alternative method of compliance or adjustment of the compliance times that provides an equivalent level of safety may be approved by the Manager, Fort Worth Airplane Certification Office, 2601 Meacham Boulevard, Fort Worth, Texas 76193–0150. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Fort Worth Airplane Certification Office.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from Fort Worth Airplane Certification Office.

(g) The inspection and modification required by this AD shall be done in accordance with Snow Engineering Report No. 138, dated July 29, 1995, Revised August 7, 1996. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Air Tractor Incorporated, P.O. Box 485, Olney, Texas 76374. Copies may be inspected at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment supersedes AD 95–20–06, Amendment 39–9384.

(i) This amendment (39–10063) becomes effective on August 25, 1997.

Issued in Kansas City, Missouri, on June 26, 1997.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–17533 Filed 7–17–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–SW–02–AD; Amendment 39–10081; AD 97–15–08]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Helicopter Systems Model 369D, E, F, FF, 500N, AH–6, and MH–6 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to McDonnell Douglas Helicopter Systems (MDHS) Model 369D, E, F, FF, 500N, AH–6, and MH–6 helicopters. This action requires replacement of certain transmission output drive gears (gears). This amendment is prompted by several reports of spalled or fractured gear teeth, most of which occurred during high-power or external-lift operations. The actions specified in this AD are intended to prevent failure of the gear, which could result in loss of main rotor control and subsequent loss of control of the helicopter.

DATES: August 4, 1997.

Comments for inclusion in the Rules Docket must be received on or before September 16, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Assistant Chief Counsel, Attention: Rules Docket No. 97–SW–02–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Mr. Bruce Conze, Aerospace Engineer, FAA, Los Angeles Aircraft Certification Office, Propulsion Branch, 3960 Paramount Blvd., Lakewood, California 90712, telephone (562) 627–5261, fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: This amendment adopts a new AD that is applicable to MDHS Model 369D, E, F, FF, 500N, AH–6, and MH–6 helicopters, equipped with main rotor transmission, part number (P/N) 369D25100, that contain a gear, P/N 369D25127–11, having the following serial numbers: serial number (S/N) 005570–0646 through S/N 005570–0765, and S/N 005570–0876 through S/N 005570–0998. This action requires replacement of gears having the affected serial numbers within a specified number of hours time-in-service (TIS). There have been several occurrences of spalled or fractured gear teeth in the last seven years. Five of the occurrences involved fractured gear teeth, and two involved spalling of the gear tooth face. All seven failures occurred on helicopters having less than 1,000 hours TIS, with the lowest being 467 hours TIS. Most of the damage and subsequent failures have occurred during high-power or external-lift operations conducted on military aircraft. This amendment is prompted by several reports of spalled or fractured gear teeth, most of which occurred during high-power or external-lift operations. Until 1996, all failures had occurred only in military operations in which it was thought to be due to overtorquing during maximum effort exercises. Since there is no reporting requirement for military use, those failures were handled under military maintenance and not reported. In 1996, a similar failure occurred in New Zealand with an external load operator. This was the first commercial failure and the first reported to the FAA by MDHS. MDHS was allowed time to examine the failure and determine the cause. Once it was determined that the failure was due to a quality control problem, the affected lots were identified and MDHS issued service information. Warping of the ring gear during carburizing heat treatment and subsequent grinding through the hardened case results in a lowering of the contact stress and fatigue resistance of the gear teeth. This could result in fracture or loss of a gear tooth, which could lead to jamming or binding of the drive system. The actions specified in this AD are intended to prevent failure of the gear, which could result in loss of main rotor control and subsequent loss of control of the helicopter.

The FAA has reviewed McDonnell Douglas Helicopter Systems Service Information Notice DN–189/EN–82/FN–69/NN–009, dated January 10, 1997, which describes procedures for determining, through an inspection of records or physical inspection, if a gear, P/N 369D25127–11, with serial number (S/N) S/N 005570–0646 through S/N 005570–0765, or S/N 005570–0876 through S/N 005570–0998 is installed.

Since an unsafe condition has been identified that is likely to exist or develop on other MDHS Model 369D, E, F, FF, 500N, AH–6, and MH–6 helicopters of the same type design, this AD is being issued to prevent failure of the gear, which could result in loss of main rotor control and subsequent loss of control of the helicopter. This AD requires an inspection to determine if an affected gear (based on the gear's serial number) is installed, and if an affected gear is installed, replacement of the gear with an airworthy gear.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity

for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the rules docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the rules docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the rules docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 97–SW–02–AD.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the rules docket. A copy of it, if filed, may be obtained from the rules docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

AD 97–15–08 McDonnell Douglas Helicopter Systems: Amendment 39–10081. Docket No. 97–SW–02–AD.

Applicability: Model 369D, E, F, FF, 500N, AH–6, and MH–6 helicopters, with main rotor transmission, part number (P/N) 369D25100, installed, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (d) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the transmission output drive gear (gear), part number P/N 369D25127–11, which could result in loss of main rotor control and subsequent loss of control of the helicopter, accomplish the following:

(a) Within the next 10 hours time-in-service (TIS) after the effective date of this AD, determine through an inspection of records, contact with the manufacturer, or using a bright light and viewing through the open liquid level plug port, if the installed gear serial number (S/N) is S/N 005570–0646 through S/N 005570–0765, or S/N 005570–0876 through S/N 005570–0998.

(b) If the gear has an affected S/N, remove the gear and replace it with an airworthy gear, that has a S/N other than the S/N's listed in paragraph (a) of this AD, as follows:

(1) For helicopters equipped with a cargo hook assembly, with a separate, permanently-maintained log of actual hours time-in-service (TIS) of external load operation, remove and replace the gear within the next 25 hours TIS for external load operations, or within the next 400 hours TIS for non-external load operation, whichever comes first.

(2) For helicopters equipped with a cargo hook assembly, with no separate, permanently-maintained log of actual external load operation, remove and replace the gear within the next 25 hours TIS after the effective date of this AD. Owners/operators may begin maintaining a separate permanent log of external load operations and comply with the requirements of paragraph (b)(1) of this AD.

(3) For helicopters without cargo hook assemblies, remove and replace the gear within the next 400 hours TIS after the effective date of this AD.

(c) Replacement of the affected gear with an airworthy gear having a S/N other than those S/N's listed in paragraph (a) of this AD is considered a terminating action for the requirements of this AD.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office. Operators shall submit their requests through a FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Los Angeles Aircraft Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles Aircraft Certification Office.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(f) This amendment becomes effective on August 4, 1997.

Issued in Fort Worth, Texas, on July 10, 1997.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 97–18932 Filed 7–17–97; 8:45 am]

BILLING CODE 4910–13–U

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404, 410, 416, and 422

[Regulation Nos. 4, 10, 16, and 22]

RIN 0960–AE45

Employees' Benefits

AGENCY: Social Security Administration.

ACTION: Final rules.

SUMMARY: These final rules amend our regulations to delete references to the Department of Health and Human Services (HHS) and the Department of Health, Education and Welfare (HEW) and to the Secretary to read the Social Security Administration (SSA) and the Commissioner, respectively. These final rules revise specific titles used by SSA internally. These final rules also standardize the name of the Department of Health and Human Services' Departmental Appeals Board and make technical changes in legal citations and renumber sections. The Social Security Independence and Program Improvements Act (SSIPIA) of 1994 established SSA as an independent agency in the executive branch of the United States Government effective March 31, 1995 and vested general regulatory authority in the Commissioner of Social Security. These regulations recognize the Commissioner of Social Security as the designated head of the agency.

EFFECTIVE DATE: These rules are effective July 18, 1997.

FOR FURTHER INFORMATION CONTACT: Suzanne DiMarino, Division of Regulations and Rulings, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–1769 for information about these rules. For information on eligibility or claiming benefits, call our national toll-free number, 1–800–772–1213.

SUPPLEMENTARY INFORMATION: Prior to March 31, 1995, the general regulatory authority for SSA programs and administration was vested in the Secretary of Health and Human Services (the Secretary) and was based on sections 205(a), 1102 and 1631(d)(1) of the Social Security Act (the Act)(42 U.S.C. 405(a), 1302, 1383(d)(1) and 30 U.S.C. 921, 936(a) and 957). The SSIPIA of 1994, Pub. L. 103–296, established SSA as an independent agency in the executive branch of the United States Government effective March 31, 1995. General regulatory authority was vested in the Commissioner of Social Security (the Commissioner) by section 702(a)(5) of the Act (42 U.S.C. 902(a)(5)). In addition, references to the regulatory authority of the Secretary in sections 205(a) and 1631(d)(1) of the Act and in 30 U.S.C. 921, 936(a) and 957 were amended to provide the Commissioner with such authority by sections 107(a) and 108(i) of the SSIPIA. It is therefore no longer appropriate, in most instances, to refer in our regulations to HHS or HEW (the predecessor to HHS), the Secretary, and other subordinate authorities within HHS. These final regulations replace such references with references to the Commissioner, SSA, and subordinate authorities within SSA. These final rules revise specific titles used by SSA internally. These final rules also standardize references to the Department of Health and Human Services' Departmental Appeals Board, and make changes to legal citations and renumber sections according to the Office of the Federal Register's guidelines and rules. These final rules do not address 20 CFR parts 401 and 422 subpart E because these parts have been rewritten and published in a separate regulations package. The following parts under 20 CFR chapter III are affected:

1. Part 404—*Federal Old-Age, Survivors and Disability Insurance (1950–);*
2. *Part 410—Federal Coal Mine Health and Safety Act of 1969, Title IV—Black Lung Benefits (1969–);*
3. Part 416—*Supplemental Security Income for the Aged, Blind, and Disabled;* and
4. Part 422—*Organization and Procedures.* (All Parts except Subpart E.)

Electronic Version

The electronic file of this document is available on the Federal Bulletin Board (FBB) at 9:00 A.M. on the date of publication in the **Federal Register**. To download the file, modem dial (202) 512–1387. The FBB instructions will explain how to download the file and the fee.

Regulatory Procedures

Pursuant to section 702(a)(5) of the Act (42 U.S.C. 902(a)(5)), SSA follows the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553 in the development of its regulations. The APA provides exceptions to its prior notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures. Section 553(b)(B) of the APA exempts application of notice and comment rulemaking procedures ''when the agency for good cause finds * * * that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' We have determined that for these final rules, notice of proposed rulemaking and public comment procedures are unnecessary. Good cause exists because these are minor technical changes which make no substantive change in the regulations and have no effect on the public. Therefore, opportunity for prior comment is unnecessary, and we are issuing these changes to our regulations as final rules.

SSA is not providing a 30-day delay in the effective date of these final rules under 5 U.S.C. 553(d). These are not substantive rules, since the rules merely make minor technical changes and reflect no change in policy. Accordingly, the requirements of 5 U.S.C. 553(d) are inapplicable.

Executive Order 12866

SSA has consulted with the Office of Management and Budget (OMB) and determined that these final rules do not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, they were not subject to OMB review.

Regulatory Flexibility Act

These proposed rules will not have a significant economic impact on a substantial number of small entities because they affect only individuals. Thus, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These final rules impose no additional reporting or recordkeeping requirements subject to OMB clearance.

(Catalog of Federal Domestic Assistance Program Nos. 96.001 Social Security—Disability Insurance; 96.002 Social Security—Retirement Insurance; 96.003 Social Security—Special Benefits for Persons Aged 72 and Over; 96.004 Social Security—Survivors Insurance; 96.005 Special Benefits for Disabled Coal Miners; 96.006 Supplemental Security Income; 96.007 Social Security—Research and Demonstration)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Blind, Old-age, Survivors and Disability benefits, Old-age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 410

Administrative practice and procedure, Black Lung benefits, Claims, Investigations, and Workers' compensation.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental Security Income, (SSI), Reporting and recordkeeping requirements.

20 CFR Part 422

Administrative practice and procedure, Organization and functions (Government agencies), Social Security.

Dated: July 3, 1997.

John J. Callahan,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, 20 CFR chapter III is amended as follows:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart A—[Amended]

1. The authority citation for subpart A of part 404 continues to read as follows:

Authority: Secs. 203, 205(a), 216(j), and 702(a)(5) of the Social Security Act (42 U.S.C. 403, 405(a), 416(j), and 902(a)(5)).

§ 404.1 [Amended]

2. Section 404.1(q) is amended by removing ''Secretary'' and ''Secretary's'' and adding ''Commissioner'' and ''Commissioner's'' respectively.

3. Section 404.2 is amended by revising paragraph (b) to read as follows:

§ 404.2 General definitions and use of terms.

* * * * *

(b) *Commissioner; Appeals Council; Administrative Law Judge defined.* (1) *Commissioner* means the Commissioner of Social Security.

(2) *Appeals Council* means the Appeals Council of the Office of Hearings and Appeals in the Social Security Administration or such member or members thereof as may be designated by the Chairman.

(3) *Administrative Law Judge* means an Administrative Law Judge in the Office of Hearings and Appeals in the Social Security Administration.

* * * * *

§ 404.2 [Amended]

4. Section 404.2(c)(1) is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 404.3 [Amended]

5. Section 404.3(b) is amended by removing ''Secretary'' and adding ''Commissioner''.

Subpart B—[Amended]

1. The authority citation for subpart B of part 404 continues to read as follows:

Authority: Secs. 205(a), 212, 213, 214, 216, 217, 223, and 702(a)(5) of the Social Security Act (42 U.S.C. 405(a), 412, 413, 414, 416, 417, 423, and 902(a)(5)).

§ 404.143 [Amended]

2. Section 404.143(a)(2) is amended by removing ''Secretary'' and adding ''Commissioner''.

3. The Appendix to subpart B is amended by removing ''Secretary'' and adding ''Commissioner''.

Subpart C—[Amended]

1. The authority citation for subpart C of part 404 continues to read as follows:

Authority: Secs. 202(a), 205(a), 215, and 702(a)(5) of the Social Security Act (42 U.S.C. 402(a), 405(a), 415, and 902(a)(5)).

2. Section 404.203 is amended by revising the definition of ''We'', ''us'' or ''our'' in paragraph (a) to read as follows:

§ 404.203 Definitions.

(a) * * *

We, us, or *our* means the Social Security Administration.

* * * * *

Subpart E—[Amended]

1. The authority for subpart E of part 404 continues to read as follows:

Authority: Secs. 202, 203, 204 (a) and (e), 205 (a) and (c), 222(b), 223(e), 224, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 403, 404 (a) and (e), 405 (a) and (c), 422(b), 423(e), 424a, 425, and 902(a)(5)).

§ 404.403 [Amended]

2. Section 404.403(d)(2) is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 404.408 [Amended]

3. Section 404.408 is amended by removing ''Secretary'' and ''Secretary of Health and Human Services'' and adding ''Commissioner'' and ''Commissioner of Social Security'' respectively in paragraphs (a)(1)(ii), (e)(2), (f), (k), and (l)(2)(ii).

§ 404.430 [Amended]

4. Section 404.430 is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraphs (c)(1)(ii)(A)(*1*), (c)(1)(ii)(A)(*2*), and (c)(2).

§ 404.460 [Amended]

5. Section 404.460 is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraphs (b)(4)(ii) and (b)(7) introductory text.

§ 404.464 [Amended]

6. Section 404.464 is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraphs (a) and (c).

§ 404.468 [Amended]

7. Section 404.468(d) is amended by removing ''Secretary'' and adding ''Commissioner''.

Subpart F—[Amended]

1. The authority citation for subpart F of part 404 continues to read:

Authority: Secs. 204 (a)–(d), 205(a), and 702(a)(5) of the Social Security Act (42 U.S.C. 404 (a)–(d), 405(a), and 902(a)(5)); 31 U.S.C. 3720A.

§ 404.520 [Amended]

2. Section 404.520 is amended by removing ''and Department of Health and Human Services regulations at 45 CFR Part 31'' in paragraph (a).

Subpart J—[Amended]

1. The authority citation for subpart J of part 404 continues to read as follows:

Authority: Secs. 201(j), 205 (a), (b), (d)–(h), and (j), 221, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 401(j), 405 (a), (b), (d)–(h), and (j), 421, 425, and 902(a)(5)); 31 U.S.C. 3720A; sec. 5, Pub. L. 97–455, 96 Stat. 2500 (42 U.S.C. 405 note); secs. 5, 6(c)–(e), and 15, Pub. L. 98–460, 98 Stat. 1802 (42 U.S.C. 421 note).

§ 404.983 [Amended]

2. Section 404.983 is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 404.984 [Amended]

3. Section 404.984 is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraphs (a), (b)(2), (b)(3), (c), and (d).

§ 404.985 [Amended]

4. Section 404.985 is amended by removing ''Department of Health and Human Services'' and adding ''Social Security Administration'' in paragraph (c)(2).

Subpart M—[Amended]

1. The authority citation for subpart M of part 404 continues to read as follows:

Authority: Secs. 205, 210, 218, and 702(a)(5) of the Social Security Act (42 U.S.C. 405, 410, 418, and 902(a)(5)); sec. 12110, Pub. L. 99–272, 100 Stat. 287 (42 U.S.C. 418 note); sec. 9002, Pub. L. 99–509, 100 Stat. 1970.

§ 404.1200 [Amended]

2. Section 404.1200 is amended by removing ''Secretary of Health and Human Services'' and ''Secretary'' and adding ''Commissioner of Social Security'' and ''Commissioner'' respectively in paragraph (a).

§ 404.1202 [Amended]

3. Section 404.1202(b) is amended by removing ''Secretary of Health and Human Services'' wherever it appears and adding ''Commissioner of Social Security'' and by removing the definition of *Secretary.*

§ 404.1206 [Amended]

4. Section 404.1206 is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraph (d).

§ 404.1211 [Amended]

5. Section 404.1211 is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraph (a).

§ 404.1214 [Amended]

6. Section 404.1214 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in paragraphs (a), (c)(1), (c)(2), (d)(3), (d)(4), (e), and (f).

§ 404.1215 [Amended]

7. Section 404.1215 is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraphs (b) and (d).

§ 404.1216 [Amended]

8. Section 404.1216 is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraph (b)(3).

§ 404.1225 [Amended]

9. Section 404.1225 is amended by removing ''Secretary'' and adding ''Commissioner'' in the undesignated paragraph following paragraph (a)(4).

§ 404.1232 [Amended]

10. Section 404.1232 is amended by removing, ''Department of Health and Human Services (HHS),'' in paragraph (a) and deleting ''or HHS'' from paragraph (b).

§ 404.1249 [Amended]

11. Section 404.1249 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in paragraphs (b)(2) (i), (ii), and (iv).

§ 404.1267 [Amended]

12. Section 404.1267 is amended by removing ''Secretary'' and adding ''Commissioner.'' This is not applicable when text is referring to the ''Secretary of the Treasury''.

§ 404.1282 [Amended]

13. Section 404.1282 is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraph (a).

§ 404.1283 [Amended]

14. Section 404.1283 is amended by removing ''Secretary'' and ''Secretary's'' and adding ''Commissioner'' and ''Commissioner's'' respectively in paragraphs (a)(1), (a)(2), (b) introductory text and (b)(1).

§ 404.1285 [Amended]

15. Section 404.1285 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in paragraph (a). This is not applicable when text is referring to the ''Secretary of the Treasury''.

§ 404.1286 [Amended]

16. Section 404.1286 is Amended by removing ''Secretary'' and adding ''Commissioner'' in paragraphs (a) and (b).

§ 404.1287 [Amended]

17. Section 404.1287 is Amended by removing ''Secretary'' and ''Secretary's'' wherever they appear and adding ''Commissioner'' and ''Commissioner's'' respectively in paragraphs (a)(1), (a)(2) introductory text, (b), (c), (d) and (e). This is not applicable when text is referring to the ''Secretary of the Treasury''.

§ 404.1289 [Amended]

18. Section 404.1289 is Amended by removing ''Secretary'' and adding ''Commissioner'' in the introductory text and the undesignated paragraph following paragraph (b).

§ 404.1290 [Amended]

19. Section 404.1290 is Amended by removing paragraph (a) and the paragraph designation from paragraph (b).

§ 404.1296 [Amended]

20. The undesignated center heading following § 404.1296 is Amended by removing ''Secretary's'' and adding ''Commissioner's''.

§ 404.1297 [Amended]

21. Section 404.1297 (a) is Amended by removing ''for the Secretary'' from the text.

Subpart O—[Amended]

1. The authority citation for subpart O of part 404 continues to read as follows:

Authority: Secs. 202(l), 205(a), (c)(5)(D), (i), and (o), 210(a)(9) and (l)(4), 211(c)(3), and 702(a)(5) of the Social Security Act (42 U.S.C. 402(l), 405(a), (c)(5)(D), (i), and (o), 410(a)(9) and (l)(4), 411(c)(3), and 902(a)(5)).

§ 404.1413 [Amended]

2. Section 404.1413 is Amended by removing ''Secretary of Health, Education, and Welfare'' and adding ''Commissioner'' in the introductory text.

Subpart P—[Amended]

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205 (a), (b), and (d)–(h), 216(i), 221 (a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405 (a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub.L. 104–193, 110 Stat. 2105, 2189.

2. Section 404.1502 is amended by removing the definition of *Secretary* and adding the definition of *Commissioner* to read as follows:

§ 404.1502 General definitions and terms for this subpart.

* * * * *

Commissioner means the Commissioner of Social Security or his or her authorized designee.

* * * * *

§ 404.1503 [Amended]

3. Section 404.1503 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in paragraphs (a), (b)(1), (c) introductory text and (e). Section 404.1503(b) introductory text is amended by removing ''the Secretary for'' from the sentence.

§ 404.1526 [Amended]

4. Section 404.1526 is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraphs (b) and (c).

§ 404.1527 [Amended]

5. Section 404.1527 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in the heading to paragraph (e) and in paragraph (e)(2).

§ 404.1529 [Amended]

6. Section 404.1529(b) is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 404.1546 [Amended]

7. Section 404.1546 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner''.

§ 404.1597a [Amended]

8. Section 404.1597a (j)(1) and (j)(2) are amended by removing ''Secretary'' and adding ''Commissioner''.

§ 404.1599 [Amended]

9. Section 404.1599 (a) and (b) are amended by removing ''Secretary'' and adding ''Commissioner''.

Subpart Q—[Amended]

1. The authority citation for subpart Q of part 404 continues to read as follows:

Authority: Secs. 205(a), 221, and 702(a)(5) of the Social Security Act (42 U.S.C. 405(a), 421, and 902(a)(5)).

§ 404.1601 [Amended]

2. Section 404.1601 is amended by removing ''Secretary'' and ''Secretary's'' wherever they appear and adding ''Commissioner'' and ''Commissioner's''

respectively in the introductory text and in paragraphs (a), (b), (c), (e), (f), and (h).

3. Section 404.1602 is amended by adding ''and Policy'' to the title ''Deputy Commissioner for Programs'' in *Other written guidelines,* by removing the definition of *Secretary,* and by adding the definition of *Commissioner* and by revising the definition of *We, us,* and *our* to read as follows:

§ 404.1602 Definitions.

* * * * *

Commissioner means the Commissioner of Social Security or his or her authorized designee.

* * * * *

We, us, and *our* refers to the Social Security Administration (SSA).

§ 404.1613 [Amended]

4. Section 404.1613(a) is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 404.1615 [Amended]

5. Section 404.1615(d) is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 404.1616 [Amended]

6. Section 404.1616(b)(2) is amended by removing ''Secretary of Health and Human Services'' and adding ''Commissioner of Social Security''.

§ 404.1626 [Amended]

7. Section 404.1626(e) is amended by removing ''Department of Health and Human Services'' and adding ''of the Social Security Administration'' after ''Inspector General''.

§ 404.1627 [Amended]

8. Section 404.1627(b) is amended by removing ''*Secretary*'' and adding ''*Commissioner*'' in the title, by removing ''Department of Health and Human Services' '' and adding ''SSA's'' before ''Inspector General'' in paragraph (b)(1).

§ 404.1641 [Amended]

9. Section 404.1641(a) is amended by removing ''Secretary's'' and adding ''Commissioner's''.

§ 404.1682 [Amended]

10. Section 404.1682 is amended by adding the words ''Department of'' before the word ''Health'', adding an apostrophe after the word ''Services'' and by removing the word ''Grant''.

§ 404.1691 [Amended]

11. Section 404.1691(a) is amended by removing ''Secretary'' from the heading and adding ''Commissioner''.

§ 404.1694 [Amended]

12. Section 404.1694 is amended by removing the word ''Grant'' from the last sentence and adding ''Departmental''.

Subpart R—[Amended]

1. The authority citation for subpart R of part 404 continues to read as follows:

Authority: Secs. 205(a), 206, and 702(a)(5) of the Social Security Act (42 U.S.C. 405(a), 406, and 902(a)(5)).

§ 404.1735 [Amended]

2. Section 404.1735 is amended by removing ''Secretary of Health and Human Services'' and adding ''Commissioner of Social Security''.

§ 404.1745 [Amended]

3. Section 404.1745 introductory text is amended by adding the words ''and Policy'' to the title of ''Deputy Commissioner for Programs''.

§ 404.1750 [Amended]

4. Section 404.1750 is amended by deleting the comma after ''Programs'', and adding the words ''and Policy'' after ''Programs'' in paragraphs (a) and (d).

§ 404.1765 [Amended]

5. Section 404.1765 is amended by deleting the comma after ''Programs'', and adding the words ''and Policy'' after ''Programs'' in paragraphs (a) and (e).

§ 404.1799 [Amended]

6. Section 404.1799 is amended by deleting the comma after ''Programs'', and adding the words ''and Policy'' after ''Programs'' in paragraphs (c) and (e).

Subpart T—[Amended]

1. The authority citation for subpart T of part 404 continues to read as follows:

Authority: Secs. 205(a), 233, and 702(a)(5) of the Social Security Act (42 U.S.C. 405(a), 433, and 902(a)(5)).

§ 404.1902 [Amended]

2. Section 404.1902 is amended by removing ''Secretary of HEW'' and adding ''Commissioner of Social Security'' in the *Competent authority* definition.

Subpart V—[Amended]

1. The authority citation for subpart V of part 404 continues to read as follows:

Authority: Secs. 205(a), 222, and 702(a)(5) of the Social Security Act (42 U.S.C. 405(a), 422, and 902(a)(5)).

§ 404.2102 [Amended]

2. Section 404.2102 is amended by removing ''Secretary'' and adding ''Commissioner'' in the introductory paragraph.

§ 404.2103 [Amended]

3. Section 404.2103 is amended by removing the definition of *Secretary* and by removing ''or the Secretary, as appropriate'' from the *We, us,* and *our* definition.

§ 404.2117 [Amended]

4. Section 404.2117 is amended by removing ''Secretary'' and adding ''Commissioner'' in the introductory paragraph.

§ 404.2120 [Amended]

5. Section 404.2120(c) is amended by adding an apostrophe to the word ''Services'' and by removing ''Grant''.

§ 404.2127 [Amended]

6. Section 404.2127 is amended by adding an apostrophe to the word ''Services'' and by deleting ''Grant'' from paragraph (a), by removing ''Grant'' and adding ''Departmental'' before ''Appeals Board'' in paragraph (b), and by removing ''Secretary'' and adding ''Commissioner'' throughout paragraph (c).

PART 410—FEDERAL COAL MINE HEALTH AND SAFETY ACT OF 1969—BLACK LUNG BENEFITS (1969–)

Subpart A—[Amended]

1. The authority citation for subpart A of part 410 is revised to read as follows:

Authority: Secs. 702(a)(5) of the Social Security Act (42 U.S.C. 902(a)(5)), Secs. 3 (g) and (h), 402, 411, 412, 413, 414, 426(a), and 508, 83 Stat. 744; 30 U.S.C. 802 (g) and (h), 902, 921–924, 936(a), and 957. Sec. 410.120 also issued under sec. 1106, 53 Stat. 1398, as amended, 42 U.S.C. 1306.

§ 410.110 [Amended]

2. Section 410.110 is amended by removing paragraph (c), redesignating paragraphs (d) through (r) as (c) through (q), by removing ''in the Department of Health, Education, and Welfare'' and adding ''(SSA)'' in newly designated paragraph (d), by removing ''the Bureau of Hearings and Appeals in the'' in newly designated paragraph (e) and by removing ''the Bureau of Hearings and Appeals of the Social Security Administration'' and adding ''SSA'' in newly designated paragraph (f).

§ 410.120 [Amended]

3. Section 410.120 is amended by removing ''Department of Health, Education, and Welfare'' and ''Department'' wherever they appear and adding ''Social Security Administration'' and ''Administration'' respectively and by removing ''45 CFR part 5'' and adding ''20 CFR part 401''.

§ 410.130 [Amended]

4. Section 410.130 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner''.

Subpart B—[Amended]

1. The authority citation for subpart B of part 410 is revised to read as follows:

Authority: Sec. 702(a)(5) of the Social Security Act (42 U.S.C. 902(a)(5)), sec. 402, 411, 412, 413, 414, 426(a), and 508, 83 Stat. 792; 30 U.S.C. 902, 921–924, 936(a), 957.

Subpart C—[Amended]

1. The authority citation for subpart C of part 410 is revised to read as follows:

Authority: Sec. 702(a)(5) of the Social Security Act (42 U.S.C. 902(a)(5)), secs. 402, 412(a), 426(a), and 508, 83 Stat. 792; 30 U.S.C. 902, 922(a), 936, and 957.

Subpart D—[Amended]

1. The authority citation for subpart D of part 410 is revised to read as follows:

Authority: Sec. 702(a)(5) of the Social Security Act (42 U.S.C. 902(a)(5)), secs. 401–426, 83 Stat. 792, as amended, 86 Stat. 150; 30 U.S.C. 901 *et. seq.*

§ 410.401 [Amended]

2. Section 410.401(c) is amended by removing ''Secretary [of Health, Education, and Welfare]'' and adding ''Commissioner''.

§ 410.474 [Amended]

3. Section 410.474 is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 410.490 [Amended]

4. Section 410.490(a) is amended by removing ''Secretary'' and adding ''Commissioner''.

Subpart E—[Amended]

1. The authority citation for subpart E of part 410 is revised to read as follows:

Authority: Sec. 702(a)(5) of the Social Security Act (42 U.S.C. 902(a)(5)), secs. 411(a), 412 (a) and (b), 413(b), 426(a), and 508, 83 Stat. 793; 30 U.S.C. 921(a), 922 (a) and (b), 923(b), 936(a), and 957; sec. 410.565 also issued under sec. 3, 80 Stat. 309, 31 U.S.C. 952, unless otherwise noted.

Subpart F—[Amended]

1. The authority citation for subpart F of part 410 is revised to read as follows:

Authority: Sec. 702(a)(5) of the Social Security Act (42 U.S.C. 902(a)(5)), secs. 413(b), 426(a), 507, and 508 of the Federal Mine Safety and Health Act of 1977; 30 U.S.C. 923(b), 936(a), 956, and 957.

§ 410.601 [Amended]

2. Section 410.601 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in paragraphs (a) and (b).

§ 410.629a [Amended]

3. Section 410.629a is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraphs (a) and (d).

§ 410.629d [Amended]

4. Section 410.629d is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraphs (a)(1), (b)(2) and (b)(5).

§ 410.629e [Amended]

5. Section 410.629e is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner''.

§ 410.629f [Amended]

6. Section 410.629f is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 410.634 [Amended]

7. Section 410.634 is amended by removing ''Director of the Bureau of Hearings and Appeals of the Administration or his delegate.'' and adding ''Deputy Commissioner for Programs and Policy, or his or her designee.'' and by removing ''Director'' wherever it appears and adding ''Deputy Commissioner''.

§ 410.635 [Amended]

8. Section 410.635 is amended by removing ''Director of the Bureau of Hearings and Appeals of the Administration or his delegate'' and adding ''Deputy Commissioner for Programs and Policy, or his or her designee''.

§ 410.639 [Amended]

9. Section 410.639 is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 410.644 [Amended]

10. Section 410.644 is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 410.650 [Amended]

11. Section 410.650(a) is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 410.669 [Amended]

12. Section 410.669(b) is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 410.670b [Amended]

13. Section 410.670b is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraphs (a), (b)(1) and (b)(4).

§ 410.670c [Amended]

14. Section 410.670c(c)(2) is amended by removing ''the Department of Health and Human Services'' and adding ''SSA''.

§ 410.686e [Amended]

15. Section 410.686e is amended by removing ''the Secretary of Health, Education, and Welfare'' and adding ''SSA''.

§ 410.687 [Amended]

16. Section 410.687(d) is amended by removing ''Secretary'' and by adding ''Commissioner''.

17. Section 410.688 is revised to read as follows:

§ 410.688 Disqualification or suspension of an individual from acting as a representative in proceedings before SSA.

Whenever it appears that an individual has violated any of the rules in § 410.687, or has been convicted of a violation under section 206 of the Social Security Act, or has otherwise refused to comply with the Commissioner's rules or regulations on representation of claimants, SSA may institute proceedings as herein provided to suspend or disqualify that individual from acting as a representative in proceedings before SSA.

§ 410.689 [Amended]

18. Section 410.689 is amended by removing '', or the Director (or Deputy Director) of the Bureau of Retirement and Survivors Insurance of the Administration'' from the first sentence and adding ''for Programs and Policy, or his or her designee,'', by removing ''Administration'' from the second sentence and adding ''SSA'', by removing '', or the Director (or Deputy Director) of the Bureau of Retirement and Survivors Insurance'' from the third sentence and adding ''for Programs and Policy, or his or her designee'' and by removing ''Bureau of Hearings and Appeals, Post Office Box 2518, Washington, DC 20013, with a copy to the Bureau of Retirement and Survivors Insurance,''.

§ 410.690 [Amended]

19. Section 410.690 is amended by removing '', or the Director (or Deputy Director) of the Bureau of Retirement and Survivors Insurance of the Administration,'' and adding ''for Programs and Policy, or his or her designee,''.

§ 410.691 [Amended]

20. Section 410.691 is amended by removing ''Bureau of Hearings and

Appeals of the Administration'' and adding ''Deputy Commissioner for Programs and Policy, or his or her designee''.

§ 410.692 [Amended]

21. Section 410.692 is amended by removing ''Director, ureau of Hearings and Appeals of the Administration or his delegate'' and adding ''Deputy Commissioner for Programs and Policy, or his or her designee'' in paragraph (a), by removing ''or the Director (or Deputy Director) of the Bureau of Retirement and Survivors Insurance of the Administration'' wherever it appears and adding ''for Programs and Policy, or his or her designee,'' and by removing '', or the Director (or Deputy Director) of the Bureau of Retirement and Survivors Insurance'' and adding ''for Programs and Policy, or his or her designee,'' in paragraph (b) respectively, by removing '', or the Director (or Deputy Director) of the Bureau of Retirement and Survivors Insurance of the Administration'' and adding ''for Programs and Policy, or his or her designee'' in paragraph (d) and by removing ''Secretary of Health, Education, and Welfare'' and adding ''Commissioner of Social Security'' in paragraph (e).

§ 410.693 [Amended]

22. Section 410.693 is amended by removing '', or the Director (or Deputy Director) of the Bureau of Retirement and Survivors Insurance'' and by adding ''for Programs and Policy, or his or her designee'' in the undesignated paragraph following paragraph (a)(2).

§ 410.697 [Amended]

23. Section 410.697 is amended by removing '', or the Director (or Deputy Director) of the Bureau of Retirement and Survivors Insurance'' and adding ''for Programs and Policy, or his or her designee''.

§ 410.699 [Amended]

24. Section 410.699 is amended by removing '', or the Director (or Deputy Director) of the Bureau of Retirement and Survivors Insurance'' and adding ''for Programs and Policy, or his or her designee'' in paragraphs (a) and (c).

Subpart G—[Amended]

1. The authority citation for subpart G of part 410 is revised to read as follows:

Authority: Sec. 702(a)(5) of the Social Security Act (42 U.S.C. 902(a)(5)), sec. 411, 82 Stat. 793 and 30 U.S.C. 902.

§ 410.700 [Amended]

2. Section 410.700 is amended by removing ''Department of Health, Education, and Welfare,'' in paragraph (b).

§ 410.704 [Amended]

3. Section 410.704(a)(1) is amended by removing ''DHEW,''.

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart A—[Amended]

1. The authority citation for subpart A of part 416 continues to read as follows:

Authority: Secs. 702(a)(5) and 1601–1635 of the Social Security Act (42 U.S.C. 902(a)(5) and 1381–1383d); sec. 212, Pub. L. 93–66, 87 Stat. 155 (42 U.S.C. 1382 note); sec. 502(a), Pub. L. 94–241, 90 Stat. 268 (48 U.S.C. 1681 note).

§ 416.101 [Amended]

2. Section 416.101(j) is amended by removing ''Secretary'' and ''Secretary's'' and adding ''Commissioner'' and ''Commissioner's''.

§ 416.105 [Amended]

3. Section 416.105 is amended by removing ''under authority delegated by the Secretary of Health and Human Services''.

§ 416.110 [Amended]

4. Section 416.110(f)(1) is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 416.120 [Amended]

5. Section 416.120(b) is amended by removing ''Secretary;'' and paragraph (b)(1) is removed in its entirety. Paragraphs (b)(2) and (b)(3) are redesignated (b)(1) and (b)(2). Section 416.120(d) is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner''.

Subpart B—[Amended]

1. The authority citation for subpart B of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1110(b), 1602, 1611, 1614, 1615(c), 1619(a), 1631, and 1634 of the Social Security Act (42 U.S.C. 902(a)(5), 1310(b), 1381a, 1382, 1382c, 1382d(c), 1382h(a), 1383, and 1383c); secs. 211 and 212, Pub. L. 93–66, 87 Stat. 154 and 155 (42 U.S.C. 1382 note); sec. 502(a), Pub. L. 94–241, 90 Stat. 268 (48 U.S.C. 1681 note); sec. 2, Pub. L. 99–643, 100 Stat. 3574 (42 U.S.C. 1382h note).

§ 416.250 [Amended]

2. Section 416.250 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in paragraphs (a) and (b).

Subpart E—[Amended]

1. The authority citation for subpart E of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1601, 1602, 1611 (c) and (e), and 1631 (a)–(d) and (g) of the Social Security Act (42 U.S.C. 902(a)(5), 1381, 1381a, 1382 (c) and (e), and 1383 (a)–(d) and (g)).

§ 416.537 [Amended]

2. Section 416.537(a) is amended by removing ''Secretary'' and adding ''Commissioner''.

Subpart I—[Amended]

1. The authority citation for subpart I of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1611, 1614, 1619, 1631 (a), (c), and (d)(1), and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382, 1382c, 1382h, 1383 (a), (c), and (d)(1), and 1383(b); secs. 4(c) and 5, 6 (c)–(e), 14(a) and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, 1382h note).

§ 416.903 [Amended]

2. Section 416.903 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in paragraphs (a), (b)(1), (c) introductory text, and (e). Section 416.903(b) introductory text is amended by removing ''the Secretary for''.

§ 416.927 [Amended]

3. Section 416.927 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in the heading to paragraph (e) and in paragraph (e)(2).

§ 416.929 [Amended]

4. Section 416.929(b) is Amended by removing ''Secretary'' and adding ''Commissioner''.

§ 416.946 [Amended]

5. Section 416.946 is Amended by removing ''Secretary'' wherever it appears and adding ''Commissioner''.

Subpart J—[Amended]

1. The authority citation for subpart J of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1614, 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382c, 1383, and 1383b).

§ 416.1001 [Amended]

2. Section 416.1001 is amended by removing ''Secretary'' and ''Secretary's'' wherever they appear and adding ''Commissioner'' and ''Commissioner's'' respectively in the introductory text and in paragraphs (a), (b), (c), (e), (f) and (h).

3. Section 416.1002 is Amended by adding ''and Policy'' to the title ''Deputy Commissioner for Programs'' in *Other*

written guidelines, by removing the definition of *Secretary* and by adding the definition of *Commissioner* and by revising the definition of and *We, us,* and *our* to read as follows:

§ 416.1002 Definitions.

* * * * *

Commissioner means the Commissioner of Social Security or his or her authorized designee.

* * * * *

We, us, and *our* refers to the Social Security Administration (SSA).

§ 416.1013 [Amended]

4. Section 416.1013(a) is Amended by removing ''Secretary'' and adding ''Commissioner''.

§ 416.1015 [Amended]

5. Section 416.1015(d) is Amended by removing ''Secretary'' and adding ''Commissioner''.

§ 416.1016 [Amended]

6. Section 416.1016(b)(2) is Amended by removing ''Secretary of Health and Human Services'' and adding ''Commissioner of Social Security''.

§ 416.1026 [Amended]

7. Section 416.1026(e) is Amended by removing ''Department of Health and Human Services'' and adding ''Social Security Administration'' after ''Inspector General''.

§ 416.1027 [Amended]

8. Section 416.1027(b) is amended by removing ''*Secretary*'' and adding ''*Commissioner*'' in the title and by removing ''Department of Health and Human Services'' and adding ''SSA's'' before ''Inspector General'' in paragraph (b)(1).

§ 416.1041 [Amended]

9. Section 416.1041(a) is amended by removing ''Secretary's'' and adding ''Commissioner's''.

§ 416.1082 [Amended]

10. Section 416.1082 is amended by adding the words ''Department of'' before the word ''Health'', adding an apostrophe after the word ''Services'' and by deleting the word ''Grant''.

§ 416.1091 [Amended]

11. Section 416.1091(a) is amended in the heading by removing ''Secretary'' and adding ''Commissioner''.

Subpart N—[Amended]

1. The authority citation for subpart N of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b).

§ 416.1453 [Amended]

2. Section 416.1453(b)(2)(ii) is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 416.1483 [Amended]

3. Section 416.1483 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner''.

§ 416.1484 [Amended]

4. Section 416.1484 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in paragraphs (a), (b) (2) and (3), (c) and (d).

§ 416.1485 [Amended]

5. Section 416.1485(c)(2) is amended by removing ''the Department of Health and Human Services'' and adding ''SSA''.

Subpart O—[Amended]

1. The authority citation for subpart O of part 416 continues to read as follows:

Authority: Secs. 702(a)(5) and 1631(d) of the Social Security Act (42 U.S.C. 902(a)(5) and 1383(d)).

§ 416.1503 [Amended]

2. Section 416.1503 is amended by adding ''(SSA)'' after the word ''Administration'' in the *We, our,* or *us* definition.

§ 416.1535 [Amended]

3. Section 416.1535 is amended by removing ''the Secretary of Health and Human Services'' and adding ''SSA''.

§ 416.1550 [Amended]

4. Section 416.1550 is amended by deleting the comma after ''Programs'', and adding the words ''and Policy'' after ''Programs'' in paragraphs (a) and (d).

§ 416.1565 [Amended]

5. Section 416.1565 is amended by deleting the comma after ''Programs'', and adding the words ''and Policy'' after ''Programs'' in paragraphs (a) and (e).

§ 416.1599 [Amended]

6. Section 416.1599 is amended by adding ''and Policy'', to the title ''Deputy Commissioner for Programs'' in paragraphs (c) and (e).

Subpart S—[Amended]

1. The authority citation for subpart S of part 416 continues to read as follows:

Authority: Secs. 702(a)(5) and 1631 of the Social Security Act (42 U.S.C. 902(a)(5) and 1383).

§ 416.1902 [Amended]

2. Section 416.1902 is amended by removing ''Secretary'' and adding ''Commissioner'' under the definition of *Interim assistance.*

Subpart T—[Amended]

1. The authority citation for subpart T of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1616, 1618, and 1631 of the Social Security Act (42 U.S.C. 902(a)(5), 1382e, 1382g, and 1383); sec. 212, Pub. L. 93–66, 87 Stat. 155 (42 U.S.C. 1382 note); sec. 8 (a), (b)(1)–(b)(3), Pub. L. 93–233, 87 Stat. 956 (7 U.S.C. 612c note, 1431 note and 42 U.S.C. 1382e note); secs. 1 (a)–(c) and 2(a), 2(b)(1), 2(b)(2), Pub. L. 93–335, 88 Stat. 291 (42 U.S.C. 1382 note, 1382e note).

§ 416.2001 [Amended]

2. Section 416.2001(c) is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 416.2030 [Amended]

3. Section 416.2030(a) is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 416.2035 [Amended]

4. Section 416.2035(b)(1) is amended by removing ''Secretary'' and adding ''Commissioner''.

§ 416.2065 [Amended]

5. Section 416.2065 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in the introductory text.

§ 416.2070 [Amended]

6. Section 416.2070 is amended by removing ''Secretary'' and adding ''Commissioner'' in the introductory text and in paragraph (a).

§ 416.2075 [Amended]

7. Section 416.2075 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in paragraphs (a) and (b).

§ 416.2095 [Amended]

8. Section 416.2095(a)(5) is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner''.

§ 416.2096 [Amended]

9. Section 416.2096 is amended by removing ''Secretary'' and adding ''Commissioner'' in paragraphs (a)(1) introductory text and (d).

§ 416.2099 [Amended]

10. Section 416.2099 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in paragraphs (a) introductory text, (b), (c) and (d).

Subpart U—[Amended]

1. The authority citation for subpart U of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1106, 1631(d)(1), and 1634 of the Social Security Act (42 U.S.C. 902(a)(5)), 1306, 1383(d)(1), and 1383(c).

§ 416.2176 [Amended]

2. Section 416.2176(b) is amended by removing ''Department of Health and Human Services, unless the State appeals the decision within 30 days after receiving it to the Department's Grant Appeals Board under procedures in 45 CFR part 16.'' and adding ''Social Security Administration.''

Subpart V—[Amended]

1. The authority citation for subpart V of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1615, 1631(d)(1) and (e), and 1633(a) of the Social Security Act (42 U.S.C. 902(a)(5), 1382d, 1383(d)(1) and (e), and 1683b(a)).

§ 416.2202 [Amended]

2. Section 416.2202 is amended by removing ''Secretary'' and adding ''Commissioner'' in the introductory text.

§ 416.2203 [Amended]

3. Section 416.2203 is amended by removing the definition of ''Secretary'' and by removing ''or the Secretary, as appropriate'' from the definition of *We*, *us* and *our*.

§ 416.2217 [Amended]

4. Section 416.2217 is amended by removing ''Secretary'' and adding ''Commissioner'' in the introductory text.

§ 416.2220 [Amended]

5. Section 416.2220 is amended by adding an apostrophe to the word ''Services'' and by removing the word ''Grant'' in paragraph (c).

§ 416.2227 [Amended]

6. Section 416.2227 is amended by adding an apostrophe to the word ''Services'' and by removing the word ''Grant'' in paragraph (a), by adding ''Departmental'' after the word ''the'' and removing the word ''Grant'' in paragraph (b) and by removing ''Secretary'' and adding ''Commissioner'' in the heading of paragraph (c) and in paragraph (c).

PART 422—ORGANIZATION AND PROCEDURES

Subpart A—[Amended]

1. The authority citation for subpart A of part 422 continues to read as follows:

Authority: Secs. 205, 218, 221, and 701–704 of the Social Security Act (42 U.S.C. 405, 418, 421, and 901–904).

§ 422.1 [Amended]

2. Section 422.1 is amended by removing the words ''Department Staff Manual on Organization, Department of Health and Human Services, part 8,'' from the third sentence of paragraph (a) and adding ''Social Security Administration Organizational Manual''.

Subpart B—[Amended]

1. The authority citation for subpart B of part 422 continues to read as follows:

Authority: Secs. 205, 232, 702(a)(5), 1131, and 1143 of the Social Security Act (42 U.S.C. 405, 432, 902(a)(5), 1320b–1, and 1320b–13).

§ 422.107 [Amended]

2. Section 422.107 is amended by removing ''Secretary of Health and Human Services'' and adding ''Commissioner of Social Security'' in paragraph (a).

Subpart C—[Amended]

1. The authority citation for subpart C of part 422 continues to read as follows:

Authority: Secs. 205, 221, and 702(a)(5) of the Social Security Act (42 U.S.C. 405, 421, and 902(a)(5)); 30 U.S.C. 923(b).

§ 422.210 [Amended]

2. Section 422.210 is amended by removing ''Secretary'' wherever it appears and adding ''Commissioner'' in paragraphs (a) and (c) and by removing ''Secretary of Health and Human Services'' and adding ''the Commissioner'' and by removing ''Secretary'' and adding ''the Commissioner'' after ''the Office of'' and by removing ''Secretary'' and adding ''Commissioner'' throughout paragraph (d).

Subpart G—[Amended]

1. The authority citation for subpart G of part 422 continues to read as follows:

Authority: 26 U.S.C. 9701–9708.

§ 422.602 [Amended]

2. Section 422.602 is amended by removing '', or the Secretary of Health and Human Services or the Secretary's delegate, as appropriate'' from the definition of *We* or *us*.

[FR Doc. 97–18523 Filed 7–17–97; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP Mobile, AL 97–16]

RIN 2115–AA97

Safety Zone Regulations; St. Andrew Bay, Panama City Florida, Hathaway Landing Marina

AGENCY: Coast Guard, DOT.

ACTION: Temporary rule.

SUMMARY: The Coast Guard is establishing a safety zone in St. Andrew Bay, Panama City Florida in the vicinity of Hathaway Landing Marina. The zone is needed to protect personnel and property associated with the Jet Ski Waverunner Exhibition. Entry into this zone is prohibited unless authorized by the Captain of the Port.

DATES: This regulation becomes effective at 11:30 a.m. July 20, 1997. It terminates at 4:30 p.m. on July 20, 1997.

FOR FURTHER INFORMATION CONTACT: LT R.A. Smith, (334) 441–5286, 150 North Royal Street, Mobile, AL 36602–2924.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after **Federal Register** publication. Publishing an NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to prevent damage to the vessels involved.

Background and Purpose

The event requiring this regulation will begin at 11:30 a.m. July 20, 1997. The Jet Ski Waverunner Exhibition will occur in the vicinity of Hathaway Landing Marina between W 85–44′ 9″, N 30–11′ 5″ and W 85–44′ 9″, N 30–11′, and W 85–45′ 1″, N 30–11′ 7″ and W 85–45′ 1″, N 30–11′ 4″. It terminates at 4:30 p.m. on July 20, 1997.

Regulatory Evaluation

This temporary rule is not a significant regulatory evaluation under Executive Order 12866 and is not significant under the ''Department of Transportation Regulatory Policies and Procedures'' (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full regulatory evaluation is unnecessary. This regulation will only be in effect for a short period of time, and the impacts on routine navigation are expected to be minimal.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that it does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this proposal and concluded that under section 2.B.2. of Commandant Instruction M16475.1 (series), this proposal is categorically excluded from further environmental documentation. A Categorical Exclusion Determination is available by contacting Commander (mps), Eighth Coast Guard District, 501 Magazine Street, New Orleans, LA 70130–3396.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Vessels, Waterways.

Regulation

In consideration of the foregoing, Subpart F of Part 165 of Chapter 33, Code of Federal Regulations, is amended as follows:

PART 165—[AMENDED]

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1225 and 1231; 50 U.S.C. 191; and 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. A new § 165.T08–041 is added to read as follows:

§ 165.TO8–041 Safety Zone: St. Andrew Bay, Panama City Florida, Hathaway Landing Marina

(a) Location. The following area is a safety zone: In the vicinity of Hathaway Landing Marina between W 85–44′ 9″, N 30–11′ 5″ and W 85–44′ 9″, N 30–11′ 3″, and W 85–45′ 1″, N30–11′ 7″ and W 85–45′ 1″, N 30–11′ 4″. The zone is needed to protect personnel and property associated with the Jet Ski Waverunner Exhibition.

(b) Effective date. This section becomes effective at 11:30 A.M. July 20, 1997. It terminates at 4:30 P.M. on July 20, 1997 unless terminated sooner by the Captain of the Port. (c) Regulations: In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port.

Dated: June 12, 1997.

J.J. Kichner,

Captain, U.S. Coast Guard, Captain of the Port Mobile, Alabama.

[FR Doc. 97–18992 Filed 7–17–97; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IN53–3; FRL–5860–4]

Approval and Promulgation of State Implementation Plan; Indiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On June 26, 1995, and June 13, 1997, the State of Indiana submitted a Rate-Of-Progress (ROP) plan to reduce Volatile Organic Compounds (VOC) emissions in Lake and Porter Counties by 15 percent (%) from 1990 baseline levels by November 15, 1996, as a requested revision to the Indiana State Implementation Plan (SIP). On April 3, 1997, EPA issued a direct final approval of the Lake and Porter Counties 15% ROP plan, 3% contingency plan, and an Indiana Agreed Order requiring VOC emission controls on Keil Chemical Division, Ferro Corporation, located in Lake County (Keil). On the same day (April 3, 1997) EPA proposed approval and solicited public written comment on these requested SIP revisions. This proposed rule established a 30-day public comment period noting that if adverse comments were received regarding the direct final rule EPA would withdraw the direct final rule and publish an additional final rule to address the public comments. Adverse comments were received during the public comment period relating to the Keil SIP revision. EPA withdrew the direct final rule on May 23, 1997. In today's action, EPA is finalizing approval of the 15% ROP plan. Final action on the 3% contingency plan and the Keil agreed order will be addressed in a subsequent rulemaking action. The 15% ROP plan has reduced VOC emissions in Lake and Porter Counties by approximately 68,242 pounds (lbs) per day. VOC emissions combine with oxides of nitrogen in the atmosphere to form ground-level ozone, a pollutant which can cause inflammation of the lungs, decrease lung capacity, and aggravate asthma. The rationale for this rulemaking is discussed below.

DATES: This final rule is effective August 18, 1997.

ADDRESSES: Copies of the SIP revision request are available for inspection at the following address: (It is recommended that you telephone Mark J. Palermo at (312) 886–6082, before visiting the Region 5 office.)

U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois, 60604.

FOR FURTHER INFORMATION CONTACT: Mark J. Palermo, Environmental Protection Specialist, Air Programs Branch (AR–18J) (312) 886–6082.

SUPPLEMENTARY INFORMATION:

I. Background on 15% ROP Requirements

On November 15, 1990, Congress enacted amendments to the 1977 Clean Air Act (Act); Public Law 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. Section 182(b)(1) requires States with ozone nonattainment areas classified as moderate and above to submit a SIP revision known as a 15% ROP plan. This plan must reflect an actual reduction in typical ozone season weekday VOC emissions of at least 15% in the area during the first 6 years after enactment (i.e., by November 15, 1996). The emission reductions needed to achieve the 15% requirement must be calculated using a 1990 anthropogenic VOC emissions inventory as a baseline, minus emissions that have been reduced by: (1) The Federal Motor Vehicle Control Program (FMVCP) measures for the control of motor vehicle exhaust or evaporative emissions promulgated before January 1, 1990; and (2) gasoline Reid Vapor Pressure (RVP) regulations promulgated by November 15, 1990 (55 FR 23666, June 11, 1990). In addition, the plan must account for net growth in emissions within the nonattainment area between 1990 and 1996.

In Indiana, two ozone nonattainment areas are subject to the 15% ROP plan requirement: The Lake and Porter Counties portion of the Chicago severe ozone nonattainment area, and the Clark and Floyd Counties portion of the Louisville moderate ozone nonattainment area. This rulemaking action addresses only the plan for Lake and Porter Counties; the Clark and Floyd Counties 15% ROP plan was approved on May 7, 1997 (62 FR at 24815).

II. Indiana's 15% ROP Submittal

The Act requires States to observe certain procedural requirements in developing SIPs and SIP revisions for submission to EPA. Section 110(a)(2)

and section 110(l) of the Act require that each State's SIP revision submitted under the Act be adopted by the State after reasonable notice and public hearing. The State of Indiana submitted a portion of the Lake and Porter Counties 15% ROP SIP revision on January 13, 1994. The SIP revision was reviewed by EPA to determine completeness shortly after submittal, in accordance with the completeness criteria set out at 40 CFR part 51, appendix V (1991), as amended by 57 FR 42216 (August 26, 1991). However, the submittal was deemed incomplete because the plan had not yet gone through public hearing and did not include fully adopted rules for all of the plan's control measures. Indiana held a public hearing on the plan on March 29, 1994. A summary of comments from that hearing and the Indiana Department of Environmental Management's (IDEM) response was submitted on July 5, 1994. IDEM sent a supplemental submittal on June 26, 1995, which included fully adopted rules for the Lake and Porter Counties 15% ROP plan. In a July 17, 1995, letter to Indiana, the State was notified that the SIP submittal was deemed complete.

III. Criteria for 15% ROP Approvals

The requirements for 15% ROP plans are found in section 182(b)(1) of the Act, and the following EPA guidance documents:

1. *Procedures for Preparing Emissions Projections*, EPA–450/4–91–019, Environmental Protection Agency, July 1991.

2. State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990; Proposed rule (57 FR 13498), **Federal Register**, April 16, 1992 (General Preamble).

3. ''November 15, 1992, Deliverables for Reasonable Further Progress and Modeling Emission Inventories,'' memorandum from J. David Mobley, Edwin L. Meyer, and G. T. Helms, Office of Air Quality Planning and Standards, Environmental Protection Agency, August 7, 1992.

4. *Guidance on the Adjusted Base Year Emissions Inventory and the 1996 Target for the 15 Percent Rate of Progress Plans*, EPA–452/R–92–005, Environmental Protection Agency, October 1992.

5. ''Quantification of Rule Effectiveness Improvements,'' memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, Office of Air Quality Planning and Standards, Environmental Protection Agency, October 1992.

6. *Guidance for Growth Factors, Projections, and Control Strategies for the 15 Percent Rate-of-Progress Plans*, EPA–452/R–93–002, March 1993.

7. ''Correction to 'Guidance on the Adjusted Base Year Emissions Inventory and the 1996 Target for the 15 Percent Rate of Progress Plans','' memorandum from G.T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, Office of Air Quality Planning and Standards, Environmental Protection Agency, March 2, 1993.

8. ''15 Percent Rate-of-Progress Plans,'' memorandum from G.T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, Office of Air Quality Planning and Standards, Environmental Protection Agency, March 16, 1993.

9. Guidance on the Relationship Between the 15 Percent Rate-of-Progress Plans and Other Provisions of the Clean Air Act, EPA–452/R–93–007, Environmental Protection Agency, May 1993.

10. ''Credit Toward the 15 Percent Rate-of-Progress Reductions from Federal Measures,'' memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, Environmental Protection Agency, May 6, 1993.

11. *Guidance on Preparing Enforceable Regulations and Compliance Programs for the 15 Percent Rate-of-Progress Plans*, EPA–452/R–93–005, Environmental Protection Agency, June 1993.

12. ''Correction Errata to the 15 Percent Rate-of-Progress Plan Guidance Series,'' memorandum from G. T. Helms, Chief, Ozone and Carbon Monoxide Programs Branch, Environmental Protection Agency, July 28, 1993.

13. ''Early Implementation of Contingency Measures for Ozone and Carbon Monoxide (CO) Nonattainment Areas,'' memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, Environmental Protection Agency, August 13, 1993.

14. ''Region III Questions on Emission Projections for the 15 Percent Rate-of-Progress Plans,'' memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, Office of Air Quality Planning and Standards, Environmental Protection Agency, August 17, 1993.

15. ''Guidance on Issues Related to 15 Percent Rate-of-Progress Plans,'' memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation, Environmental Protection Agency, August 23, 1993.

16. ''Credit Toward the 15 Percent Requirements from Architectural and Industrial Maintenance Coatings,'' memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, Environmental Protection Agency, September 10, 1993.

17. ''Reclassification of Areas to Nonattainment and 15 Percent Rate-of-Progress Plans,'' memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, Environmental Protection Agency, September 20, 1993.

18. ''Clarification of 'Guidance for Growth Factors, Projections and Control Strategies for the 15 Percent Rate of Progress Plans','' memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, Office of Air Quality Planning and Standards, Environmental Protection Agency, October 6, 1993.

19. ''Review and Rulemaking on 15 Percent Rate-of-Progress Plans,'' memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, Office of Air Quality Planning and Standards, Environmental Protection Agency, October 6, 1993.

20. ''Questions and Answers from the 15 Percent Rate-of-Progress Plan Workshop,'' memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, Environmental Protection Agency, October 29, 1993.

21. ''Rate-of-Progress Plan Guidance on the 15 Percent Calculations,'' memorandum from D. Kent Berry, Acting Director, Air Quality Management Division, Environmental Protection Agency, October 29, 1993.

22. ''Clarification of Issues Regarding the Contingency Measures that are Due November 15, 1993 for Moderate and Above Ozone Nonattainment Areas,'' memorandum from D. Kent Berry, Acting Director, Air Quality Management Division, Environmental Protection Agency, November 8, 1993.

23. ''Credit for 15 Percent Rate-of-Progress Plan Reductions from the Architectural and Industrial Maintenance (AIM) Coating Rule,'' memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, Environmental Protection Agency, December 9, 1993.

24. ''Guidance on Projection of Nonroad Inventories to Future Years,'' memorandum from Philip A. Lorang, Director, Emission Planning and Strategies Division, Office of Air and Radiation, Environmental Protection Agency, February 4, 1994.

25. ''Discussion at the Division Directors Meeting on June 1 Concerning the 15 Percent and 3 Percent Calculations,'' memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, Office of Air Quality

Planning and Standards, Environmental Protection Agency, June 2, 1994.

26. ''Future Nonroad Emission Reduction Credits for Court-Ordered Nonroad Standards,'' memorandum from Philip A. Lorang, Director, Emission Planning and Strategies Division, Office of Air and Radiation, Environmental Protection Agency, November 28, 1994.

27. ''Credit for the 15 Percent Rate-of-Progress Plans for Reductions from the Architectural and Industrial Maintenance (AIM) Coating Rule and the Autobody Refinishing Rule,'' memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, Environmental Protection Agency, November 29, 1994.

28. ''Transmittal of Rule Effectiveness Protocol for 1996 Demonstrations,'' memorandum from Susan E. Bromm, Director, Chemical, Commercial Services and Municipal Division, Office of Compliance, Environmental Protection Agency, December 22, 1994.

29. ''Future Nonroad Emission Reduction Credits for Locomotives,'' memorandum from Philip A. Lorang, Director, Emission Planning and Strategies Division, Office of Air and Radiation, Environmental Protection Agency, January 3, 1995.

30. ''Credit for the 15 Percent Rate-of-Progress Plans for Reductions from the Architectural and Industrial Maintenance (AIM) Coating Rule,'' memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, Environmental Protection Agency, March 22, 1995.

31. ''Fifteen Percent Rate-of-Progress Plans—Additional Guidance,'' memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, Environmental Protection Agency, May 5, 1995.

32. ''Update on the Credit for the 15 Percent Rate-of-Progress Plans for Reductions from the Architectural and Industrial Maintenance Coatings Rule,'' memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, Environmental Protection Agency, March 7, 1996.

33. ''Date by which States Need to Achieve all the Reductions Needed for the 15% Plan from Inspection and Maintenance (I/M) and Guidance for Recalculation,'' memorandum from Margo Oge, Director, Office of Mobile Sources, and John S. Seitz, Director, Office of Air Quality Planning and Standards, Environmental Protection Agency, August 13, 1996.

34. ''Sample City Analysis: Comparison of Enhanced Inspection and Maintenance (I/M) Reductions Versus Other 15 Percent Rate of Progress Plan Measures,'' E.H. Pechan and Associates, December 12, 1996.

35. ''Modeling 15 Percent Volatile Organic Compound (VOC) Reduction(s) from I/M in 1999: Supplemental Guidance,'' memorandum from Gay MacGregor, Director, Regional and State Programs Division, and Sally Shaver, Director, Air Quality Strategies and Standards Division, Environmental Protection Agency, December 23, 1996.

36. ''15% Volatile Organic Compound (VOC) State Implementation Plan (SIP) Approvals and the 'As Soon As Practicable' Test,'' memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, and Richard B. Ossias, Deputy Associate General Counsel, Division of Air and Radiation, Office of General Counsel, Environmental Protection Agency, February 12, 1997.

For a 15% ROP plan SIP to be approved, the plan must adequately justify how much emission reduction is needed to achieve 15% emission reduction by November 15, 1996, and how the plan's control strategy will secure that reduction. The procedure for calculating the needed emission reduction is as follows:

(A) Calculate the ''1990 ROP inventory'' by subtracting from the area's ''1990 base year inventory'' [1] biogenic emissions, emissions outside of the nonattainment area, and pre-enactment banked emission credits;

(B) Calculate the ''1990 adjusted base year inventory'' by subtracting from the 1990 ROP inventory any emission reductions from the pre-1990 FMVCP and 1990 RVP Federal regulations which occur between 1990 and 1996; [2]

(C) Calculate ''15% of adjusted base year emissions'' by multiplying the 1990 adjusted base year inventory by 15%;

(D) Calculate the ''total required reductions by 1996'' by adding emission reductions from the pre-1990 FMVCP and 1990 RVP federal rules to 15% of adjusted base year emissions calculation; [3]

(E) Calculate the ''1996 emissions target level'' by subtracting from the 1990 ROP base year inventory the total required reductions by 1996;

(F) Calculate the ''1996 projected emission estimate'' by either adding growth factors to the 1990 adjusted base-year inventory, or adding growth factors and required emission reductions to the 1990 ROP inventory; and,

(G) Calculate the ''reduction required by 1996 to achieve 15% net of growth'' by subtracting the 1996 target emissions level from the 1996 projected emissions level.

In determining what control measures a State can use in its 15% ROP plan strategy, the Act provides under section 182(b)(1)(C) that emission reductions from control measures are creditable to the extent that they have actually occurred before November 15, 1996. In keeping with this requirement, the General Preamble states that all credited emission reductions must be real, permanent, and enforceable, and that regulations needed to implement the plan's control strategy must be adopted and implemented by the State by November 15, 1996.

IV. Prior Rulemaking Action

On April 3, 1997, EPA published a direct final rulemaking action approving the Lake and Porter Counties 15% ROP plan and a 3% contingency measure plan for Lake and Porter Counties (62 FR 15844). As part of the 15% ROP plan, Indiana also submitted an agreed order requiring VOC emission controls on Keil Chemical Division, Ferro Corporation, located in Lake County (Keil). On the same day (April 3, 1997), EPA proposed approval and solicited public comment on these requested SIP revisions (62 FR 15867). The proposed rule established a 30-day public comment period, noting that if adverse comments were received regarding the

[1] Sections 172(c)(3) and 182(a)(1) of the Act require that nonattainment plan provisions include a comprehensive, accurate inventory of actual emissions which occurred in 1990 from all sources of relevant pollutants in the nonattainment area. This inventory provides an estimate of the amount of VOC and oxides of nitrogen produced by emission sources such as automobiles, powerplants and the use of consumer solvents in the household. Because the approval of such inventories is necessary to an area's 15% ROP plan and attainment demonstration, the emission inventory must be approved prior to or with the 15% ROP plan submission.

[2] The 1990 adjusted base year inventory represents the ''baseline emissions'' from which the 15 percent reduction is to be calculated, as specified under section 182(b)(1)(B) of the Act. Section 182(b)(1)(B) defines baseline emissions to mean the total amounts of actual VOC emissions from all anthropogenic sources in the ozone nonattainment areas during the calendar year of 1990, excluding emissions that are eliminated by the pre-1990 FMVCP and 1990 RVP regulations. In the General Preamble, EPA interprets ''calendar year'' emissions to consist of typical ozone season weekday emissions, based on the fact that the ozone National Ambient Air Quality Standard (NAAQS) (0.12 parts per million, one-hour average) is generally exceeded or violated during ozone season weekdays when ozone precursor emissions and meteorological conditions are most conducive to ozone formation. Ozone seasons are typically the summer months.

[3] Under section 182(b)(1)(D), emission reductions pre-1990 and 1990 RVP regulations are not creditable toward meeting 15%. The emission reductions which occurred by 1996 from these regulations are added to emissions required to meet 15% to determine the total amount of emission reduction by 1996 for the area.

direct final rule EPA would withdraw the direct final rule and publish an additional final rule to address the public comments. The only set of comments received during the public comment period was from the Ferro Corporation regarding the Keil agreed order. Because these comments raised questions about the anticipated emissions reductions of the agreed order, EPA withdrew the direct final rulemaking on May 23, 1997 (62 FR at 28349).

Indiana originally claimed emission reductions from the Keil agreed order in the Lake and Porter 15% plan. The July 29, 1994, agreed order (Cause No. A–2250) requires the facility to meet certain control requirements. The agreed order was submitted with the 15% ROP plan for incorporation into the Indiana SIP so that the State could properly take credit for Keil's emission reductions.

Ferro Corporation's comment supported the Lake and Porter Counties 15% ROP plan, but requested that EPA recognize that Keil's VOC control installed pursuant to the agreed order has achieved more emission reductions than required under federal and State control regulations, and, consequently, the excess emission reductions ''should be credited as a banked pollutant for the future.'' Ferro Corporation also indicated that EPA and Indiana are still reviewing Keil's compliance determination method for the 25 tons per year VOC emission limit under the agreed order. Ferro requested that EPA agree that Keil should not be held in violation of the SIP for the 25 tons per year limit if EPA and Indiana determine that Keil should use a different compliance determination method.

EPA is currently evaluating the Ferro Corporation comments. To expedite final approval of the 15% ROP plan, Indiana submitted a letter on June 13, 1997, which states that it has changed the allocation of control measure reductions between the Lake and Porter Counties 15% ROP plan and the 3% contingency plan. The agreed order emission reductions (5327 lbs VOC per day) will be shifted from the 15% ROP plan to the 3% contingency plan, and remaining reductions from Inland Steel Flat Product's coke oven shutdown (759 lbs VOC per day) and the State's automobile refinishing rule (4619 lbs VOC per day) have been shifted from the 3% contingency plan to the 15% ROP plan. The amount of emission reductions claimed for the coke oven shutdown and automobile refinishing rule was found by EPA to be acceptable in the April 3, 1997, direct final approval.

In today's action, EPA is promulgating final approval of the 15% ROP plan as adjusted by Indiana's June 13, 1997, letter. Because shifting emission reduction credit between the two plans does not affect the implementation of the plans' control measures, nor the achievement of 15% reduction required under the Act, reproposing approval of the 15% ROP plan is unnecessary. The 3% contingency plan is a separate requirement of the Act, and approval of the 3% contingency plan is not a prerequisite for approval of the 15% ROP plan. EPA will promulgate a final rulemaking on the 3% contingency plan once EPA completes its evaluation of the Ferro Corporation comments.

V. Analysis of Lake and Porter Counties 15% ROP Plan

Indiana's 15% ROP summary for Lake and Porter Counties is provided in the following table. This table has been adjusted from the table which appeared in the direct final to reflect the State's June 13, 1997, letter. (See part IV of this rulemaking).

15% ROP SUMMARY FOR LAKE AND PORTER COUNTIES

Calculation of Reduction needs by 1996	Lbs Voc/ DayAY
1990 Lake and Porter Counties Total VOC Emissions	424,721
1990 ROP Emissions (Anthropogenic only)	381,841
1990–1996 Noncreditable Reductions (Reductions from 1990 RVP and Pre-1990 FMVCP Regulations)	58,838
1990 Adjusted Base Year Emissions (1990 ROP Emissions minus Noncreditable Reductions)	323,003
15% of Adjusted Base Year Emissions	48,450
Total Required Emission Reductions by 1996 (15% of Adjusted Base Year Emissions plus Noncreditable Reductions)	107,288
1996 Target Level (1990 ROP Emissions minus Total Required Emission Reductions by 1996)	274,553
1996 Projected Emissions (1990 Adjusted Base Year Emissions plus Growth Factors)	342,683
Reduction needs by 1996 to achieve 15 percent net of growth (1996 Projected Emission minus 1996 Target Level)	68,130
Creditable Reduction from Mandatory Controls	
Mobile Sources:	
Enhanced Vehicle Inspection and Maintenance (I/M) Program (326 IAC 13–1.1)	6,817
Federal Reformulated Gasoline Program (40 CFR Part 80, Subpart D)	14,905
Area Sources:	
Stage II Gasoline Vapor Recovery (326 IAC 8–4–6)	9,824
Federal Architectural and Industrial Maintenance (AIM) Coatings Rule	2,920
Point Sources:	
Non-Control Techniques Guideline (CTG) Reasonably Available Control Technology (RACT) Rule (326 IAC 8–7)	4,559
Subtotal—Reductions from Mandatory Controls	39,025
Creditable Reductions From Non-Mandatory Controls	
Point Sources:	
Coke Oven Battery Shutdowns at Inland Steel Flat Products (326 IAC 6–1–10.1(k)(5))	23,609
Area Sources:	
Automobile Refinishing (326 IAC 8–10)	4,679
Residential Open Burning (326 IAC 4–1)	929
Subtotal—Reduction From Non-Mandatory Controls	29,217
Total Creditable Reductions from 15% ROP plan	68,242

A. Calculation of the 1990 Adjusted Base Year Emission Inventory

To determine the 1990 adjusted base year inventory, Indiana used the 1990 base year emission inventory approved by EPA on January 4, 1995 (60 FR 375), which was found to meet the requirements of sections 172(c)(3) and 182(a)(1) of the Act for Lake and Porter Counties. Total VOC emissions estimated from this inventory are 424,721 lbs VOC/day. Indiana subtracted biogenic emissions and emissions from outside Lake and Porter Counties from the 1990 base year inventory to determine that the 1990 ROP inventory level is 381,841 lbs VOC/day. No pre-enactment banked emission credit was included in this inventory.

Indiana used EPA's Mobile Source Emissions Model (MOBILE)5a to calculate the emission reductions from the pre-1990 FMVCP and 1990 RVP regulations; these reductions were subtracted from the 1990 ROP inventory level to find the 1990 adjusted base year inventory level of 323,003 lbs VOC/day. Indiana's documentation includes the actual 1990 motor vehicle emissions using 1990 vehicle miles traveled (VMT) and MOBILE5a emission factors, and the adjusted emissions using 1990 VMT and the MOBILE5a emission factors in calendar year 1996 with the appropriate RVP for the nonattainment area as mandated by EPA. The plan includes adequate documentation showing how the MOBILE5a model was run to calculate the expected emission reductions from FMVCP and RVP.

B. 1996 ROP Target Emission Level

To calculate the 1996 target emission level for Lake and Porter Counties, Indiana first multiplied the 1990 adjusted base year inventory by 0.15 to determine that the 15% required emission reduction by 1996 is 48,450 lbs VOC/day. Then, 58,838 lbs VOC/day of reductions from non-creditable control measures (pre-1990 FMVCP and 1990 RVP) were added to the 15% required reduction to find that the total required reductions by 1996 is 107,288 lbs VOC/day. Finally, Indiana subtracted the 1996 total required emission reductions from the 1990 ROP emission inventory to determine that the 1996 emission target level for Lake and Porter Counties is 274,553 lbs VOC/day.

The 15% ROP plan submittal adequately documents the calculations used to determine the Lake and Porter Counties target level by showing each step, discussing any assumptions made, and stating the origin of the numbers used in the calculations.

C. Projected Emission Inventory

To determine the 1996 projected emission inventory, Indiana has included in the 15% ROP plan the growth factors used together with documentation for the assumptions made. The point, area, and non-road mobile source emission inventories were projected using either source supplied data, population forecasts, historical data, or, where historical data were unavailable or not suitable to project, the U.S. Department of Commerce Bureau of Economic Analysis (BEA) regional growth data were used. The on-road mobile source emission inventory was projected using MOBILE5a. The State's calculations for growth in the on-road mobile, off-road mobile, industrial, and area source sectors is 10,180 lbs VOC/day, 1,298 lbs VOC/day, 4,692 lbs VOC/day, and 3,510 lbs VOC/day, respectively, for a total of 19,680 lbs VOC/day. These growth estimates were calculated in a manner consistent with EPA's guidance documents. The projected emissions were added to the 1990 adjusted base year inventory to determine that the 1990 projected emission inventory level is 342,683 lbs VOC/day.

D. Creditable Reductions from Control Measures

From the calculation of the 1996 target emission level and 1996 projected emission level, Indiana must reduce emissions in Lake and Porter Counties by 68,130 lbs VOC/day, to secure the 15% ROP reduction. The Lake and Porter Counties 15% ROP plan does meet this requirement. The total creditable emission reductions achieved by the 15% ROP plan are 68,242 lbs VOC/day. Emission reductions not needed to meet the 15% ROP requirement will be applied toward achieving post-1996 ROP reductions, leading to attainment of the ozone air quality standard.

The SIP submittal includes documentation indicating the sources or source categories which are expected to be affected by each control measure, the sources' projected 1996 emissions without controls, and the assumptions used to estimate how much the sources' 1996 emissions would be reduced by each control measure. These assumptions were derived primarily from Midwest Research Institute's April 30, 1993, document entitled ''Support Document for Indiana's Lake and Porter Nonattainment Area 1996 Rate of Progress Plan,'' which was contracted by EPA to assist Indiana in developing the 15% ROP and contingency plans. A review of the emission reduction credit taken for each control measure follows:

Enhanced I/M Program

Of the 15% ROP plans originally submitted to EPA, most contain enhanced I/M programs because they achieve more VOC emission reductions than most, if not all other, control strategies. However, because most States experienced substantial difficulties implementing enhanced I/M programs, only a few States are currently actually testing cars using the original enhanced I/M protocol.

On September 18, 1995 (60 FR 48029), EPA finalized revisions to its enhanced I/M rule allowing States significant flexibility in designing I/M programs appropriate for their needs. Further, Congress enacted the National Highway Systems Designation Act of 1995 (NHSDA), which provides States with more flexibility in determining the design of enhanced I/M programs. The substantial amount of time needed by States to re-design enhanced I/M programs in accordance with the final enhanced I/M rules and/or the guidance contained within the NHSDA, to secure State legislative approval when necessary, and set up the infrastructure to perform the testing program has precluded States from obtaining emission reductions from enhanced I/M by November 15, 1996.

Given the heavy reliance by many States on enhanced I/M programs to help satisfy 15% ROP plan requirements, and the recent NHSDA and regulatory changes regarding enhanced I/M programs, EPA has recognized that it was not possible for many States to achieve the portion of the 15% ROP reductions that are attributed to enhanced I/M by November 15, 1996. Under these circumstances, disapproval of the 15% ROP plan SIPs would serve no purpose. Consequently, under certain circumstances, EPA will allow States that pursue re-design of enhanced I/M programs to receive emission reduction credit from these programs in their 15% ROP plans, even though the emission reductions from the I/M program will occur after November 15, 1996.

Specifically, the EPA will approve 15% ROP SIPs if the emission reductions from the revised, enhanced I/M programs, as well as from the other 15% ROP plan measures, will achieve the 15% level as soon after November 15, 1996, as practicable. To make this ''as soon as practicable'' determination, the EPA must determine that the 15% ROP plan contains all VOC control strategies that are practicable for the nonattainment area in question and that

meaningfully accelerate the date by which the 15% level is achieved. The EPA does not believe that measures meaningfully accelerate the 15% date if they provide only an insignificant amount of reductions.

Indiana's enhanced I/M program for Lake and Porter Counties was approved by EPA on March 19, 1996 (61 FR 11142), and the State began testing vehicles under the new program on January 1, 1997. A single contractor, Envirotest, Inc., operates a test-only centralized network for inspections and re-inspection. The Indiana I/M program requires coverage of all 1976 and newer gasoline powered light duty passenger cars and light duty trucks up to 9,000 pounds Gross Vehicle Weight Rating (GVWR). All applicable 1981 and newer vehicles will be subject to a transient, mass emissions tailpipe test that includes the purge and pressure test. All applicable 1976 through 1980 vehicles will be subject to a BAR90 single-speed idle test that includes the pressure test. The I/M contractor has acquired all the emission test sites required under the State I/M contract, and all the test stations required have been constructed.

EPA has analyzed Indiana's enhanced I/M program to predict when the emission reductions claimed in the Lake and Porter Counties 15% ROP plan for the program will actually be secured. This analysis was based on the methodology specified in EPA's policy memoranda, ''Date by Which States Need to Achieve all the Reductions Needed for the 15% Plan from I/M and Guidance for Recalculation,'' August 13, 1996, and ''Modeling 15% VOC Reduction(s) from I/M in 1999—Supplemental Guidance,'' December 23, 1996. MOBILE5b runs were used to evaluate the credit using inputs that reflect actual program startup. Some of the input parameters of the modeling included: a January 1, 1997, program start date; start-up cutpoints as recommended by EPA; and expected evaporative test procedures available at start-up. The State has taken credit in the Lake and Porter Counties 15% ROP plan for 6,817 lbs VOC/day, or 3.41 tons per day reductions from enhanced I/M. Based on EPA's analysis, the emission reduction claimed will be secured by November 1999. See EPA's August 13, 1996, policy memorandum titled ''Date by Which States Need to Achieve all the Reductions Needed for the 15% Plan from I/M and Guidance for Recalculation,'' for further discussion on the November 1999 date.

To determine whether there are other available potential control measures which can meaningfully accelerate the date by which a 15% reduction in VOC emissions in Lake and Porter Counties can be achieved, EPA compared the Lake and Porter Counties 15% ROP and 3% contingency plans with control measures included in 15% ROP plans nation-wide, which are listed in EPA's report, ''Sample City Analysis: Comparison of Enhanced I/M Reductions Versus other 15 Percent ROP Plan Measures,'' December 12, 1996, referenced in EPA's policy document ''15% VOC SIP Approvals and the 'As Soon As Practicable' Test,'' February 12, 1997. Based upon the report, EPA believes there are no other potential control measures beyond those already included in the Lake and Porter Counties 15% ROP and 3% contingency plans which can secure a significant amount of emission reduction before November 1999.

Because Indiana's enhanced I/M program will secure emission reductions claimed under the Lake and Porter Counties 15% ROP plan by November 1999, and because there are no other potential control measures which can meaningfully accelerate the achievement of a 15% reduction in the counties before November 1999, the EPA finds that the Lake and Porter Counties 15% ROP plan does secure a 15% emission reduction as soon as practicable. On this basis, the emission reduction claimed for the Lake and Porter Counties enhanced I/M program under the 15% ROP plan is approvable.

Federal Reformulated Gasoline Program

The federal reformulated gasoline program (40 CFR part 80, subpart D) requires gasoline providers in Lake and Porter Counties to sell only gasoline which meets certain blending requirements to reduce pollution. The VOC reduction from reformulated gasoline was determined using the MOBILE5a model to estimate the difference between 1996 highway mobile source emissions at RVP 9.0, the level of control upon gasoline in Lake and Porter Counties before the reformulated gasoline requirement, and 1996 highway mobile source emissions with reformulated gasoline. Indiana has credited a 14,905 lbs VOC/day emission reduction from this program, which is acceptable.

Stage II Gasoline Vapor Recovery Rule

Indiana's Stage II rule (326 IAC 8–4–6) requires facilities that sell more than 10,000 gallons of gasoline per month to operate Stage II vapor recovery systems certified to have a control effectiveness of at least 95%. Indiana has estimated that the rule has a 84% program in-use efficiency, accounting for annual inspection program effects and the exemption of facilities with a monthly gasoline throughput of less than 10,000 gallons. Indiana has credited a 9,824 lbs VOC/day emission reduction from this rule, which is acceptable.

Federal AIM Coatings Rule

Pursuant to section 183(e) of the Act, EPA proposed on June 25, 1996 (61 FR 32729), a national rule requiring manufacturers of AIM coatings to meet VOC content limitations. The March 7, 1996, EPA memorandum ''Update on the Credit for the 15 Percent Rate-of-Progress Plans for Reductions from the Architectural and Industrial Maintenance Coatings Rule'' allows States to take credit for a 20% reduction in AIM coating emissions, even though promulgation of the rule has been delayed. Based on this policy, Indiana has taken an emission reduction credit of 2,920 lbs VOC/day, which is acceptable.

Non CTG RACT Rule

Indiana's Non-CTG RACT rule (326 IAC 8–7) requires VOC controls on sources which have the potential to emit 25 tons of VOC emissions per year, and are not already covered under an existing CTG or part of a post-1990 CTG category.[4] Sources subject to this rule are allowed to demonstrate compliance by choosing among any one of the following three available options: (1) Achieve an overall VOC reduction in baseline actual emissions of 98% by the addition of add-on controls or documented reduction in VOC-containing materials used; (2) achieve a level of reduction equal to 81% of baseline actual emission by the same means as stated above, where it is demonstrated that a 98% reduction in source emissions is not achievable; or (3) achieve an alternative overall emission reduction by the application of RACT as determined by the State and EPA. Indiana estimates that the rule's overall control efficiency is 81%, and has a rule effectiveness of 80%. Indiana has credited 4,559 lbs VOC/day in emission reductions from this rule, which is acceptable.

Coke Oven Battery Shutdowns at Inland Steel Flat Products

Inland Steel is required under Indiana's Particulate Matter rule 326 IAC 6–1–10.1(k)(5) to shut down

[4] RACT is the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available, considering technological and economic feasibility. CTGs are EPA documents which provide recommendations on what EPA considers the presumptive norm for RACT for particular industries. Indiana was required to adopt the Non-CTG RACT rule by section 182(b)(2) of the Act.

numbers 6 through 11 coke batteries before 1996. The 1990 base year inventory emissions from these coke batteries, 23,609 lbs VOC/day, are being credited as emission reductions. These reductions are acceptable.

Residential Open Burning Rule

Under Indiana's rule 326 IAC 4–1, residential open burning is banned in Lake and Porter Counties. Indiana estimates 80% emission reduction and 80% rule effectiveness from this rule. An emissions reduction credit of 929 lbs VOC/day from the rule is acceptable.

Automobile Refinishing Rule

The State rule 326 IAC 8–10 requires automobile and mobile equipment refinishing shops to use lower VOC coatings, less-emitting spray-gun and spray-gun cleaning equipment, and improved work practices to reduce VOC. To improve rule effectiveness, this rule also requires refinishing coating suppliers in the area to sell only coatings which meet the VOC limits required in the rule. In addition to documentation contained in the submittal, Indiana submitted supplemental documentation which indicates that an overall 77.8% emission reduction can be expected from all the control measures required by this rule, with 100% rule effectiveness. This documentation has been included in the docket for this rulemaking. Indiana has taken an emission reduction credit of 4,679 lbs VOC/day from this rule, which is acceptable.

E. Enforceability Issues

All measures and other elements in the SIP must be enforceable by the State and EPA (See sections 172(c)(6), 110(a)(2)(A) of the Act, and 57 FR 13556). The EPA criteria addressing the enforceability of SIPs and SIP revisions were stated in a September 23, 1987 memorandum (with attachments) from the Assistant Administrator for Air and Radiation (see 57 FR 13541). Nonattainment area plan provisions must also contain a program that provides for enforcement of the control measures and other elements in the SIP (see section 110(a)(2)(C) of the Act).

The control measures included in the Lake and Porter 15% ROP plan have been fully adopted by Indiana and have been submitted to EPA as revisions to the State's ozone SIP. The EPA has independently reviewed each control measure to determine conformance with SIP requirements under section 110 and part D of the Act, and the overall enforceability of the measure's requirements. Rulemaking action on each control measure is as follows:

Control measure	Date of EPA approval
Enhanced I/M Program (326 IAC 13–1.1)	March 19, 1996 (61 FR 11142).
Reformulated Gasoline (40 CFR Part 80, Subpart D)	Federal regulation promulgated February 16, 1994 (59 FR 7716).
Stage II Gasoline Vapor Recovery (326 IAC 8–4–6)	April 28, 1994 (59 FR 21942).
Federal AIM Coatings Rule	Proposed federal regulation for which Indiana can take credit. (See memorandum dated March 7, 1996, from John Seitz, Director, Office of Air Quality Planning and Standards to Regional Air Division Directors).
Non-CTG RACT (326 IAC 8–7)	July 5, 1995 (60 FR 34857).
Residential Open Burning Ban (326 IAC 4–1)	February 1, 1996 (61 FR 3581).
Auto Refinishing (326 IAC 8–10)	June 13, 1996 (61 FR 29965).
Coke Oven Battery Shutdown (326 IAC 6–1–10.1(k)(5))	June 15, 1995 (60 FR 31412).

F. Transportation Conformity 1996 Mobile Source Emissions Budget

Section 176(c) requires States to submit SIP revisions establishing the State's criteria and procedures for assessing the conformity of federal actions (transportation and general) to the SIP's purpose of eliminating or reducing the severity and number of violations of the NAAQS and achieving expeditious attainment of such standards, and that such activities will not: (1) Cause or contribute to any new violation of any standard in any area, (2) increase the frequency or severity of any existing violation of any standard in any area, or (3) delay timely attainment of any standard or any required interim emission reductions or other milestones in any area. To assure conformity with the SIP, conformity analyses for transportation projects must take into account the amount of on-road mobile source emissions that can be emitted in accordance with SIP emission reduction milestones. For the purposes of EPA transportation conformity determinations, the 1996 emission level for on-road mobile sources that is achieved from the 15% ROP plan, constitutes the 1996 VOC mobile source emission budget for Lake and Porter Counties. This level, which is derived from MOBILE5a using 1996 projected on-road mobile source emissions with reformulated gasoline and enhanced I/M, is 50,015 lbs VOC/day. Therefore, final approval of the 15% ROP plan also approves the 1996 mobile source VOC emission budget of 50,015 lbs VOC/day.

For years after 1996, conformity determinations addressing VOCs must demonstrate consistency with this plan revision's motor vehicle emissions budget, and satisfaction of the build/no-build test, as defined under 40 CFR part 93.

G. Concluding Statement on 15% ROP Plan

The EPA has reviewed the Lake and Porter Counties 15% ROP plan SIP revision submitted to EPA as described above, and finds that the plans satisfy the requirements of section 182(b)(1) of the Act, as well as EPA guidance for such plans. Therefore, the EPA, in this action, is approving this plan as a revision to the Indiana ozone SIP.

VI. Final Rulemaking Action

The EPA approves Indiana's 15% ROP plan for Lake and Porter Counties, as a revision to the SIP. For transportation conformity purposes, final approval of the 15% ROP plan also approves the 1996 mobile source emission budget of 50,015 lbs VOC/day. This action will be effective on August 18, 1997.

Nothing in this action should be construed as permitting, allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

VII. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

B. Regulatory Flexibility

Under the Regulatory Flexibility Act, 5 U.S.C. section 600 *et seq.*, EPA must prepare a regulatory flexibility analysis

assessing the impact of any proposed or final rule on small entities. 5 U.S.C. sections 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, the Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of the State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *EPA.*, 427 U.S. 246, 256–66 (1976); 42 U.S.C. 7410(a)(2).

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995, signed into law on March 22, 1995, EPA must undertake various actions in association with any proposed or final rule that includes a Federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. This Federal action approves pre-existing requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or the private sector, result from this action.

D. Submission to Congress and the General Accounting Office

Under section 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a major rule as defined by section 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 16, 1997. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Ozone.

Dated: July 8, 1997.

Michelle D. Jordan,

Acting Regional Administrator.

For the reasons stated in the preamble, part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

2. Section 52.777 is amended by adding paragraph (k) to read as follows:

§ 52.777 Control Strategy: Photochemical Oxidants (hydrocarbon).

* * * * *

(k) On June 26, 1995, and June 13, 1997, Indiana submitted a 15 percent rate-of-progress plan for the Lake and Porter Counties portion of the Chicago-Gary-Lake County ozone nonattainment area. This plan satisfies the counties' requirements under section 182(b)(1) of the Clean Air Act, as amended in 1990.

[FR Doc. 97–18972 Filed 7–17–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP–300507; FRL–5727–9]

RIN 2070–AB78

Vinclozolin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the pesticide vinclozolin, [3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione] and its metabolites containing the 3,5-dichloroanaline (3,5-DCA) moiety at 2.0 parts per million (ppm) in or on the food commodity succulent beans. The tolerance will expire and is revoked on October 1, 1999. A petition was submitted by BASF Corporation to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170) requesting the tolerance. BASF has requested that EPA revoke the tolerances for prunes, plums, tomatoes, grapes (excluding grapes grown for wine production), raisins, dried prunes and grape pomace. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations. BASF has deleted all residential uses, as well as, turf in parks, school grounds and recreational areas which would be expected to result in significant exposure to children from its vinclozolin registrations under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

DATES: This regulation becomes effective on May 30, 1997. Written objections and hearing requests must be received on or before September 16, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–30507], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket control number and submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file

format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300507]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Mary Waller, Acting Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 265, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–9354, e-mail: waller.mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the March 19, 1997 **Federal Register** (62 FR 13000)(FRL–5592–6), which announced that BASF Corporation had submitted a pesticide petition (PP) 9F3762 to EPA requesting that the Administrator, pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C section 346a, amend 40 CFR part 180 to establish a tolerance for residues of the fungicide vinclozolin [3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione; EPA Chemical No. 113201; CAS Reg. No. 50471-44–8] and its metabolites containing the 3,5-dichloroanaline moiety in or on the food commodity, succulent beans. The proposed tolerance levels for vinclozolin and its metabolites were 5.0 ppm. As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act (FQPA), Pub. L. 104–170, BASF included in the notice of filing a summary of the petition and authorization for the summary to be published in the Federal Register in a notice of receipt of the petition. The summary of the petition prepared by the petitioner contained conclusions and assessments to support its contention that the petition complied with the FQPA elements set forth in section 408(d)(3) of the FFDCA.

EPA has accepted these amendments to the vinclozolin registrations. Revisions to existing tolerances and revocation of affected tolerances will be addressed by the Agency in later actions.

I. Statutory Background

Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., as amended by the Food Quality Protection Act of 1996 (FQPA), Pub. L. 104–170) authorizes the establishment of tolerances (maximum residue levels), exemptions from the requirement of a tolerance, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on food commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore ''adulterated'' under section 402(a) of the FFDCA, and hence may not legally be moved in interstate commerce. For a pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C. 136 et seq.).

Section 408 was substantially amended by the FQPA. Among other things, the FQPA amends the FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. New section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through food, drinking water, and from pesticide use in gardens, lawns, or buildings (residential and other indoor uses) but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue***.''

II. Discussion of Comments

Fifteen comments were received in response to the notice of filing of this petition. Most of the commentors supported the tolerance requested by BASF on economic grounds and thus raised issues outside the scope of section 408. Only one commentor submitted comments in opposition to the tolerance proposed in the notice of filing. The principal objections to the proposed tolerance were:

1. The notice of filing was not sufficient to provide the public a meaningful opportunity to comment.

2. The notice did not adequately address exposure to vinclozolin in drinking water.

3. The notice did not adequately address residential and other non-occupational exposures to vinclozolin.

4. The notice did not adequately address the issue of cumulative exposures to pesticides with a common mechanism of toxicity.

5. The notice did not adequately address vinclozolin's carcinogenic potential.

6. The notice did not adequately address risks to infants and children.

Each of these principal objections is addressed below. In addition, all of the scientific issues raised in the objections are addressed in more detail elsewhere in this document.

A. Sufficiency of Notice to Allow for Public Comment

While it is clear that the commentor believed that the discussion of various scientific issues in the summary provided by BASF was unconvincing, it is unclear whether the commentor was contending that the summary was legally insufficient for the Agency to proceed with the publication of the notice of filing pursuant to section 408(d) of the FFDCA or that EPA was obligated to include in the notice of filing any additional analysis or information it might eventually rely upon in determining whether to grant the tolerance. Whatever the basis for the argument, the commentor's conclusion was that the notice of filing was insufficient to allow for meaningful public comment.

The short answer to this comment is that the depth and breadth of the comments submitted by the commentor would seem to demonstrate that significant meaningful public comment was not foreclosed by any alleged inadequacies in the notice of filing. While the commentor asserted that more information should have been provided on the various scientific issues discussed below, the commentor did not explain why the failure to supply such additional information rendered the summary provided by BASF legally insufficient to meet the requirements set forth in section 408(d)(2) of the FFDCA. That section does not require the development of the additional information adverted to in the comments, and the Agency has not at this time required by regulation (or otherwise) the development of such additional information. The Agency believes the summary was legally sufficient to support publication of the notice of filing.

As is clear from the remainder of this document, the Agency did not agree with all the arguments propounded by BASF in its summary. Section 408(d) sets forth the procedures that must be followed in determining whether to grant a petition for a tolerance; that section does not require that the Agency publish its own analysis for comment before a tolerance can be granted. In light of the facts that section 408(g) provides an opportunity for a person objecting to the issuance of a tolerance to file with the Administrator objections challenging the issuance of a tolerance and the notice in this particular case allowed interested parties an opportunity to meaningfully comment on the significant issues raised by the petition (as demonstrated by the comments submitted by this commentor), the Agency does not believe publication of an additional notice was either necessary or appropriate.

B. Exposure to Vinclozolin from Drinking Water

The commentor challenged BASF's argument that the Agency should assume no exposure to vinclozolin from water, and instead argued that the Agency should at least apply a default figure of 10% to represent the portion of the allowable risk that could be attributed to residues in water. As the discussion of this issue in this document makes clear, the Agency did not ignore potential exposure to vinclozolin or its toxic metabolites in water. Rather than use the default figure identified in the comment, the Agency applied a more conservative model to identify an upper bound to the contribution to overall risk from vinclozolin and its metabolites in water. The use of this conservative model actually resulted in an estimate of the contribution to overall risk from water exposure greater than the 10% default that the commentor urged the Agency to use.

The commentor also seemed to argue that, pursuant to the new FQPA, BASF was obligated to submit additional data on water-related exposure (and on other issues). Section 408(b)(2)(D) obligates the Agency to consider ''available information'' concerning a number of factors, including non-dietary, non-occupational exposures. The Agency does not agree that the new section 408 requires that such information automatically be developed (although the Agency does have the authority to require that such information be developed and submitted to the Agency).

C. Exposure to Vinclozolin from Residential/Non-Occupational Use

The commentor challenged BASF's treatment of exposure from residential and other non-occupational uses of vinclozolin. Some time after publication of the Notice of Filing, BASF agreed to remove all residential uses from its labels and to request deletion of most of them from the registration, with the others not being revived on labels until such time as the Agency determines that any related exposures would be safe. BASF also agreed to add label language that specifically limits turf uses of vinclozolin to commercial and industrial sites, golf courses, and greenhouses and nurseries. The language does not permit use on turf in parks, school grounds, and recreational areas that could be expected to be significant sources of exposure to children; these uses have already been removed from BASF's new labels. Consistent with the procedures set forth in FIFRA section 6(f), the Agency expects to grant the requested use deletions later this year. In light of the above described circumstances, the Agency does not expect that residential and non-occupational uses will result in any further meaningful exposure to vinclozolin.

D. Common Mechanism of Toxicity

The commentor argued that vinclozolin, iprodione and procymidone should be treated as having a common mechanism of toxicity because the chemicals share similar toxicological and structural properties. Iprodione and vinclozolin share a common metabolite, and exposures to the metabolite resulting from iprodione have been included in the aggregate exposures considered in determining whether the requested tolerance for vinclozolin on snap beans meets the safety standard set forth in section 408(b)(2)(A). Although vinclozolin shares structural and toxicological similarities with iprodione and procymidone, the Agency does not have at this time sufficient methodologies in place to resolve common mechanism issues in such circumstances in any meaningful way. The Agency has therefore concluded that it does not have sufficient available and reliable information concerning common mechanism of toxicity of vinclozolin, iprodione, and procymidone to analyze the common mechanism issue in a scientifically valid manner in this tolerance decision. This tolerance decision was reached based upon the best available and useful information for these chemicals and the supporting risk assessment was performed assuming that no common mechanism of toxicity exists. Furthermore, this tolerance decision will be reexamined by the Agency after EPA establishes methodologies and procedures for integrating information concerning common mechanism into its risk assessments.

E. Carcinogenicity

The commentor argued that vinclozolin has more carcinogenic potential than BASF asserted in its summary. The Agency's conclusions on the carcinogenic potential of vinclozolin and its metabolite 3,5-DCA are set forth in detail elsewhere in this Final Rule.

F. Risk to Children

The commentor argued that the discussion of risks to children in the notice of filing was flawed for a number of reasons. The commentor contended that exposures should be considered separately for separate ages, rather than by considering children between the ages of one and six together. They also asserted that BASF failed to adequately address exposures *in utero*, breast milk, early infancy, or puberty, all periods when protective measures may be necessary to protect against vinclozolin's anti-androgenic effects. Finally, the commentor argued that application of separate, additional tenfold safety factors are compelled because of the lack of good data on exposure to children and because of uncertainties associated with how endocrine disrupting compounds actually work. Because of the need to include these additional safety factors, the commentor asserted that the RfD proposed for use in the notice of filing should be lowered by a factor of 100.

Given the completeness and reliability of the data base for vinclozolin, the Agency concluded that a margin of safety of 100 (without the additional safety factors suggested by the commentor) would be safe for children. In terms of different potential exposures to children between the ages of one and six, it should be noted that the most sensitive subgroup would be women of child-bearing age because of the potential *in utero* and post-natal effects. The Agency has determined that there is sufficient information to characterize the risk to this subgroup, and that the tolerance announced in this Final Rule is safe for this subgroup. The data on the anti-androgenic effects of vinclozolin are of sufficient quantity and quality that an additional uncertainty factor is not necessary in order to assure that infants and children will be safe from such effects.

III. Risk Assessment and Statutory Findings—Background

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once the studies have been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. An aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered by EPA to pose a reasonable certainty of no harm. For threshold effects other than those assessed under the RfD, EPA generally calculates a margin of exposure (MOE). The MOE is a measure of how close the exposure comes to the NOEL. The NOEL is selected from a study of appropriate duration and route of exposure. The MOE is the NOEL from the selected study divided by exposure. MOEs greater than 100 are generally considered to show a reasonable certainty of no harm.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or margin of exposure calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water and exposures resulting from indoor and outdoor residential uses. Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Consistent with sections 408(b)(2)(C) and (D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has also assessed the toxicology data base for vinclozolin in its evaluation of the application for registration on succulent beans. EPA has sufficient data to assess the hazards of vinclozolin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for granting a tolerance for residues of vinclozolin on succulent beans at 2.0 ppm. EPA's assessment of the database, dietary exposures and risks associated with establishing this tolerance follows.

IV. Toxicology Database

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by vinclozolin are discussed below.

A. Data Evaluated

1. *Acute toxicity studies.* A battery of acute toxicity studies placing technical vinclozolin in toxicity category IV for acute oral toxicity (LD_{50} of >10,000 millgrams per kilogram (mg/kg)), and acute inhalation toxicity ((LD_{50} of 29.1 miligram per liter (mg/l)); and toxicity category III for acute dermal toxicity ((LD_{50} of >5,000 mg/kg). Technical vinclozolin caused minimal eye and dermal irritation and the technical material is a positive skin sensitizer.

2. *Chronic feeding—dog.* A 1–year feeding study in dogs fed dosages of 0, 1.1 , 2.4, 4.9, and 48.7 mg/kg/day with a No-Adverse-Effect Level (NOAEL) of 2.4 mg/kg/day based on the following effects:

(i) Slight decrease in hematological and increase in clinical chemistry values in the 48.7 mg/kg/day dose group (highest dose tested - HDT).

(ii) Increased absolute and/or relative weights for the testes (male only), adrenal, liver, spleen, and thyroids in the 4.9 or 48.7 mg/kg/day dose groups.

(iii) A dose-related atrophy of the prostate in the 4.9 or 48.7 mg/kg/day dose groups; and (iv) microscopic findings in the adrenal and testes (males) in the 48.7 mg/kg/day dose group and liver findings for both male and female dogs in the 48.7 mg/kg/day dose groups and in the females in the 4.9 mg/kg/day dose group, only.

3. *Chronic feeding/carcinogenicity—rat.* A combination of two chronic feeding studies and one carcinogenicity study resulted in rats being fed combined dosages of 0, 1.2, 2.4, 7.0, 23, 71, 143, and 221 mg/kg/day (males) and 0, 1.6, 3.1, 7.0, 23, 71, 180, and 221 mg/kg/day (females) with a NOAEL of 1.2 mg/kg/day (males) and 1.6 mg/kg/day (females) based on the following effects:

(i) Decreased body weights in both male and female rats at dose levels >23 mg/kg/day with a progression of severity to the upper levels.

(ii) Decreased food consumption in both male and female rats at dose levels >71 mg/kg/day with a progression of severity to the upper dose levels.

(iii) Cataracts with associative histopathology at dose levels >23 mg/kg/day and lenticular changes at dose levels >7.0 mg/kg/day for male and female rats.

(iv) Hematological and clinical chemistry value changes at dose levels >71 mg/kg/day dose groups with increase of severity at the higher doses tested.

(v) Increased absolute and/or relative weights for adrenal at dose levels >143 mg/kg/day, for the liver at dose levels >71 mg/kg/day, for the testes at dose levels >23 mg/kg/day, and for the ovaries at dose levels >143 mg/kg/day.

(vi) Microscopic findings were observed in the liver, adrenal, pancreas, testes (males), ovaries and uterus (females) at dose levels of >7.0 mg/kg/day with a progression of severity of histological effects in the upper dose levels.

(vii) An increased incidence of neoplasms occurred at dose levels greater than the maximum tolerated dose (MTD) of 23 mg/kg/day in the liver, adrenal, pituitary, prostate (males), uterus (females), and ovaries (females) at dose levels >143 mg/kg/day. In the testes (males), Leydig cell adenomas were seen at the MTD for dose levels >23.0 mg/kg/day due the antiandrogenic nature of vinclozolin.

4. *Carcinogenicity— mice*. A carcinogenicity study in mice fed dosages of 0, 2.1, 20.6, 432, and 1,225 (HDT) mg/kg/day (males) and 0, 2.8, 28.5, 557, and 1,411 (HDT) mg/kg/day (females) with a NOAEL of 20.6 mg/kg/day (males) and 28.5 mg/kg/day (females) based on the following effects:

(i) Increased mortality in the highest dose tested (HTD) as compared to controls.

(ii) Decreased body weights and significant signs of clinical toxicity were observed in both male and female mice at the upper two dose levels with a progression of severity.

(iii) Hematological and clinical chemistry value changes were observed at the highest dose tested.

(iv) Increased absolute and/or relative weights for adrenal and liver were observed at the upper two dose levels, atrophic seminal vesicles and coagulation glands with reduction of the prostate (males) and atrophic uteri were observed at the upper two dose levels.

(v) Microscopic findings were observed in the liver, adrenal, testes (males), ovaries and uterus (females), and related sexual organs in the upper two dose levels.

(vi) An increased incidence of neoplasms occurred at dose levels greater than the maximum tolerated dose (>28.5 mg/kg/day) in the liver of female mice.

5. *Developmental toxicity— rat*. In four developmental toxicity studies vinclozolin was given orally from gestational day (gd) 6 through 19 as follows: Study 4 - dose levels of 0, 15, 50, or 150 mg/kg/day; study 5 - dose levels of 0, 50, 100, 200 mg/kg/day, study 6 - dose levels of 0, 200, 400 mg/kg/day and study 8 - dose levels of 0, 600, 1,000 mg/kg/day. At the gd 20, the fetuses were evaluated.

Maternal toxicity was demonstrated at 600 and 1,000 mg/kg/day by the statistically significant increase in absolute and relative adrenal and liver weight in study 8. This was the only study where organ weights were determined. A maternal NOEL could not be established and therefore, the study was not considered to demonstrate any extra sensitivity. No histology was conducted on the organs, but other studies have demonstrated lipid accumulation in the adrenals, and centrilobular cloudiness of the liver. In addition, a dermal developmental study has indicated adrenal and liver weight increases occurred at 180 mg/kg/day and higher. Statistically significant increases and decreases occurred in the body weight gain and in food consumption with no apparent dose relatedness in any of the studies. The relative efficiency of food utilization was too variable to be definitive.

Statistically significant male and female fetal body weight decrement occurred at 1,000 mg/kg/day. These weight decrements were considered test material related. A statistically significant decrease occurred in anogenital distance (ambiguous sex) among male fetuses. The term pseudohermaphroditism was used to describe the effect because these males exhibited decreased anogenital distances, but exhibited superficially normal internal testes. The anogenital distance in male fetuses was statistically decreased at 50 mg/kg/day and higher in studies 4, 6, and 8. (The anogenital index was statistically significantly depressed at 150 mg/kg/day and higher). The anogenital distance and index were not determined in study 5. The response was dose related. Although anogential index was not statistically significantly depressed at 50 mg/kg/day, it was nominally depressed. Considering the significantly depressed anogenital distance at 50 mg/kg/day and higher and the nominally depressed anal-genital index at 50 mg/kg/day, the NOEL for this study was considered to be 15 mg/kg/day, the LDT. These results are consistent with hormonal or anti-hormonal effects from the test material.

Soft tissue examination of fetuses indicated that increased incidence occurred in dilated renal pelvis and hydro-ureter at 400 mg/kg/day in study 6. At higher dose levels in study 8, the incidence of dilated renal pelvis and hydro-ureter was nominally increased. The failure of the dilated renal pelvis, and hydro-ureter to be significantly increased in study 8 was attributed to the fewer litters used (7, 5, and 8 in controls, 600, and 1000 mg/kg/day). The NOEL for these renal effects is considered to be 200 mg/kg/day.

Skeletal examination of fetuses indicated increased incidence of accessory 14th rib at 400 mg/kg/day and in fetuses and litters at 600, and 1,000 mg/kg/day. These effects on the 14th rib may be related to dose administration. Evaluation of the Preliminary Study suggested a dose related increase in 14th ribs at these high dose levels. No other dose related effects were reported.

The developmental toxicity NOEL was set at 15 mg/kg/day and the developmental LOEL was 50 mg/kg/day based on decreased anogenital distance in males (ambiguous sex). Increased incidence of dilated renal pelvis, hydro-ureter, and accessary 14th rib may have occurred at 400 mg/kg/day and higher. The maternal toxicity LOEL was < 600 mg/kg/day based on increases in absolute and relative adrenal and liver weight. Organ weights were not determined at lower dose levels.

A developmental study in rats via dermal exposure for 6 hours/day on intact skin with dosages of 0, 60, 180, and 360 mg/kg/day (HDT) had a developmental NOAEL of 60 mg/kg/day and a maternal NOAEL of 60 mg/kg/day based on the following: (1) increased absolute liver weights at dose levels > 180 mg/kg/day; and (2) decreased anogenital distance and index at dose levels > 180 mg/kg/day.

6. *Developmental toxicity—rabbit*. A developmental study in rabbits via oral gavage resulted in dosages of 0, 20, 80, and 300 mg/kg/day (HDT) with a developmental NOAEL of 300 mg/kg/day and a maternal NOAEL of 300 mg/kg/day based on no signs of maternal or meaningful fetal toxicity observed at any of the dose levels mentioned.

A second developmental study in rabbits via oral gavage resulted in dosages of 0, 50, 200, and 800 mg/kg/day (HDT) with a development toxicity NOAEL of 200 mg/kg/day and a maternal toxicity NOAEL of 50 mg/kg/day based on the following: (1) severe maternal toxicity with simultaneous change in hematological values and high number of abortions at the HDT; and (2) increased absolute and/or

relative weights for adrenal in the mid and high dose groups.

7. *Two-generation reproduction— rat.* A two-generation reproduction study (consisting of two studies: study A - dose levels of 0, 2.0 and 4.1 mg/kg/day; study B - dose levels of 0, 4.9, 29, 100, and 307 mg/kg/day) with rats fed dosages of 0, 2.0, 4.1, 4.9, 29, 100, and 307 mg/kg/day with a reproductive NOAEL of 4.9 mg/kg/day based on feminization of males and their inability to mate at dose levels >100 mg/kg/day and pup effects at 29 mg/kg/day; and with a parental NOAEL of 4.9 mg/kg/day based on general toxicity consistent with previous rat studies at levels >29 mg/kg/day. Study A was performed to clarify an equivocal finding of decreased absolute and relative weight of the epididymides without any morphological correlation in the male FY and FZ generations in Study B. However, the Agency concluded that the effects at the 4.9 mg/kg/day dose level were minimal and considered sufficiently close to the NOAEL. The study is acceptable and 4.9 mg/kg/day dose level was considered to be the NOEL.

8. *Mutagenicity.* A Modified Ames Test (three studies, point mutation): a Host-Mediated Assay (point mutation), a Mouse Lymphoma Test (point mutation), *In Vitro* CHO Cells (point mutation), *In Vitro* Cytogenetics - CHO Cells (Chromosome Aberrations), *In Vivo* Dominant Lethal Test - Male NMRI Mouse (Chromosome Aberrations), Rec Assay (two test, DNA damage and repair) *In Vitro* UDS Test Using Hepatocyte (DNA damage and repair), *In Vivo* SCE Using Chinese Hamster (DNA damage and repair) showed no evidence of mutagenic activity.

9. *Mechanistic studies —anti-androgenicity activity.* A series of mechanistic studies (*In Vivo* and *In Vitro*) were conducted to define the anti-androgenic properties of vinclozolin. The results of these studies showed that vinclozolin elicits the inhibition of the androgen receptor in androgen sensitive organs.

B. Toxicology Profile

1. *Toxicity endpoint for dietary exposure*— i. *Acute toxicity.* To assess acute dietary exposure, the Agency used a NOEL of 3.0 mg/kg/day from a rat developmental toxicity study for evaluating acute risk to females 13+ years. The dose of 5.5 mg/kg/day was calculated using the bracketed conversion (3 mg/kg/day × 3.91/2.12 = 5.5 mg/kg/day), in order to obtain the single day internal dose corresponding to the NOEL of 3 mg/kg/day.

ii. *Chronic effects.* A RfD of 0.012 mg/kg/day was established based on a 2–year rat feeding study with a NOEL of 1.2 mg/kg/day and an uncertainty factor of 100.

iii. *Carcinogenicity.* Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified vinclozolin as a Group C chemical - possible human carcinogen. The Agency Cancer Peer Review Committee (CPRC) chose a non-linear approach [MOE] based on a NOEL of 4.9 mg/kg/day for hormone-related effects [decreased epididymal weight at 30 mg/kg/day] in the 2-generation oral rat reproductive toxicity study to quantify human risk. The MOE approach was chosen because the remaining tumors [Leydig cell] were benign at dose levels which were not considered to be excessive.

2. *Toxicity endpoints for non-dietary exposure*—i. *Short- and intermediate term risk for infants and children ages 1-12.* For short- and intermediate-term MOE calculations, the Agency decided to use of a NOEL of 5.0 mg/kg/day from an oral rat study based on delayed puberty in young rats at the LOEL of 15 mg/kg/day based on available data.

ii. *Short and intermediate term risk for females age 13 and older.* For short- and intermediate-term MOE calculations, the Agency decided to use a NOEL of 3 mg/kg/day from an oral rat developmental study based on the occurrence of pseudohermaphroditism (reduced anogenital distance) in male fetuses and nipple development. The maternal toxicity NOEL/LOEL were also 3 and 6 mg/kg/day respectively based on reduced sex organ weights.

iii. *Chronic non-dietary exposure.* A chronic risk exposure scenario has not been identified for the proposed use, although the chronic tolerance endpoint selection is based on the NOEL of 1.2 mg/kg/day.

C. Dietary Exposure

1. *Food and feed uses.* For purposes of assessing the potential chronic dietary exposure (food only) from the use of vinclozolin, EPA has used the percent of crop treated/percent imported data to refine the risk estimates for selected commodities (apricots, beans, raspberries, cherries, cucumbers, lettuce, nectarines, onions, peaches, peppers, and strawberries), while other commodities were assumed to be 100% treated/imported (caneberries (other than raspberries), cranberries, endive, garlic, wine/sherry, kiwifruit, and shallots). No chronic anticipated residue refinement has been performed. Therefore, the resulting exposure (food only) estimates should be viewed as partially refined; further refinement using anticipated residues and additional percent of crop treated/percent imported data would result in lower chronic dietary exposure estimates. The Anticipated Residue Contribution (ARC) for chronic dietary exposure estimates is equivalent to 12% of the RfD for the U.S. population (48 states). The ARC for infants and children and other subgroups ranged from 7 to 15% of the RfD. In the best judgement of the Agency, the vinclozolin dietary (food source only) chronic risk from the currently registered uses and this section 3 registration on snap beans does not exceed the level of concern. No feed items are associated with succulent beans. Therefore, secondary residues are not expected as a result of this proposed section 3 registration.

Section 408(b)(2)(F) allows EPA to use data on the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings:

(1) That the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues.

(2) That the exposure estimate does not underestimate the exposure for any significant subpopulation.

(3) Where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, EPA must provide for periodic evaluation of any estimates used.

The percent of crop treated estimates for vinclozolin were derived from Federal and market survey data. EPA considers these data reliable. A range of estimates are supplied by this data and the upper end of this range was used for the exposure assessment. By using this upper end estimate of percent crop treated, EPA is reasonably certain that exposure is not underestimated for any significant subpopulation. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows EPA to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. To provide for the periodic evaluation of these estimates of percent crop treated, EPA has issued a data call-in under section 408(f) to all vinclozolin registrants for data on percent crop treated. That data call-in requires such data to be

submitted every 5 years as long as the tolerances remain in force.

The acute dietary (food only) risk assessment used Monte Carlo analysis which creates an exposure distribution by randomly pairing a distribution of residue chemistry data with a distribution of food consumption and percent of crop treated or percent imported data for selected commodities (apricots, beans, raspberries, cherries, cucumbers, lettuce, nectarines, onions, peaches, peppers, and strawberries.), while other commodities were assumed to be 100% treated/imported (caneberries, other than raspberries; cranberries; endive; garlic; wine/sherry; kiwifruit; and shallots). Tier 2 anticipated residue refinement was performed for the mixed commodity wine/sherry. For imported, single-serving commodities, acute anticipated residue refinement was performed by using the highest field trial value in the Monte Carlo analysis. For all commodities which have a corresponding Section 3 registration, the Monte Carlo analysis used the full range of field trial residue data which reflected the existing (or proposed) use directions.

For the subgroup of concern, females 13+ years, the resulting high-end (99.9th percentile) dietary (food only) exposure estimate of 0.013587 mg/kg/day resulting in a MOE of 405. This estimate should be viewed as a refined risk estimate; further refinement using additional percent of crop treated or percent imported data may result in a slightly lower acute dietary exposure estimate.

2. *Potable water.* The Agency does not have drinking water monitoring data available to perform a quantitative drinking water risk assessment for vinclozolin at this time. Tier 1 estimated environmental concentrations (EEC's) were produced for surface water using the Generic Expected Environmental Concentration (GENEEC) model to estimate the human health risk to vinclozolin. The calculated acute EEC is 27.04 g/L and the calculated chronic EEC is 1.06 g/L. The model was performed using residues of vinclozolin per se. However, due to the very conservative nature of the Tier 1 GENEEC run and the low estimated metabolite level in relation to the parent compound, this estimate should be applicable to the sum total of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.

Exposure from surface water was calculated for various subgroups of the population from which risk estimates were developed. For acute risk, the MOE was estimated to be 6,100 for females 13 years and older which was the only subgroup of concern. For chronic risk, exposure was less than 1% of the RfD of 0.012 mg/kg/day for all subgroups. For cancer, an MOE (dietary water only) of 160,000 was calculated for the U.S. population from the exposure value of 0.0000303 mg/kg/day.

3. *Non-dietary uses.* Exposure in this category has been significantly reduced through elimination of all residential uses from product labeling. Therefore, any non-dietary, non-occupational exposure is expected to be minimal particularly for infants and children.

An approximation of the aggregate risk from the remaining non-dietary use (postapplication exposure to vinclozolin-treated produce at ''U-pick'' farms indicates that the calculated MOE's are ≤ 100 for children and adults. These are considered conservative risk estimates. The exposure estimates are based on studies of workers harvesting produce as wage earners. This may overestimate the exposure for non-occupational harvesters picking produce at ''U-pick'' farms for non-monetary purposes.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(V) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Vinclozolin, iprodione, and procymidone are structurally-related pesticides belonging to the imide class. Each of these three pesticides can metabolize to 3,5-dichloroaniline (3,5-DCA). Under FQPA, EPA is also required to estimate the risk for consumption of food and water containing 3,5-DCA across vinclozolin, iprodione, and procymidone.

There is no toxicological database; thus no RfD or Q_1* for 3,5-DCA. However, EPA has used the Q_1* for *p*-chloroaniline (PCA) to assess the carcinogenic risk for other structurally related chloroanilines because EPA does not have any evidence that 3,5-DCA is not carcinogenic. In 1988, the Q_1* for PCA was estimated to be 0.039 $(mg/kg/day)^{-1}$. However, a revised Q_1* of 0.059 $(mg/kg/day)^{-1}$ for PCA has been used for this assessment based on more recent data on male and female tumors.

The following routes of exposure for 3,5-DCA were evaluated: In food as a result of application of iprodione, in food as a result of application of vinclozolin, in imported wine as a result of application of procymidone, in water as a result of application of iprodione to a crop, and in water as a result of application of vinclozolin to a crop. There are no U.S. registrations for procymidone; therefore, an evaluation of exposure to procymidone in water was not appropriate.

Metabolism data of iprodione indicated that 3,5-DCA represented 1% TRR (total radioactive residue) in eggs, smaller proportions in other livestock commodities, and was not detected in primary or rotational crops. Metabolism data of vinclozolin indicated that 3,5-DCA represented 9.6% TRR in peaches, smaller proportions in strawberries and

was not detected in lettuce or grapes. Wine grapes were also included in the analysis even though the metabolism studies for procymidone indicated that the 3,5-DCA metabolite was not detected in grapes, but was formed in wine.

Two models were used for estimating potential concentrations of 3,5-DCA in surface water. PRZM/EXAMS was used to estimate 3,5-DCA concentrations as a result of applications of vinclozolin or iprodione on peaches. A conservative screening model, GENEEC, was used to estimate 3,5-DCA concentrations as a result of application of vinclozolin on strawberries. The estimation process also used surrogate fate data, a molecular weight conversion, proportion of acreage treated, and assumptions of the percent conversion of parent chemical to metabolite.

The following risk values were estimated for 3,5-DCA:

Route of Exposure	Dose	Estimated Risk
In food as a result of application of iprodione.	0.00000009219	5.4×10^{-9}
In food as a result of application of vinclozolin.	0.0000143224	8.4×10^{-7}
In imported wine as a result of application of procymidone.	0.0000058	2.5×10^{-7}
In water as a result of application of iprodione to peaches.	0.0000189	1.1×10^{-6}
In water as a result of application of vinclozolin to strawberries (not in California).	0.0000005	3.0×10^{-8}
In water as a result of application of vinclozolin to peaches.	0.000007	4.1×10^{-7}
Total Food and Wine only.		1.1×10^{-6}
Total Water as a result of application at a peach site.		1.5×10^{-6}
Total Food, Wine and Water.		2.6×10^{-6}

The total carcinogenic risk for consumption of food and wine containing residues of 3,5-DCA as a result of applications of iprodione, vinclozolin, and procymidone is 1.1×10^{-6}. This can be considered to be a slight over-estimate since metabolism studies were used to estimate the TRRs to convert iprodione or vinclozolin to 3,5-DCA used in the calculations. There is also an uncertainty to the risk estimate because a surrogate Q_1* was used for 3,5-DCA.

The total carcinogenic risk for drinking water containing residues of 3,5-DCA as a result of applications of iprodione and vinclozolin was estimated at 1.5×10^{-6} for the most highly exposed populations. Although, there is a high degree of uncertainty to this analysis, these are the best available estimates of concentrations of 3,5-DCA in drinking water. EPA believes that these risk numbers do justify asking for fate data and monitoring data for 3,5-DCA in both ground and surface water from both the registrants of iprodione and vinclozolin.

EPA believes that the total risk estimate estimated for 3,5-DCA for food, wine, and drinking water of 2.6×10^{-6} generally represents a negligible risk, as EPA has traditionally applied that concept. EPA has commonly referred to a negligible risk as one that is at or below 1 in 1 million (1×10^{-6}). Quantitative cancer risk assessment is not a precise science. There are a significant number of uncertainties in both the toxicology used to derive the cancer potency of a substance and in the data used to measure and calculate exposure. Thus, EPA generally does not attach great significance to numerical estimates for carcinogenic risk that differ by approximately a factor of 2½.

The registrant must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether vinclozolin shares a common mechanism of toxicity with any other substance and, if so, whether any tolerances for vinclozolin need to be modified or revoked.

V. Determination of Safety for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed effect level in the animal study appropriate to the particular risk assessment. This hundredfold uncertainty (safety) factor/margin of exposure (safety) is designed to account for combined inter- and intra-species variability. EPA believes that reliable data support using the standard hundredfold margin/factor not the additional tenfold margin/factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin/factor.

In assessing the potential for additional sensitivity of infants and children to residues of vinclozolin, EPA considered data from developmental toxicity studies in the rat and rabbit and a reproductive toxicity study in rats. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to the mother. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

1. *Developmental toxicity—rats.* In oral developmental toxicity study in rats, the developmental NOEL was 3 mg/kg/day based on the occurrence of pseudohermaphroditism (reduced anogenital distance) in male fetuses and nipple development. The maternal toxicity NOEL/LOEL were not determined in this segment of the study.

2. *Developmental toxicity—rabbits.* From the developmental toxicity study in rabbits the maternal (systemic) NOEL was 50 mg/kg/day, based on increased absolute and relative liver weight, reduced defecation, and reddish-brown urine at the LOEL of 200 mg/kg/day. The developmental (fetal) NOEL was 200 mg/kg/day, based on early resorptions, fetal weight increase, decreased live litter size and possible increased skeletal anomalies at the LEL of 400 mg/kg/day.

3. *Reproductive toxicity— rats.* From the reproductive toxicity studyin rats, the parental (systemic) NOEL was 4.9 mg/kg/day, based on decreased epididymal weights at the LOEL of 30 mg/kg/day. The reproductive/developmental (pup) NOEL was 4.9 mg/kg/day, based on reduced epididymal

weights and lenticular degeneration at the LEL of 30 mg/kg/day.

Based on current toxicological data requirements, the database relative to pre- and post natal toxicity is complete. From these data EPA concludes that extra (greater than 100) uncertainty factors were not necessary when used with the developmental toxicity endpoint of 3 mg/kg/day. Agency documents are available through the docket which detail this decision. The bases of the Agency's finding is as follows:

- Vinclozolin has an adequate and extensive toxicity data base including mechanistic data.
- Mechanistic data (androgen receptor inhibition) showing that vinclozolin probably results in analogous developmental effects in the rat and human.
- There are probably only minor differences in kinetics and metabolism of vinclozolin between rats and humans.
- Postnatal studies show effects in parents and offsprings at similar dose levels, although, the effects in offsprings are more severe.
- The 3 mg/kg/day NOEL for decreased ano-genital distance (AGD) as a measure of developmental effects is a very sensitive measure of decreased androgenization of the fetus/offspring.
- The decreased AGD has only been seen in rat studies. Neither the rabbit nor the mouse developmental toxicity studies show obvious anti-androgen related effects.
- The 3 mg/kg/day endpoint may be overprotective since the next higher dose level (6 mg/kg/day) was not statistically significantly different from the control. Based on additional analysis by the Science Advisory Board (SAB) statisticians, the NOEL may be as high as 12 mg/kg/day.

VI. Determination of Safety for U.S. Population Including Infants and Children

1. *Chronic dietary exposure/risk*. Based of the exposure assumptions discussed above and the completeness and reliability of the toxicity database, the Agency estimates that the food only exposure to vinclozolin for the subgroup of concern, Non-Nursing Infants < 1 year old, will utilize 14% of the RfD. The population subgroup with the largest percentage of the RfD occupied is U.S. Population, Western Region at 15% of the RfD. EPA generally has no concern for exposure below 100 percent of the RfD.

2. *Aggregate risk*—i. *Acute aggregate risk*. For the subgroup of concern, females 13+ years, the calculated dietary (food only) MOE value is 405. This estimate should be viewed as a refined risk estimate; further refinement using additional percent of crop treated or percent imported data may result in a slightly lower acute dietary exposure estimate. When the surface water exposure estimate (it appears the surface water estimate is worst case) is added (based on limited data for ground water and environmental fate data), the aggregate acute dietary risk (food + water) estimate results in an MOE of 380. This MOE value does not exceed the Agency's level of concern for acute dietary exposure.

ii. *Chronic aggregate risk*. The aggregate chronic risk is equal to the sum of the chronic risk from food + water + non-dietary exposure. Vinclozolin is not currently registered for any residential uses and no other chronic exposure scenario's have been identified from the registered uses of vinclozolin. Therefore, the aggregate chronic risk for vinclozolin is equal to the sum of the chronic risk from food + water, and is equivalent to less than 13% of the RfD for the U.S. population. Other subgroups ranged from 8 to 16% of the RfD.

iii. *Short- and intermediate-term aggregate risk*. The aggregate short- and intermediate-term risk is equal to the sum of the chronic risk from food + water (considered to be a background exposure level) + non-dietary exposure (exposure from ''U-pick'' farms). The calculated MOE values for the aggregate short- and intermediate-term risk from vinclozolin range from 140 for children 1 to 6 years old to 150 for children 7 to 12 years old. The MOE's do not exceed the Agency's level of concern. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to vinclozolin residues.

iv. *Cancer aggregate risk*. The aggregate cancer risk for vinclozolin is equal to the sum of the chronic risk from food + water. The Anticipated Residue Contribution (ARC) for the U.S. Population was calculated to be 0.001383 mg/kg/day from food and 0.0000303 from dietary water, for a total dietary exposure (food + water) of 0.001413. Using the formula where the Margin of Exposure (MOE) = NOEL (mg/kg/day) ÷ Exposure (mg/kg/day), or 4.9 mg/kg/day ÷ 0.001413 mg/kg/day, the calculated MOE (food + water) is 2,100.

VII. Other Considerations

A. Endocrine Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) may effect humans similar to an effect produced by a naturally occurring estrogen, or such other endocrine effects. The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. The endocrine modulating effects of vinclozolin are adequately understood.

The *in vivo* studies show that vinclozolin or it's metabolites/degradation products disrupt the androgen endocrine system through inhibition of androgen receptors. This receptor inhibition results in reduced androgen to androgen sensitive organs, such as the prostate seminal vesicles and epididymides (anti-androgen effects). In the pituitary gland, this inhibition results in increased luteinizing hormone which in turn stimulates the testicular Leydig cells. Continuous stimulation of the testicular Leydig cells result in the Leydig cell adenomas seen in the chronic and carcinogenicity studies.

The *in vitro* data are studies on androgen receptor inhibition by two metabolism/degradation products (M1 and M2) of the vinclozolin. This androgen receptor inhibition results in the reduced ano-genital distance seen in the developmental toxicity studies with vinclozolin.

B. Metabolism in Plants and Animals

The metabolism of vinclozolin in plants and animals is adequately understood for the purpose of this tolerance. A CODEX Maximum Residue Limit (MRL) for residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety has been established for common beans at 2.0 ppm. Residue data were examined at the Joint meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. The field trials were conducted in Germany, the Netherlands, Japan, United Kingdom, and France. It was concluded that a 2.0 ppm MRL should be established based on rates of 0.19 (3 applications) to 1.0 kg a.i./ha. (three(3) applications) and a PHI of 7 days. These rates are equivalent to 0.17 to 0.89 lbs a.i./A.

Residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline (DCA) moiety are not expected to exceed 2.0 ppm in/on snap beans as a result of this Section 3

registration. There are no processed commodities or feed items associated with snap beans. Therefore, secondary residues are not expected as a result of this proposed Section 3 registration.

There is a practical analytical method available for determination of residues of vinclozolin. Adequate enforcement methodology (gas chromatography/electron capture detector) for plant and animal commodities is available to enforce the tolerances. As a condition of registration, EPA has requested that revisions and clarifications be made to the submitted methodology, and that the animal commodity method be improved by eliminating the use of hazardous materials. Once this method has been submitted, EPA will provide information on this method to FDA. In the interim, the analytical method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm 1128, 1921 Jefferson Davis Hwy., Arlington, VA 22202, 703–305–5805.

C. Tolerance Revocation and Data Requirements

1. *Tolerance Revocation.* BASF has requested that EPA revoke the tolerances for prunes, plums, tomatoes, grapes (excluding grapes grown for wine production), raisins, dried prunes and grape pomace, and that all residential uses, as well as, turf in parks, school grounds and recreational areas which would be expected to result in significant exposure to children be deleted from its vinclozolin registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA accepts these amendments to the vinclozolin registrations. Revisions to existing tolerances and revocation of affected tolerances will be addressed by the Agency in later actions.

2. *Data Requirements.* In accordance with section 408(b)(2)(E)(ii) of the Federal Food, Drug, and Cosmetic Act(FFDCA), the Agency is requiring, pursuant to subsection (f)(1), that data be provided five years after the date on which the tolerance is established, modified,, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

VIII. Summary of Findings

The risk analysis for vinclozolin shows that there is reasonable certainty that no harm will result from aggregate exposure to vinclozolin. This analysis includes all current tolerances including the tolerances that BASF requested to be cancelled. All population subgroups examined by EPA are exposed to vinclozolin residues at levels below 100 percent of the RfD for chronic effects. Based on the information and data considered, EPA concludes that the proposed tolerances will be safe. Therefore the tolerances are established as set forth below.

FQPA has eliminated all distinctions between tolerances for raw agricultural commodities and processed foods. Therefore, EPA is combining the tolerances that now appear in § § 185.1850 and 186.1850 with the tolerances in § 180.380 and is eliminating § § 185.1850 and 186.1850.

IX. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''Object'' to a tolerance regulation issued by EPA under the new section 408(d) as was provided in the old section 408 and in section 409. However, period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which given the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use its current procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by September 16, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(I). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

X. Public Docket

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP–300507] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number (insert docket number). Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

XI. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

XII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Parts 180, 185 and 186

Environmental protection, Animal feeds, Administrative practice and procedure, Agricultural commodities, Food additive, Pesticides and pest, Reporting and recordkeeping requirements.

Dated: July 14, 1997.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

1. In part 180:

a. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

b. By revising § 180.380 to read as follows:

§ 180.380 Vinclozolin; tolerances for residues.

(a) *General.* Tolerances are established for the combined residues of the fungicide vinclozolin (3-(3,5-dichlorophenyl)-5-ethenyl-5- methyl-2,4-oxazolidinedione) and its metabolites containing the 3,5-dichloroaniline moiety in or on the food commodities in the table below. There are no U.S. registrations for Belgian endive, cucumbers, grapes, peppers and tomatoes as of (May 30, 1997). The time-limited tolerance will expire and is revoked on the date(s) listed in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Beans, succulent	2.0	10/1/99
Belgian endive, tops	5.0	None
Cucumbers	1.0	None
Grapes	6.0	None
Grape, pomace, dry (as a result of application to grapes)	42.0	None
Kiwifruit	10.0	None
Lettuce, head	10.0	None
Lettuce (leaf)	10.0	None
Onions (dry bulb)	1.0	None
Peppers (bell)	3.0	None
Prunes	75	None
Raisins (as a result of application to grapes)	30	None
Raspberries	10.0	None
Stonefruits	25.0	None
Strawberries	10.0	None
Tomatoes	3.0	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

PART 185—[AMENDED]

2. In part 185:

a. The authority citation continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.1850 [Removed]

b. Section 185.1850 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation continues to read as follows:

Authority: 21 U.S.C. 342, 348 and 701.

§ 186.1850 [Removed]

b. Section 186.1850 is removed.

[FR Doc. 97–19087 Filed 7–16–97; 1:30 pm]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[MD Docket No. 96–186; DA 97–1463]

Assessment and Collection of Regulatory Fees For Fiscal Year 1997

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission revised its Schedule of Regulatory Fees on June 16, 1997, in order to recover the amount of regulatory fees that Congress has required it to collect for fiscal year 1997. *See Report and Order in the Matter of Assessment and Collection of Regulatory Fees for Fiscal Year 1997,* Md Docket 96–186, FCC 97–215, released June 26, 1997, 62 FR 37408 (July 11, 1997). The attached *Order* establishes the dates when these regulatory fees must be paid.

DATES: September 15, 1997, through September 19, 1997, for all annual fee payors. Beginning on September 15, 1997, for applicants who pay fees in advance in combination with their application fee for new, renewal and reinstatement authorizations in the private wireless services.

FOR FURTHER INFORMATION CONTACT: Terry D. Johnson, Office of Managing Director at (202) 418–0445.

SUPPLEMENTARY INFORMATION:

Adopted: July 14, 1997.

Released: July 16, 1997.

1. The Managing Director has determined the dates for collection of the fees adopted in the above-captioned proceeding. *See Assessment and Collection of Regulatory Fees for Fiscal Year 1997,* FCC 97–215, released June 26, 1997, 62 FR 37408 (July 11, 1997). We are establishing collection dates as indicated below.

2. Annual regulatory fees for regulatees in the cable television, common carrier, international, mass media, and commercial wireless services are due during the period beginning *September 15, 1997,* and ending *September 19, 1997.* Parties paying these fees electronically are requested to submit them on *September 15th* or *September 16th.*

3. Applicants for new, renewal and reinstatement licenses in the private wireless services (also includes the domestic public fixed microwave services) which pay annual fees of $10.00 in advance for each year of their license term in combination with the appropriate application fee are to begin paying the new fee on *September 15, 1997.* For private wireless licensees paying $5.00 in advance for each year of their license term in combination with the appropriate application fee, they also are to begin paying the new fee on *September 15, 1997.*

4. Since the time for collecting fees is extremely limited, we are unable to offer installment payments for fiscal year 1997.

5. Accordingly, *it is ordered* that the dates for collection of fiscal year 1997 regulatory fees are as provided in paragraphs 2 and 3 of this *Order.* This action is taken under delegated authority pursuant to § 0.231(a) and § 1.1157(b)(1) of the Commission's rules. 47 U.S.C. § 0.231(a) and § 1.1157(b)(1).

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 97–18883 Filed 7–17–97; 8:45 am]

BILLING CODE 6712–01–P

GENERAL SERVICES ADMINISTRATION

48 CFR Part 552

[APD 2800.12A, CHGE 75]

RIN 3090–AG30

Acquisition Regulation; Remittance of Industrial Funding Fee in U.S. Dollars Under Federal Supply Schedules Program

AGENCY: Office of Acquisition Policy, GSA.

ACTION: Final rule.

SUMMARY: The General Services Administration Acquisition Regulation (GSAR) is amended to revise the contract clauses at 552.238–72 and 552.238–77 to require remittance of the industrial funding fee under Federal Supply Schedules (FSS) program in U.S. dollars, define the basis for converting the value of sales in foreign currency, update references to termination for cause, and clarify reporting and remittance requirements.

DATES: Effective Date July 18, 1997.

FOR FURTHER INFORMATION CONTACT: Gloria Sochon, GSA Acquisition Policy Division, (202) 208–6726.

SUPPLEMENTARY INFORMATION:

A. Background

The General Services Administration's FSS program charges ordering activities an industrial funding fee (IFF) to recoup the program's operating costs. The IFF is included in contract prices, collected by contractors, and remitted quarterly to GSA. Some contractors under the International Federal Supply Schedule have remitted the IFF in foreign currency. This practice causes many problems, particularly impeding GSA's ability to meet U.S. Department of the Treasury requirements to record deposits timely. Checks in foreign currency require significant processing, often taking several weeks to complete the deposit. The government loses interest on the funds during this delay.

The revised contract clauses require payment of the IFF in U.S. dollars. It also establishes standards for conversion to address fluctuations in rates of exchange. Contractors will use the U.S. Department of the Treasury, ''Treasury Reporting Rates of Exchange,'' in effect on the last day of the reporting period to convert the value of sales in foreign currency to U.S. dollars. In addition, the references to termination for cause are revised, as different clauses now apply in different situations. It also clarifies reporting and remittance requirements by defining the close-out report, defining how the contractor is to provide supporting information when reimbursing GSA by check, and updating information on electronic funds transfers.

B. Executive Order 12866

This rule was submitted to the Office of Management and Budget (OMB) under Executive Order 12866.

C. Regulatory Flexibility Act

This final rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The rule requires only that FSS contractors use U.S. dollars to report the value of sales and to remit the IFF to GSA. The only additional administrative burden on contractors is the need to calculate the conversion of sales made in foreign currency once each quarter. Most of the contractors affected by this rule will be foreign entities, with their place of business located outside of the U.S.

D. Paperwork Reduction Act

The revised clause at 552.238–72, Contractor's Report of Sales, contains an information collection requirement subject to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). However, the revisions to the clause made by this rule do not affect the information collection requirement which was approved previously by OMB and assigned control number 3090–0121.

The revised clause at 552.238–77, Industrial Funding Fee, contains an information collection requirement

subject to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). However, the revisions to the clause made by this rule do not affect the information collection requirement previously approved under GSA's blanket approval under control number 3090–0250 from OMB for information collections with a zero burden estimate.

E. Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule under 5 U.S.C. 804. This rule was submitted to Congress and GAO under 5 U.S.C. 804.

F. Determination to Issue a Final Rule

GSA expects this rule will have no significant cost or administrative burden on contractors or offerors. The only additional administrative burden on contractors is the need to calculate the conversion of sales made in foreign currency once each quarter. Therefore, GSA is promulgating this final rule without prior opportunity for public comment.

List of Subjects in 48 CFR Part 552

Government procurement.

Accordingly, 48 CFR 552 is amended as follows:

1. The authority citation for 48 CFR Part 552 continues to read as follows:

Authority: 40 U.S.C. 486(c).

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

2. Section 552.238–72 is amended by revising the clause date; revising paragraph (a); redesignating paragraphs (b), (c), and (d) as (c), (d), and (e) respectively; adding a new paragraph (b); redesignating paragraph (e) in Alternate I as paragraph (f) and revising the reference ''paragraph (e)'' in Alternate I introductory text to read ''paragraph (f)''; and revising the Alternate I date to read ''May 1997''; and revising paragraphs (c) and (d) to read as follows:

552.238–72 Contractor's report of sales.

* * * * *

CONTRACTOR'S REPORT OF SALES (MAY 1997)

(a) The Contractor must furnish quarterly the dollar value (in U.S. dollars and rounded to the nearest whole dollar) of all sales under the contract during the preceding 3-month period, to include any partial month. The dollar value of a sale is the price paid by the schedule user for products and services on a schedule contract delivery order, as recorded by the Contractor. The reported contract sales value must include the industrial funding fee (see Clause 552.238–77). The Contractor must prepare and submit a separate report for each National Stock Number (NSN), Special Item Number (SIN), or subitem, unless otherwise specified, on GSA Form 72A.

(b) The Contractor must convert the total value of any sales made in foreign currency to U.S. dollars using the ''Treasury Reporting Rates of Exchange,'' issued by the U.S. Department of Treasury, Financial Management Service. The Contractor must use the issue of the Treasury report in effect on the last day of the contract quarter. The report is available from: Department of the Treasury, Financial Management Service, International Funds Branch, 3700 East-West Highway, PGCII, Room 5A19, Hyattsville, MD 20782, Telephone: (202) 874–7994, Internet: http://www.ustreas.gov/treasury/bureaus/finman/intn.html.

(c) The report is due in the office specified below or specified at the time of award 30 days following the completion of the reporting period. The Contractor must provide a close-out report within 120 days after the expiration date of the contract. This close-out report must cover all sales not shown in the final quarterly report and reconcile all errors and credits. If the Contractor reported all contract sales and reconciled all errors and credits on the final quarterly report, then show zero sales in the close-out report.

(d) The Government reserves the right to inspect without further notice, such records of the Contractor as pertain to sales under this contract. Willful failure or refusal to furnish the required reports, or falsification thereof, constitutes sufficient cause for terminating the contract for cause under the termination provisions of this contract.

* * * * *

3. Section 552.238–77 is amended by revising the clause date; revising paragraph (a); redesignating paragraphs (b), (c), and (d) as (c), (d), and (e) respectively; adding a new paragraph (b); revising newly designated paragraphs (c), introductory text and (c)(2); and revising newly designated paragraph (e) to read as follows:

552.238–77 Industrial funding fee.

* * * * *

INDUSTRIAL FUNDING FEE (MAY 1997)

(a) The Contractor must pay the Federal Supply Service, GSA, an Industrial Funding Fee (IFF), in U.S. dollars, at the end of each contract quarter. The Contractor must remit the IFF at the same time the GSA Form 72A, Contractor's Report of Sales, is submitted under clause 552.238–72, Contractor's Report of Sales. The IFF equals _____* of total sales reported on GSA Form 72A. The IFF reimburses the GSA Federal Supply Service for the costs of operating the Federal Supply Schedules Program and recoups its operating costs from ordering activities. Offerors should include the IFF in the prices submitted with their offer. The fee is included in the award price(s) and reflected in the total amount charged to ordering activities.

(b) The Contractor must remit any monies due as a result of the close-out report required by clause 552.238–72 at the time the close-out report is submitted to GSA.

(c) The IFF amount due must be paid by check or, electronic funds transfer through the Automated Clearing House (ACH), to the ''General Services Administration.'' If the payment involves multiple special item numbers or contracts, the Contractor may consolidate the IFFs into one payment. To ensure that the payment is credited properly, the Contractor should identify the check or electronic transmission as an ''Industrial Funding Fee'' and include the following information: contract number(s); report amount(s); and report period(s). If the Contractor makes payment by check, provide this information on either the check, check stub, or remittance material. The GSA Form 72A is not remittance material.

* * * * *

(2) If the IFF payment is made by electronic funds transfer through ACH, the Contractor must call GSA, Financial Information Control Branch, Receivables, Collections and Sales Section (6BCDR) at (contracting officer to insert phone number) to make arrangements.

* * * * *

(e) Failure to submit sales reports, falsification of sales reports, and/or failure to pay the IFF in a timely manner may result in termination or cancellation of this contract. Willful failure or refusal to furnish the required reports, falsification of sales reports, or failure to make timely payment of the IFF constitutes sufficient cause for terminating the contract for cause under the termination provisions of this contract.

(End of Clause)

* * * * *

Dated: May 15, 1997.

Ida M. Ustad,

Deputy Associate Administrator, Office of Acquisition Policy.

[FR Doc. 97–18944 Filed 7–17–97; 8:45 am]

BILLING CODE 6820–61–P

ENVIRONMENTAL PROTECTION AGENCY

48 CFR Parts 1535 and 1552

[FRL–5860–6]

Acquisition Regulation: Removal of Certification Requirements Regarding Collection, Use, Access, Treatment, and Disclosure of Confidential Business Information (CBI)

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is amending the Environmental Protection Agency Acquisition Regulation (EPAAR) (48 CFR Chapter 15) by removing certification requirements regarding the collection, use, access, treatment, and disclosure of confidential business information (CBI) which are not specifically imposed by statute, and to

amend CBI clauses to remove such certification requirements.

Existing contract clauses for the protection of CBI submitted pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA) are amended to mandate that prior to receipt of FIFRA CBI and TSCA CBI by the contractor, the contractor will ensure that their employees have read and are familiar with the handling, control, and data security requirements without the need for a certification. This accomplishes the objective of the certifications.

EFFECTIVE: August 18, 1997.

FOR FURTHER INFORMATION CONTACT: Paul Schaffer at (202) 260–9032.

SUPPLEMENTARY INFORMATION:

A. Statutory Authority

Section 4301(b) of the Clinger-Cohen Act of 1996 (formerly the Federal Acquisition Reform Act of 1996—''FARA'') requires agencies to remove all non-statutory certifications from their acquisition regulation, unless the head of the agency approves a justification for the retention of a certification requirement. The basis for the justification must be that there is no less burdensome means for administering and enforcing the certification requirement.

The following two non-statutory certification requirements are removed:

1. 48 CFR 1552.235–72 Control and Security of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Confidential Business Information (Apr 1996).

2. 48 CFR 1552.235–74 Control and Security of Toxic Substances Control Act (TSCA) Confidential Business Information (Apr. 1996).

B. Background

The proposed rule was published in the **Federal Register** (61 FR 55126) on October 24, 1996, providing for a 60-day comment period. Interested persons have been afforded an opportunity to participate in the making of this rule. Due consideration has been given to the five comments received. The following is a summary of each comment received and the Agency's disposition of these comments.

1. *Comment:* The certification should be retained since there is no less burdensome means for administering and enforcing the protection of CBI.

EPA disagrees with this comment. Amending existing contract clauses to require that the contractor ensure that its employees have read and are familiar with the handling, control, and data security requirements is a less burdensome means of achieving such familiarity. The contractor would still be bound by the terms of the contract to ensure that its employees have read and are familiar with the security requirements. Moreover, existing statutory criminal penalties for unauthorized disclosure of CBI are unaffected by this change.

2. *Comment:* The requirement for a person's signature certifying compliance with EPA data security procedures will in fact cause individuals to be more aware of and diligent in their adherence to EPA's requirements for handling CBI.

EPA disagrees with this comment. In fact, under both the TSCA and FIFRA security manuals, contractor (as well as Federal) employees given access to CBI are required to sign an agreement to adhere to those procedures.

3. *Comment:* The proposed elimination of CBI certifications should not be contemplated at this time in light of EPA's potential loss of approximately 200 TSCA CBI documents by an Agency contractor.

EPA disagrees with this comment. The Agency is currently reviewing the circumstances surrounding the unaccounted for documents. However, the subject of the certification at issue is unrelated to the document processing procedures under review.

4. *Comment:* The retention of a signed certification by contractors will make it easier for EPA to meet its data security goals.

See response to comment 1.

5. *Comment:* Without proper CBI protections, companies will not be willing to initiate new product development. EPA has an obligation under TSCA and FIFRA to protect CBI.

EPA, for the reasons discussed in the response to comment 1, does not believe that this change will result in the lack of proper protection of CBI.

EPA has not changed the final rule from the proposed rule as a result of these comments.

C. Executive Order 12866

This is not a significant regulatory action for the purposes of Executive Order 12866; therefore, no review was required by the Office of Information and Regulatory Affairs.

D. Paperwork Reduction Act

This rule does not contain information collection requirements that require the approval of OMB under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*)

E. Regulatory Flexibility Act

EPA certifies that this rule does not exert a significant economic impact on a substantial number of small entities, pursuant to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule imposes no reporting, record-keeping, or any compliance costs. Therefore, no regulatory flexibility analysis was prepared.

F. Submission to Congress and the General Accounting Office

This action is not a major rule as defined by 5 U.S.C. 804(2). Pursuant to 5 U.S.C. 801(a)(1)(A), EPA submitted this action to the U.S. Senate, the U.S. House of Representatives and the Comptroller General prior to its publication in today's **Federal Register**.

G. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of certain regulatory actions on State, local, and tribal governments and the private sector, and to seek input from State, local, and tribal governments on certain regulatory actions. Because this rule removes rather than adds regulatory requirements, EPA has determined that this action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. Therefore, this action is not subject to the requirements of sections 202 and 205 of the UMRA. The requirements of sections 203 and 204 of UMRA which relate to regulatory requirements that might significantly or uniquely affect small governments and to regulatory proposals that contain a significant Federal intergovernmental mandate, respectively, also do not apply to today's rule.

List of Subjects in 48 CFR Parts 1535 and 1552

Government procurement.

Therefore, 48 CFR Chapter 15 is amended as set forth below:

1. The authority citations for Parts 1535 and 1552 continue to read as follows:

Authority: Sec. 205(c), 63 stat. 390, as amended, 40 U.S.C. 486(c).

2. Section 1535.007 is revised to read as follows:

1535.007 Solicitations.

(a) Contracting officers shall insert 48 CFR 1552.235–73, Access to Federal Insecticide, Fungicide, and Rodenticide Act Confidential Business Information, in all solicitations when the contracting officer has determined that EPA may furnish the contractor with confidential

business information which EPA had obtained from third parties under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*).

(b) Contracting officers shall insert 48 CFR 1552.235–75, Access to Toxic Substances Control Act Confidential Business Information, in all solicitations when the contracting officer has determined that EPA may furnish the contractor with confidential business information which EPA had obtained from third parties under the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*).

1552.235–72 and 1552.235–74 [Removed and Reserved]

3. Sections 1552.235–72 and 1552.235–74 are removed and reserved.

4. Section 1552.235–77 is amended by revising the section heading and clause heading dates to read ''June 1997'' and by revising paragraph (a)(3) to read as follows:

1552.235–77 Data Security for Federal Insecticide, Fungicide and Rodenticide Act Confidential Business Information (June 1997)

* * * * *

(a) * * *

(3) Prior to receipt of FIFRA CBI by the Contractor, the Contractor shall ensure that all employees who will be cleared for access to FIFRA CBI have been briefed on the handling, control, and security requirements set forth in the FIFRA Information Security Manual.

* * * * *

5. Section 1552.235–78 is amended by revising the section heading and clause heading dates to read ''June 1977'' and by revising paragraph (a)(1) to read as follows:

1552.235–78 Data Security for Toxic Substances Control Act Confidential Business Information (June 1997)

(a) * * *

(1) The Contractor and Contractor's employees shall follow the security procedures set forth in the TSCA CBI Security Manual. The manual may be obtained from the Director, Information Management Division (IMD), Office of Pollution Prevention and Toxics (OPPT), U.S. Environmental Protection Agency (EPA), 401 M Street, SW, Washington, DC 20460. Prior to receipt of TSCA CBI by the Contractor, the Contractor shall ensure that all employees who will be cleared for access to TSCA CBI have been briefed on the handling, control, and security requirements set forth in the TSCA CBI Security Manual.

* * * * *

Dated: July 7, 1997.

Betty L. Bailey,

Director, Office of Acquisition Management.

[FR Doc. 97–18971 Filed 7–17–97; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 1

[OST Docket No. 1; Amdt. 1–289]

Organization and Delegation of the Powers and Duties Delegation to the Commandant, United States Coast Guard

AGENCY: Office of the Secretary, DOT

ACTION: Final rule

SUMMARY: The Secretary of Transportation is delegating to the Commandant, United States Coast Guard, the authority contained in the Coast Guard Authorization Act of 1996. The Secretary is also delegating the authority pertaining to: benefits for Coast Guard members being separated or recently separated; procurement for Coast Guard family housing and long term lease authority; and rewards for MARPOL informants.

DATES: July 18, 1997.

FOR FURTHER INFORMATION CONTACT: Ms. Gwyneth Radloff, Office of the General Counsel, C–50, (202) 366–9305, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION: Public Law 104–324 is the Coast Guard Authorization Act of 1996 (Act). The Act authorizes and directs actions by the Secretary, on behalf of the Coast Guard. This rule amends 49 CFR 1.46, by adding a new paragraph (iii) to reflect the delegation of the Secretary's authority under the Coast Guard Authorization Act of 1996.

The National Defense Authorization Bill of Fiscal Year 1995, Pub. L. 103–337, contained an amendment to 10 U.S.C. Chapter 58. Chapter 58 pertains to the Secretary's authorization regarding benefits and services for members of the Coast Guard that are being separated or have recently been separated. This rule amends 49 CFR 1.46 by adding a new paragraph (jjj) to reflect the delegation of the Secretary's authority under the National Defense Authorization Bill of Fiscal Year 1995 (10 U.S.C. Chapter 58).

14 U.S.C. 670 authorizes the Secretary to procure real property or real property interests for use as Coast Guard family housing units. 14 U.S.C. 672 authorizes the Secretary to enter into lease agreements for navigation and communication systems sites. This rule amends 49 CFR 1.46 by adding a new paragraph (kkk) to reflect the delegation of the Secretary's authority under 14 U.S.C. 670 and 14 U.S.C. 672.

33 U.S.C. 1908(b) authorizes the Secretary to pay up to one-half of the civil penalties assessed for violations of the MARPOL Protocol, Annex IV to the Antarctic Protocol, or regulations issued thereunder, to persons that provide information leading to assessment of those penalties. This rule amends 49 CFR 1.46 by adding a new paragraph (lll) to reflect the delegation of the Secretary's authority under 33 U.S.C. 1908(b).

Since this amendment relates to departmental management, organization, procedure, and practice, notice and comment on it are unnecessary under 5 U.S.C. 553(b). Further, since the amendment expedites the Coast Guard's ability to meet the needs of the U.S. maritime industry, and the fulfillment of statutory and regulatory obligations, the Secretary finds good cause under 5 U.S.C. 553(d)(3) for the final rule to be effective on the date of publication in the **Federal Register**.

List of Subjects in 49 CFR Part 1

Authority delegations (Government agencies), Organization and functions (Government agencies).

In consideration of the foregoing, Part 1 of Title 49, Code of Federal Regulations, is amended to read as follows:

PART 1—[AMENDED]

1. The authority citation for Part 1 continues to read as follows:

Authority: 49 U.S.C. 322; Pub. L. 101–552, 28 U.S.C. 2672, 31 U.S.C. 3711(a)(2).

2. Section 1.46 is amended by adding the following paragraphs (iii), (jjj), (kkk), and (lll) to read as follows:

§ 1.46 Delegations to Commandant of the Coast Guard.

* * * * *

(iii) Carry out the functions and responsibilities and exercise the authorities vested in the Secretary by the Coast Guard Authorization Act of 1996, Pub. L. 104–324.

(jjj) Carry out the functions and responsibilities and exercise the authorities vested in the Secretary by the National Defense Authorization Bill of Fiscal Year 1995, Pub. L. 103–337, pertaining to benefits for Coast Guard members that are being separated or

have recently been separated (10 U.S.C. Chapter 58).

(kkk) Carry out the functions and responsibilities and exercise the authorities vested in the Secretary by 14 U.S.C. 670 pertaining to procurement authority for Coast Guard family housing and by 14 U.S.C. 672 pertaining to long-term lease authority for navigation and communications systems sites.

(lll) Carry out the functions and responsibilities and exercise the authorities vested in the Secretary by 33 U.S.C. 1908(b), that pertain to payments of civil penalties assessed for violations of the MARPOL Protocol, Annex IV to the Antarctic Protocol, or regulations issued thereunder, to persons who provide information leading to the assessment of such penalties.

Issued at Washington, DC, this 8th day of July, 1997.

Rodney E. Slater,

Secretary of Transportation.

[FR Doc. 97–18986 Filed 7–17–97; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 227

[Docket No. 970424096-7155-02; I.D. 042597A]

RIN 0648–AG56

Endangered and Threatened Species; Interim Rule Governing Take of the Threatened Southern Oregon/Northern California Coast Evolutionarily Significant Unit (ESU) of Coho Salmon

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Interim rule; request for comments.

SUMMARY: By a rule published on May 6, 1997, NMFS, on behalf of the Secretary of Commerce (Secretary), determined to list as threatened the Southern Oregon/Northern California Coast (SONCC) ESU of coho salmon (*Oncorhynchus kisutch*). Under section 4(d) of the Endangered Species Act (ESA), the Secretary is required to adopt such regulations as he deems necessary and advisable for the conservation of species listed as threatened. Such regulations may include application of the prohibitions contained in section 9(a) of the ESA, which apply to endangered species. In this interim rule, NMFS imposes the section 9(a) prohibitions for endangered species, except with respect to certain benign and beneficial actions in Oregon and California, and specified actions taken consistent with the Oregon Coastal Salmon Restoration Initiative (OCSRI) and implemented consistent with the April 1997 Memorandum of Agreement (MOA) between NMFS and the Governor of Oregon. The **Federal Register** document containing the final listing determination describes the relevant details of the OCSRI and the implementing MOA.

DATES: Comments on this rule must be received by September 16, 1997.

This interim rule is effective August 18, 1997.

ADDRESSES: Comments should be sent to Protected Species Program, Environmental and Technical Services Division, NMFS, Northwest Region, 525 NE Oregon Street, Suite 500, Portland, OR 97232–2737.

FOR FURTHER INFORMATION CONTACT: Garth Griffin at 503–231–2005; Craig Wingert at 310–980–4021; or Joe Blum at 301–713–1401.

SUPPLEMENTARY INFORMATION:

Background

The final rule determining to list the SONCC coho salmon ESU as threatened, published on May 6, 1997 (62 FR 24588), describes the current range and status of this ESU, previous Federal actions on this species, a summary of the comments and recommendations received in response to NMFS' proposal to list the ESU, descriptions of the factors affecting its continued existence, the reasons why critical habitat is not being proposed, and the conservation measures recommended by NMFS or otherwise available to this ESU.

Section 4(d) of the ESA provides that, whenever a species is listed as a threatened species, the Secretary shall issue such regulations as he deems necessary and advisable to provide for the conservation of the species, including any or all of the prohibitions applicable to endangered species under section 9(a). Those section 9(a) prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to take (including harass, harm, pursue, hunt, shoot, wound, kill, trap, or collect; or to attempt any of these), import or export, ship in interstate commerce in the course of commercial activity, or sell or offer for sale in interstate or foreign commerce any wildlife species listed as endangered. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally.

When NMFS first proposed the ESU for listing as threatened (60 FR 38011, July 25, 1995), it also proposed to apply the prohibitions of section 9(a) to this species. NMFS continues to find that the prohibitions for endangered species are generally necessary and advisable for conservation of the species. NMFS further finds that take of the SONCC coho salmon should not be prohibited when it results from a specific subset of activities adequately regulated by Federal, state, and local governments. Accordingly, this interim rule revises the earlier proposal by providing certain additional exceptions.

NMFS has chosen to make this rule interim rather than final in order to give the public the opportunity to comment on the additional exceptions that are included in the new § 227.22. NMFS will consider all comments submitted during the comment period before issuing a final rule.

Interim Take Exceptions in Oregon

Following NMFS' proposal to list Oregon Coast and SONCC coho salmon, the State of Oregon initiated a major effort to address the factors for decline of these at-risk stocks. That effort culminated in the adoption by Oregon of the OCSRI. The OCSRI contains significant improvements in hatchery management and in harvest management. Previous harvest rate reductions on Oregon coastal coho, as refined and incorporated in the OCSRI, are expected to result in an increase in the near-term stability of the populations. The OCSRI also includes a broad array of state agency and other measures affecting habitat.

NMFS sought to ensure that the adaptive management program contained in the OCSRI would rapidly lead to the ultimate implementation of measures and rules that NMFS would consider adequate in these areas. Accordingly, NMFS entered into an MOA with the Governor of Oregon in April 1997 to clarify how NMFS and Oregon will work together toward implementation, necessary adjustments, and adaptive changes to the OCSRI. (Copies of the MOA are available from NMFS; see ADDRESSES.)

Based on a review and assessment of the OCSRI and MOA, NMFS has determined that it is unnecessary to prohibit certain benign and beneficial actions in Oregon, as well as certain measures provided under the OCSRI and implemented in accordance with the MOA. The actions NMFS believes do not require prohibition are related to harvest carried out in accordance with

the OCSRI, artificial production carried out in accordance with the OCSRI, research and monitoring, and habitat restoration. These exceptions do not exempt actions funded, authorized, or carried out by Federal agencies, which must comply with section 7 and other applicable provisions of the ESA.

With respect to harvest, the OCSRI provides a comprehensive package of measures that reduce harvest rates to an average harvest rate of less than 15 percent. Harvest rates would be permitted to increase only under carefully specified conditions characterized by significant increases in escapement and productivity and in no case would exceed 35 percent.

With respect to artificial production, Oregon production is reduced from a high of 6.4 million smolts in 1990 to 2.3 million by 1998. The OCSRI also specifies that hatchery strays may not exceed 10 percent of natural spawning. In addition, the take of naturally produced broodstock for hatchery production will be counted against the total allocation of fish for harvest and is only allowed if it is not deemed detrimental to the recovery of the species. Incorporation of naturally produced coho into the hatchery broodstock will minimize genetic divergence between the two populations, and will also preserve hatchery populations as a ''safety net'' for assisting the natural population in the event of a serious decline.

With respect to the research and monitoring activities consistent with the OCSRI, NMFS finds that these activities are vital to improving understanding of risks facing salmon in this ESU and to judge the effectiveness of conservation measures. They also provide critical information to the adaptive management approach of the OCSRI, allowing revision of habitat-related actions to ensure best management in the future.

With respect to habitat measures, NMFS finds that certain habitat restoration activities are likely to assist in conserving coho. NMFS is aware that many projects, particularly those that are part of the Southwest Oregon Salmon Restoration Initiative, already have been developed and, in some cases, funded. NMFS determines it is advisable that incidental take associated with restoration activities that are part of the Southwest Oregon Salmon Restoration Initiative not be prohibited during the 1997 field season.

Projects developed, prioritized, and carried out based on at least a watershed scale assessment and action plan, and, where possible, a sub-basin or basin scale, are likely to be the most beneficial. The interim rule therefore provides that section 9 take prohibitions will not apply to activities conducted pursuant to watershed action plans or watershed restoration plans that are consistent with NMFS-approved guidelines and are approved by the appropriate state agency and NMFS. To approve a plan, NMFS must concur that the plan is consistent with those guidelines.

Until a watershed action plan for the watershed in which an activity is proposed has been approved, or for 2 years following the effective date of this interim rule (whichever comes first), an individual habitat restoration activity that is consistent with state guidelines that meet the standards of 50 CFR 222.22 is not prohibited. Guidelines for approving individual activities and plans will be developed by Oregon and NMFS. After a watershed plan has been approved, only activities conducted pursuant to the plan are not subject to the section 9 take prohibitions. If no plan has been approved for a watershed after 2 years following the effective date of this interim rule, the general section 9 take prohibitions of this interim rule would apply to individual restoration activities the same as to all other habitat-affecting activities.

Interim Take Exceptions in California

NMFS has determined that it is unnecessary to prohibit specific benign and beneficial actions carried out by state, tribal, and local governments in the California portion of the SONCC coho salmon ESU. These include: (1) Certain fishery management activities conducted by the State, (2) fisheries research and monitoring activities permitted or conducted by the State, and (3) certain State, local, tribal, and private habitat restoration activities. These exceptions do not exempt actions funded, authorized, or carried out by Federal agencies, which must comply with section 7 and other applicable provisions of the ESA.

The State of California has jurisdiction over fisheries within 3 miles (approximately 5 km) of its coast. The California Fish and Game Commission (CFGC) and the California Department of Fish and Game (CDFG) are responsible for establishing the State's sport and commercial ocean salmon fishing regulations, respectively, within 3 miles (approximately 5 km) of the coast each year. Typically, the CFGC and CDFG conform the State's ocean salmon fishing regulations to those adopted by NMFS for the Federal Exclusive Economic Zone (EEZ). NMFS has determined that it is advisable that incidental take of coho salmon associated with these State fisheries management activities not be prohibited provided the regulations issued by the State are consistent with the ocean salmon fishing regulations implemented by NMFS for the Federal EEZ.

In carrying out its fisheries management responsibilities in California, the CDFG conducts or permits a wide range of research and monitoring studies on various fisheries, including studies on coho salmon which occur in the California portion of the SONCC ESU. NMFS finds that these activities are vital for improving our understanding of the status and risks facing coho salmon and other species in this ESU and will provide critical information for assessing the effectiveness of current and future management practices.

There are numerous ongoing local habitat restoration and watershed planning efforts that are expected to contribute to the conservation of coho salmon in the California portion of the SONCC coho salmon ESU. These include, but are not limited to, restoration efforts in the Scott River watershed, the Shasta River watershed, the South Fork Trinity Watershed, and the Mattole River. In addition, there are county-based Resource Conservation Districts throughout the range of coho in the California portion of this ESU that are providing a focus for agricultural interests and local conservation groups to develop and prioritize habitat restoration plans. NMFS believes that certain activities in California are likely to assist in conserving coho salmon, provided that California puts in place a program that assures technically supported watershed assessments and coordinated long-term monitoring strategies for watershed protection plans and activities. This interim rule, therefore, does not apply section 9 prohibitions to activities conducted in accordance with such a program and an approved watershed plan or guidelines, under similar conditions as described in the section ''Interim Take Exceptions in Oregon,'' above.

Coho salmon in the SONCC ESU are currently harvested by the Yurok and Hoopa Indian tribes, incidental to larger subsistence fisheries for chinook salmon in the Klamath and Trinity Rivers. These fisheries are conducted in accordance with the tribes' existing federally reserved fishing rights. Harvest management practiced by both tribes is conservative, focuses on the harvest of chinook salmon stocks, and has had limited impacts on coho salmon in the SONCC ESU. In recognition of the tribes' federally reserved fishing rights, special status, and other tribal conservation programs, NMFS intends

to work with the tribal governments in California to identify an appropriate mechanism for authorizing the incidental take of coho salmon in these chinook fisheries. NMFS may consider promulgation of a separate 4(d) regulation, consistent with the conservation of SONCC coho salmon, to achieve this objective.

The prohibitions of section 9 will not apply to activities specified in an application for a permit for scientific purposes or to enhance the propagation or survival of the species, provided that an application has been received by the Assistant Administrator for Fisheries, NOAA (AA), by September 16, 1997. This exception will cease upon the AA's rejection of the application as insufficient, upon issuance or denial of a permit, or on January 20, 1998, whichever occurs earliest.

Take Guidance

NMFS and the U.S. Fish and Wildlife Service published in the **Federal Register** on July 1, 1994 (59 FR 34272), a policy that NMFS shall identify, to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the ESA. The intent of this policy is to increase public awareness of the effect of a listing on proposed and on-going activities within the species' range. NMFS believes that, based on the best available information, the following actions will not result in a violation of this interim rule:

1. Possession of coho salmon from the Southern Oregon/Northern California Coast ESU acquired lawfully by permit issued by NMFS pursuant to section 10 of the ESA, or by the terms of an incidental take statement pursuant to section 7 of the ESA.

2. Federally funded or approved projects that involve activities such as silviculture, grazing, mining, road construction, dam construction and operation, discharge of fill material, stream channelization or diversion for which section 7 consultation has been completed, and when such activity is conducted in accordance with any terms and conditions provided by NMFS in an incidental take statement accompanied by a biological opinion pursuant to section 7 of the ESA.

Activities that NMFS believes could potentially harm, injure or kill coho salmon in the Southern Oregon/Northern California Coast ESU and result in a violation of this rule include, but are not limited to:

1. Land-use activities that adversely affect coho salmon habitat in this ESU (e.g., logging, grazing, farming, road construction in riparian areas, and areas susceptible to mass wasting and surface erosion);

2. Except for the habitat alteration activities that are excepted from take prohibitions in this rule, destruction or alteration of coho salmon habitat in this ESU, such as removal of large woody debris and ''sinker logs'' or riparian shade canopy, dredging, discharge of fill material, draining, ditching, diverting, blocking, or altering stream channels or surface or ground water flow;

3. Discharges or dumping of toxic chemicals or other pollutants (e.g., sewage, oil, gasoline) into waters or riparian areas supporting the listed coho salmon;

4. Violation of discharge permits;

5. Pesticide applications;

6. Interstate and foreign commerce of coho salmon from the SONCC coho ESU and import/export of coho salmon from this ESU without an ESA permit, unless the fish were harvested pursuant to this rule;

7. Except as provided in this interim rule, collecting or handling of coho salmon from this ESU. Permits to conduct these activities are available for purposes of scientific research or to enhance the propagation or survival of the species;

8. Introduction of non-native species likely to prey on coho salmon in this ESU or displace them from their habitat.

These lists are not exhaustive. They are intended to provide some examples of the types of activities that might or might not be considered by NMFS as constituting a take of SONCC ESU coho salmon under the ESA and its regulations. Questions regarding whether specific activities will constitute a violation of this rule, and general inquiries regarding prohibitions and permits, should be directed to NMFS (see **ADDRESSES**).

Classification

For the following reasons, the Assistant General Counsel for Legislation and Regulation of the U.S. Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration, pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, that this rule will not have a significant economic impact on a substantial number of small entities.

NMFS canvassed business activity by economic sector (SIC codes) in Curry, Jackson, and Josephine counties in Oregon, and Del Norte, Humboldt, Siskiyou, and Mendocino counties in California. NMFS identified fishing, agriculture, sand and gravel mining, construction, and timber harvest as the economic sectors likely to be affected by the prohibitions of this interim 4(d) rule. These sectors are all relatively heavily regulated at Federal and/or state levels independent of this action.

For each sector, NMFS estimated the number of small businesses within the geographic range of this ESU, the approximate number of employees in that sector, and the annual revenues of those businesses. NMFS then used available data to identify what, if any, incremental economic impacts the 4(d) prohibitions might create over and above impacts attributable to other state or Federal controls, including ESA § 7 consultations. In the Commercial and Recreational Fishing sector, existing ocean salmon fishing regulations that control harvest of SONCC coho salmon prohibit retention of coho and limit any incidental take of coho resulting from other fisheries to between 10 and 13 percent. Because NMFS has determined that these restrictions are sufficient to avoid jeopardizing coho in the SONCC ESU, the interim 4(d) rule excepts ocean fishing activities conducted under these regulations from take prohibitions. Similarly, the interim rule excepts ocean, bay, and freshwater fisheries under Oregon's jurisdiction from take prohibitions, so long as the activity complies with agreed-upon Oregon regulations. Hence the rule will not impose any additional burdens on small entities associated with commercial or recreational ocean harvest or upon inland recreational fishing in Oregon.

Existing California regulations for bay and freshwater coho fisheries are not as stringent and do not warrant an exception. However, California estimates the contribution of coho salmon to in-river sport catch in the California portion of the ESU to be small. The impacts of the rule will be associated with ensuring that coho salmon are not targeted in any fishing efforts and that any coho salmon that are incidentally hooked are released. NMFS does not expect the take prohibitions to result in any fishery closures in California's inland waters or a decrease in fishing effort. Consequently, the interim 4(d) rule will cause very little, if any, loss of revenue for small entities involved in inland recreational fishing activities in the California range of the SONCC coho salmon ESU.

NMFS has determined there are approximately 5,000 agriculture businesses within the geographic area of the ESU, with a combined annual revenue of approximately $275 million. All entities are assumed for this analysis to be small. The majority of agricultural activities that might result in take of SONCC coho are those affecting water

quality, such as sediment from cultivation or livestock movements on the banks or in the beds of streams, temperature increases from clearing vegetation, confined animal feeding operations, overgrazing, and the like. Unscreened water diversions and reduction of flows through irrigation could also result in take. To the extent an agricultural activity causes water quality impairments, that activity is subject to the water pollution control requirements of the Clean Water Act (CWA), as administered by the states. For example, in Oregon, Agricultural Water Quality Management plans are being developed under State law for all water quality impaired stream segments and will result in agricultural practices that do not ''take'' through impairing water quality. Similar regulation of agricultural activities in California fall under the Regional Water Quality Control Board and other entities associated with the State's Non-point Source Management Plan. Therefore, any additional costs over and above those imposed by existing law with respect to water quality related activities are likely to be quite small.

However, it is unlikely that these water quality plans will completely protect all important physical habitat conditions from further degradation, particularly with respect to reductions in remaining riparian vegetation. Therefore, NMFS expects some loss of productivity where an agricultural operation ceases to cultivate or remove vegetation in a riparian area because of this interim rule. Even assuming that all riparian agricultural activity were to be halted within 50 ft of coho streams and that none of that restriction were attributed to water quality requirements (unrealistically conservative assumptions), this would take less than 1 percent of the agricultural land within the ESUs out of production.

To avoid taking juvenile coho, farmers who irrigate will have to have proper screening of irrigation pumps or diversions. A relatively high proportion of diversions in Oregon are already properly screened in accord with existing state requirements. The average cost of screening is about $1,000 per screen, and the one-time total cost would be in the range of 2 percent of an estimated ''low end'' of annual farm income. Oregon has a screening program that defrays much of the cost of screen installation and, in any case, this capital cost does not represent a significant portion of capital available to agricultural operations, considering external financing capabilities and cost share opportunities.

Thus, the two major areas in which agricultural activity may need adjustment to comply with the 4(d) prohibitions will result in economic impact in the 3–percent range of annual revenue, calculated on the most conservative of assumptions. Even if there are some additional circumstances where farm practices need adjustment (such as irrigation alterations or exclusion of livestock from a redd area not already dealt with for water quality reasons), the incremental costs and revenue loss attributable to the interim 4(d) rule would be well below 5 percent of annual gross revenues for the most affected entities.

A total of eight businesses within the ESU were identified as mining sand and gravel, some or all of which likely involve in-water work and hence potentially affecting listed coho. These businesses employ substantially fewer than 200 people in total, with an estimated gross production value in the range of $10 million, and most are small entities. Gravel, sand, or other removal activities in navigable waters are regulated by the U.S. Army Corps of Engineers (Corps) under section 10 of the Rivers and Harbors Act. NMFS' consultations with the Corps triggered by the listing of the SONCC ESU will set the baseline for impacts of most in-water mining activities in the lower reaches of stream systems at a level that will not result in take, and this rule will not result in any additional lost revenue in those locations. Those few entities that may be operating in the upper reaches of a river system may sustain economic impacts, but the extent of those impacts cannot be known until assessments of annual gravel recruitment and patterns of deposition is completed for each river system so that limits of permissible removal may be set for any particular site. That information dictates reduction in volume removed or changes in timing or methods, and the rule could cause loss of revenue or increased cost to small business (for instance in locating new sources of gravel) for one or more of the eight small entities engaged in gravel removal, but the extent of that impact cannot be projected at this time. NMFS seeks comments and/or data that can assist in making projections.

Specific construction categories that might be affected by the interim 4(d) regulation were examined, including highway and street construction, heavy construction, concrete work, and excavation work. Approximately 200 businesses within the ESU were primarily engaged in these categories, although only some of them would be affected by the rule. These businesses employ just over 1,000 people, with annual revenues under $140 million. Over 90 percent of these construction businesses within the ESU were found to be small entities.

Construction activities likely to be affected include construction of irrigation withdrawal structures, construction of docks and piers, fill in wetlands for roads, private residences or commercial development, and installation of industrial and municipal wastewater outfalls. The Corps regulates in-water fill activities under § 404 of the Clean Water Act (regardless of amount) and impacts to navigation (docks, etc.) under § 10 of the Rivers and Harbors Act. Any of the above actions likely to affect coho in the SONCC ESU will be examined during Corps consultation with NMFS under ESA § 7, through which any changes in the activity necessary to avoid jeopardizing the coho will be required. Hence, the rule is unlikely to additionally affect businesses engaged in any of these in-water activities.

Within the ESU, between four and five hundred businesses are engaged in either forestry or logging. These firms employ 3,000 to 4,000 people, with total revenue estimated at approximately $700 million. Approximately 80 percent of the forestry businesses and 100 percent of the logging businesses are considered small entities under SBA classification guidelines. The interim 4(d) rule could affect logging operations and timber revenues by limiting the extent of harvest activity in riparian areas in order to protect water quality, protect sources of large woody debris, etc. All forest activity on Federal lands, which comprise 53 percent of the land in this ESU, is conducted under the Northwest Forest Plan, which has already been determined adequate to protect coho salmon habitat. Therefore, logging on, or timber availability from, Federal forests will not be affected by the rule.

Approximately 1.9 million acres in this ESU are private non-industrial forest lands, which can be equated generally with small businesses. Harvest on these lands is subject to state regulation of forest practices, which require some degree of buffer protection. The Oregon Forest Practice rules set riparian management areas (RMA) ranging up to 100 ft in width, prohibit removal of any trees in the first 20 ft of the riparian area on large and medium size streams, and require retention of varying additional amounts of timber in the remaining RMA. The California Forest Practice Rules set protective zones ranging up to 150 ft in width, with a similarly complex set of timber

retention requirements depending on stream size, slope, etc. NMFS does not consider either of these state regulatory schemes fully adequate to protect coho, and, therefore, would expect the 4(d) rule to result in some curtailment of harvest on lands owned by small entities over and above the impacts of state regulation.

For purposes of estimating a maximum impact small entity timber harvest operations might experience from the rule, this analysis assumes a uniform, entirely unmanaged and unharvested (e.g. ''no touch'') buffer of 150 ft (the maximum *managed* width under existing California regulation). Based on the ratio of stream miles (8,500) to total forest acres (11 million) in this ESU, that buffer would constitute an average of 2.4 percent of the total forest acreage.

Obviously, not all forest lands will be adjacent to streams that contribute to coho habitat, and also some landholdings will be affected above the average amount. There also could be some incremental impacts related to non fish-bearing streams over and above what would result from water quality requirements and the Northwest Forest Plan, but these are speculative and cannot be quantified. Absent any data to identify these ratios or other impacts, NMFS assumes that the land owners most affected have double the average riparian frontage. The maximum reduction in timber harvest with that assumption would be below 5 percent, with the impacts of existing state regulation subtracted out. That incremental impact may be further lessened because of tightened harvest regulations needed to meet Clean Water Act concerns.

Logging companies would presumably be affected to an even lesser extent, since they operate on Federal as well as private lands, and would not be limited to harvest operations on the most affected private lands. Thus, the interim rule may have an incremental economic impact ranging from zero to 5 percent on small timber owning entities and logging companies.

To sum up, impacts of this interim 4(d) rule fall below NMFS' threshold criteria for determining that a rule will cause significant economic impact on a substantial number of small entities. These standards include: (a) Five percent loss of revenue for twenty percent of the small entities; (b) ten percent increase in compliance costs for twenty percent of the small entities; (c) two percent of the small entities cease operations; or (d) capital costs of compliance are a significant portion of capital available considering internal cash flow and external financing capabilities.

Of the several thousand small entities operating in sectors that may be impacted by the interim 4(d) rule, estimates of revenue reduction on the entities most seriously impacted by the rule range from zero (construction and fishing businesses) to under 5 percent (forestry). In the sand and gravel mining sector, it is not possible to project the range of impact, but fewer than eight entities would potentially be affected. Hence, of all small entities potentially substantially impacted by the interim 4(d) rule prohibitions, far fewer than 20 percent have any potential for a revenue reduction exceeding 5 percent. Any impacts on small governments will likely fall within the impacts in one or more of these same categories (e.g., road construction).

The interim 4(d) rule places no reporting or recordkeeping compliance costs on small entities. The capital cost of potential irrigation screening should not represent a significant portion of capital available, especially recognizing existing state programs to defray some of those costs. NMFS has identified no entities likely to be forced to cease business operations as a result of this rule.

This interim rule has been determined to be not significant for purposes of Executive Order 12866.

This interim rule contains a collection-of-information requirement subject to the provisions of the Paperwork Reduction Act which has been approved by the Office of Management and Budget under control Number 0648-0230. Public reporting burden for the approval of Watershed Plans under exceptions 227.22(e) and (f) is estimated to average less than 30 hours per response, including the time for formatting, copying, preparing transmittal letter, and responding to any inquiries.

Comments are invited on: (a) Whether the proposed collection of information to provide these exceptions (without which restoration actions would require a section 10 permit) is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to NMFS (see **ADDRESSES**) and to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC. 20503 (Attention: NOAA Desk Officer).

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

National Environmental Policy Act

NMFS will comply with the National Environmental Policy Act (NEPA) of 1969 in implementing the provisions of this interim rule, completing NEPA requirements before the final rule is issued.

List of Subjects in 50 CFR Part 227

Endangered and threatened species, Exports, Imports, Marine mammals, Transportation.

Dated: July 9, 1997.

David L. Evans,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 227 is amended as follows:

PART 227—THREATENED FISH AND WILDLIFE

1. The authority citation for part 227 continues to read as follows:

Authority: 16 U.S.C. 1531–1543; subpart B, § 227.12 also issued under 16 U.S.C. 1361 *et seq.*

2. In subpart C, § 227.21 is revised to read as follows:

§ 227.21 Threatened salmon.

(a) *Prohibitions.* The prohibitions of section 9 of the ESA (16 U.S.C. 1538) relating to endangered species apply to the threatened species of salmon listed in § 227.4 (f), (g), (h), and (i), except as provided in paragraph (b) of this section. These prohibitions shall become effective for the threatened species of salmon listed in § 227.4(i) on August 18, 1997.

(b) *Exceptions.* (1) The exceptions of section 10 of the ESA (16 U.S.C. 1539) and other exceptions under the Act relating to endangered species, including regulations implementing such exceptions, also apply to the threatened species of salmon listed in § 227.4 (f), (g), (h), and (i). This section supersedes other restrictions on the applicability of parts 217 and 222 of this chapter, including, but not limited to,

the restrictions specified in §§ 217.2 through 222.22(a) of this chapter with respect to the species identified in § 227.21(a).

(2) The prohibitions of paragraph (a) of this section relating to threatened species of salmon listed in § 227.4(i) do not apply to activities specified in an application for a permit for scientific purposes or to enhance the propagation or survival of the species, provided that the application has been received by the Assistant Administrator for Fisheries, NOAA (AA), by September 16, 1997. This exception ceases upon the AA's rejection of the application as insufficient, upon issuance or denial of a permit, or on Janury 20, 1998 whichever occurs earliest.

(3) The prohibitions of paragraph (a) of this section relating to threatened species of salmon listed in § 227.4(i) do not apply to any employee or agent of the NMFS, any other Federal land management agency, or the Oregon Department of Fish and Wildlife (ODFW) or the California Department of Fish and Game (CDFG), who is designated by his/her agency for such purposes, when that employee or agent, acting in the course of his/her official duties, takes a coho salmon in California or Oregon without a permit if such action is necessary to: (1) Aid a sick, injured, or stranded individual, (2) dispose of a dead individual, or (3) salvage a dead individual, which may be useful for scientific study.

3. In subpart C, section 227.22 is added to read as follows:

§ 227.22 Southern Oregon/Northern California Coast (SONCC) coho salmon.

The following exceptions to the prohibitions of section 227.21(a) apply to SONCC coho salmon:

(a) Take of SONCC coho salmon within three miles (approximately 5 km) of the coast, and in bay, estuarine or freshwater fisheries regulated under the sole authority of the State of Oregon is not prohibited, if the take results from a fisheries harvest program conducted in accordance with the Oregon Coastal Salmon Restoration Initiative of March 1997 (OCSRI), provided that NMFS has issued written concurrence that the fisheries regulations are consistent with the OCSRI using information provided through the April 1997 Memorandum of Agreement (MOA) between the State of Oregon and NMFS.

(b) Incidental take of SONCC coho salmon in ocean fisheries within 3 miles (approximately 5 km) of the coast that are regulated under the sole authority of the State of California is not prohibited, provided that the ocean salmon fishing regulations adopted by the California Fish and Game Commission and CDFG for recreational and commercial fisheries within 3 miles (approximately 5 km) of the coast are consistent with the Pacific Fishery Management Council's Fishery Management Plan for Ocean Salmon Fisheries and the annual ocean salmon fishing regulations issued by the Secretary of Commerce for the Federal EEZ.

(c) Take of SONCC coho salmon in a hatchery program regulated under the sole authority of the State of Oregon is not prohibited, if the take results from a hatchery program conducted in accordance with the OCSRI, and the take is counted against the total allocation of harvest-related mortality as specified in the OCSRI, provided that NMFS has issued written concurrence that the hatchery program is consistent with the OCSRI including the hatchery and genetic management plan adopted pursuant to the OCSRI, using information provided through the MOA.

(d) Take of SONCC coho salmon in fisheries research and monitoring activities conducted in California and Oregon is not prohibited *provided that*:

(1) Research and monitoring involving directed take of coho salmon is conducted by CDFG personnel (in California) and ODFW personnel (in Oregon).

(2) The CDFG and ODFW, respectively, provide NMFS with a list of all research and monitoring activities involving coho salmon directed take planned for the coming year for NMFS' review and approval, including an estimate of the total directed take that is anticipated, a description of the study design including a justification for taking the species and a description of the techniques to be used, and a point of contact.

(3) The CDFG and ODFW, respectively, annually provide NMFS with the results of research and monitoring studies directed at SONCC coho salmon, including a report of the directed take resulting from the studies.

(4) The CDFG and ODFW, respectively, provide NMFS annually with a list of all research and monitoring studies each permits that may incidentally take listed coho salmon during the coming year and report the level of incidental take of listed coho salmon from the previous year's research and monitoring activities, for NMFS' review and approval.

(5) The research and monitoring activities do not include the use of electrofishing in any body of water known or suspected to contain coho salmon.

(e) Incidental take of the SONCC coho salmon in Oregon that results from a habitat restoration activity, as defined in paragraph (4), is not prohibited, *provided that*:

(1) The activity is conducted pursuant to a watershed action or restoration plan that the state has affirmed in writing is consistent with state watershed plan guidelines that NMFS has found meet the standards set forth in 50 CFR 222.22(c), and NMFS concurs in writing that the plan is consistent with those guidelines; or

(2) Until a watershed action or restoration plan is approved by both Oregon and NMFS as described in paragraph (e)(1) of this section, or until August 18, 1999, whichever occurs first, the ODFW has made a written finding that the activity is consistent with state restoration activity guidelines that NMFS has agreed in writing meet the standards set forth in 50 CFR 222.22(c); or January 19, 1998.

(3) Until January 20, 1998, the activity is any restoration action listed in the Southwest Oregon Salmon Restoration Initiative (OCSRI ch. 17F), provided that any action involving in-water work receives written approval from ODFW as to timing, scope, and methods.

(4) ''Habitat restoration activity'' is defined as an activity that has the sole objective of restoring natural aquatic or riparian habitat conditions or processes.

(f) Incidental take of the SONCC coho salmon in California that results from a habitat restoration activity, as defined in paragraph (3) of this section, is not prohibited, provided that California has a program in effect that NMFS finds will assure technically supported watershed assessments and coordinated long-term monitoring strategies for watershed protection plans and activities and:

(1) The activity is conducted pursuant to a watershed protection plan that CDFG has affirmed in writing is consistent with state watershed plan guidelines for California's Watershed Protection Program that NMFS has found meet the standards set forth in 50 CFR 222.22(c), and NMFS concurs in writing that the plan is consistent with those guidelines; or

(2) Until a watershed protection or restoration plan is certified by the State of California and NMFS as described in paragraph (f)(1) of this section, or until August 18, 1999, whichever occurs first, NMFS has made a written finding that the activity is consistent with State of California conservation guidelines that NMFS has previously found meet the standards set forth in 50 CFR 222.22(c).

(3) ''Habitat restoration activity'' is defined as an activity that has the sole

objective of restoring natural aquatic or riparian habitat conditions or processes.

[FR Doc. 97–18804 Filed 7–17–97; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 285

[Docket No. 960816226–7172–05; I.D. 061897C]

RIN 0648–AJ04

Atlantic Tuna Fisheries; Regulatory Adjustments

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to amend the regulations governing the Atlantic tuna fisheries to prohibit the use of aircraft to assist fishing vessel operators in the location and capture of Atlantic bluefin tuna (ABT), with the exception of vessels permitted in the Purse Seine and Harpoon categories, and to establish a deadline for permit category changes for 1997 only. These regulatory amendments are necessary to achieve the domestic management objectives for the Atlantic tuna fisheries.

DATES: Effective July 14, 1997.

ADDRESSES: Copies of supporting documents, including an Environmental Assessment and Regulatory Impact Review (EA/RIR), are available from, Rebecca Lent, Chief, Highly Migratory Species Management Division, Office of Sustainable Fisheries (F/SF1), NMFS, 1315 East-West Highway, Silver Spring, MD 20910–3282.

FOR FURTHER INFORMATION CONTACT: John Kelly, 301–713–2347.

SUPPLEMENTARY INFORMATION: The Atlantic tuna fisheries are managed under the authority of the Atlantic Tunas Convention Act (ATCA). The ATCA authorizes the Secretary of Commerce (Secretary) to issue regulations as may be necessary to carry out the recommendations of the International Commission for the Conservation of Atlantic tunas (ICCAT). The authority to issue these regulations has been delegated from the Secretary to the Assistant Administrator for Fisheries, NOAA (AA).

Background information about the need for revisions to the Atlantic tunas fishery regulations was provided in the preamble to the proposed rule (62 FR 9726, March 4, 1997) and is not repeated here. All measures in the proposed rule, except for the prohibition on the use of aircraft, were addressed in an earlier final rule (62 FR 30741, June 5, 1997). Additionally, NMFS issued an interim final rule that suspended the May 15 deadline for switching permit categories for calendar year 1997 until the remaining regulatory issues which could influence category selection were resolved and a new deadline set. Final quotas were published on June 30, 1997 (62 FR 35107) and the spotter aircraft issue is addressed by this final rule. As there are no remaining regulatory issues to be resolved that would influence category selection, vessel owners now have sufficient information to select an appropriate permit category for 1997. The deadline for switching permit categories for calendar year 1997 is set as July 28, 1997. After 1997, the deadline will revert to May 15.

Relation to Proposed Consolidation

The regulatory amendments contained in this final rule, when proposed, were drafted to be consistent with a proposed rule to consolidate all of the regulations for Atlantic highly migratory species (HMS) fisheries, published on November 6, 1996 (61 FR 57361). The proposed consolidation would group all regulations pertaining to Atlantic HMS under 50 CFR part 630. The final consolidated regulations have not yet been issued. Accordingly, the regulatory amendments contained in this final rule were revised to make the appropriate changes to the existing text at 50 CFR part 285. The regulatory amendments contained in this final rule will eventually be incorporated into the final consolidated regulations at 50 CFR part 630. Copies of the proposed consolidation rule may be obtained by writing (see **ADDRESSES**) or calling the contact person (see **FOR FURTHER INFORMATION CONTACT**).

Spotter Aircraft Prohibition

Since the mid-1980's, fishery participants have raised concerns that the use of spotter aircraft in the ABT fishery accelerates catch rates and compromises conservation, equal opportunity and safety. In 1996, a voluntary agreement was signed by the majority of active tuna aircraft spotters that would limit their activity in the General category to harpoon vessels. NMFS recognized that the voluntary agreement warranted a trial period but also indicated that the agency would continue to monitor the situation and would take appropriate action if necessary. Fishery management concerns continue to be expressed, anecdotal information suggests that the number of spotter aircraft has increased, and vessel safety issues continue to be raised. Accordingly, NMFS has reconsidered the need to take action. By this final rule, the use of aircraft to assist fishing vessel operators in the location and capture of ABT, with the exception of vessels operating in the Harpoon and Purse Seine categories, is prohibited. These regulatory changes will improve NMFS' ability to achieve domestic management objectives for the Atlantic tuna fisheries.

Comments and Responses

NMFS conducted several public hearings on the proposed rule and received written and oral comments over a 30-day comment period. Nearly two thousand comments (letters and comments) were received regarding the proposed ban on spotter aircraft. Responses to the comments on the spotter aircraft issue are provided below.

Comment: Those in favor of the prohibition commented that it would restore equal opportunity for vessels of different categories and lengthen the Harpoon and General category seasons without the use of further effort controls.

Response: Although data on the use and effects of spotter aircraft on the ABT fishery are not sufficient for a quantitative analysis of impacts, it is undeniable that there is a decrease in search time when spotter aircraft are used. Data regarding recent closures in the General and Harpoon categories support the conclusion that seasons are shortened. The International Commission for the Conservation of Atlantic Tunas (ICCAT) has recognized the effect of spotter aircraft on catch rates; in 1996, ICCAT adopted a recommendation that the use of spotter aircraft by purse seine vessels in the Mediterranean be prohibited due to the aircrafts' effect of accelerating catch rates. NMFS agrees that the use of spotter aircraft accelerates catch rates. Accelerated catch rates are inconsistent with the regulatory goal of extending the ABT season for the General and Angling categories, and with actions taken this year and in previous years to accomplish that goal. Extending the season for the rod-and-reel fisheries in these two categories helps improve scientific monitoring of the stock by allowing catch-per-unit-effort (CPUE) data collection over a wider geographical area and a longer period of time. Extending the season also provides fishing opportunities over a wider area. Data from the Harpoon and Purse Seine categories have not been

incorporated into any of the currently usable CPUE indices, therefore the effect of spotter aircraft accelerating catch rates in these categories is less significant for scientific monitoring.

Comment: Some commenters questioned why the Purse Seine category is exempted from the prohibition on the use aircraft to locate and capture ABT.

Response: The purse seine fishery in the United States is managed under an individual vessel quota program; therefore, the Purse Seine category allocation cannot be exceeded. It is within each vessel's discretion to use aircraft that may have the effect of accelerating catch rates by assisting in locating schools of large fish. The Purse Seine category does not provide CPUE data for stock assessment. Likewise, Harpoon category CPUE data are not currently used to assess the ABT stock. The harpoon fishery is managed under a quota program which is monitored on a real-time basis through landing cards. Accordingly, accelerated catch rates would not likely cause the quota to be exceeded.

Comment: Some constituents indicated that spotter aircraft aid in aerial surveys and enforcement, and in the provision of emergency assistance for boats and marine mammals. Constituents argued that a ban would affect stock assessments, potentially increase undersized discards and mortality, and be impossible to enforce. Some argued that the use of aircraft is historical and should be considered as another type of fishing gear. Others noted that the banning of spotter aircraft would compromise the safety of vessels at sea.

Response: NMFS will continue to work with spotter pilots, industry members and organizations, and scientific researchers to develop an aerial index of abundance that can be used in stock assessments. The comments on the effects of a spotter aircraft ban with respect to the harpoon fishery are noted. Exempting the Harpoon category preserves the status quo for that category. Regarding enforcement, there is a commitment by industry members to work with NMFS enforcement by providing information on potential violations of fishery regulations. NMFS enforcement agents are special investigators and have been trained to collect the necessary evidence to build a successful case. Information suggests near collisions of spotter aircraft due to multiple aircraft flying at low altitude, and near collisions of fishing vessels due to aircraft attracting too many vessels to the same area.

Comment: Some General and Harpoon category permit holders expressed concern that NMFS would not decide the spotter aircraft issue until after May 15, the last day to change categories.

Response: Given the significance of spotter aircraft use in making a permit category selection, NMFS extended indefinitely the deadline for category selection for 1997 (62 FR 27518, May 20, 1997). With the publication of this final rule, NMFS establishes a deadline for selecting a permit category in 1997 of July 28, 1997.

Comment: Comments were received noting that the proposed ban on spotter aircraft would have a significant impact on a substantial number of small entities in that 83 percent of the fish spotters would be forced out of business.

Response: These commenters submitted no data to NMFS which would justify this claim. The greater part of the spotter aircraft activity currently occurs in the Purse Seine and Harpoon categories. By exempting these two categories from the prohibition on the use of spotter aircraft, the impact of the prohibition on aerial fish spotters is substantially lessened.

Further, the aerial fish spotting business is only a small portion of the small business aviation sector. While some spotter pilots will likely suffer revenue losses, no evidence is available to NMFS that the majority of small aviation businesses derive all or most of their income from services provided to ABT fishing vessels.

Comment: The proposed rule would have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act and NMFS should prepare a Regulatory Flexibility Analysis.

Response: See discussion of Regulatory Flexibility Act in the Classification section below.

Changes from the Proposed Rule

For the reasons stated above, NMFS exempts Harpoon category vessels from the prohibition on spotter aircraft use. Other than that exemption, the final rule remains as proposed. All measures in the proposed rule, except for the prohibition on the use of aircraft, were addressed in an earlier final rule (62 FR 30741, June 5, 1997). Additionally, NMFS issued an interim final rule that suspended the May 15 deadline for switching permit categories for calendar year 1997 until the remaining regulatory issues which could influence category selection were resolved and a new deadline set. Final quotas were published on June 30, 1997 (62 FR 35107) and the spotter aircraft issue is addressed by this final rule. As there are no remaining regulatory issues to be resolved that would influence category selection, vessel owners now have sufficient information to select an appropriate permit category for 1997. The deadline for switching permit categories for calendar year 1997 is set as July 28, 1997.

Classification

This rule is published under the authority of ATCA, 16 U.S.C. 971 *et seq*. The Assistant Administrator has determined that the regulations in this final rule are necessary for management of the Atlantic tuna fisheries.

NMFS prepared an EA for this final rule with a finding of no significant impact on the human environment. In addition, an RIR was prepared with a finding of no significant impact.

The Assistant General Counsel for Legislation and Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that the proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities, therefore no Regulatory Flexibility Analysis was prepared. That certification covered not only the proposed spotter aircraft prohibition, but the other provisions of the rule published in an earlier final rule (62 FR 30741, June 5, 1997).

During the comment period, NMFS received comments from the public that the proposal to ban the use of spotter aircraft in all but the Purse Seine category exceeded the threshold for significant impact on a substantial number of small entities. The aerial fish spotting business is only a small portion (less than 2 percent) of the small businesses in the ABT fishing sector, and for that matter, the aerial fish spotting business is only a very small portion of the small business aviation sector. While there may be some loss of revenue to small aircraft businesses that engage in fish spotting activities, no evidence is available to NMFS that the majority of revenues to these businesses is from ABT fish spotting. Further, the greater part of the spotter aircraft activity currently occurs in the Purse Seine and Harpoon categories. By exempting these two categories from the prohibition on the use of spotter aircraft, the impact of the prohibition on aerial fish spotters is substantially lessened.

Accordingly, there is no basis to change the conclusion of that the spotter aircraft prohibition provision of the rule will not have a significant economic impact on a substantial number of

businesses. Thus, a Final Regulatory Flexibility Analysis was not prepared.

This final rule has been determined to be not significant for purposes of E.O. 12866.

The AA has determined that there is good cause to waive partially the 30-day delay in the effective date normally required by 5 U.S.C. § 553(d). The fishery is currently underway and further delay in implementing the prohibition on the use of spotter aircraft in assisting ABT vessels in other than the Harpoon and Purse Seine categories would be contrary to the public interest by reducing the likelihood of achieving the desired effects of this rule. The desired effects of the rule are to extend the season to provide improved scientific monitoring and fishing opportunities for the rod-and-reel fisheries. Further, providing a 30-day delay in the effective date is unnecessary since the only act necessary to come into compliance with the prohibition is to cease ABT aircraft spotting activity. Therefore the ban is effective July 14, 1997. A two-week period for changing permit categories is necessary for vessel operators to gather relevant information, decide on the appropriate category, and submit an application for the category change. Given NMFS' ability to rapidly communicate these rule changes to fishing interests through the FAX network and NOAA weather radio, NMFS feels it is sufficient to implement the spotter aircraft prohibition immediately and allow fourteen days in which to make requests for permit category changes.

List of Subjects in 50 CFR Part 285

Fisheries, Fishing, Penalties, Reporting and recordkeeping requirements, Treaties.

Dated: July 14, 1997.

Rolland A. Schmitten,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble 50 CFR part 285 is amended as follows:

PART 285—ATLANTIC TUNA FISHERIES

1. The authority citation for part 285 continues to read as follows:

Authority: 16 U.S.C. 971 *et seq.*

2. In § 285.2, definition for ''Aircraft'' is added to read as follows:

§ 285.2 Definitions.

* * * * *

Aircraft means any contrivance used for flight in air.

* * * * *

3. In § 285.21, paragraph (b)(7) is revised to read as follows:

§ 285.21 Vessel Permits.

* * * * *

(b) * * *

(7) Except for purse seine vessels for which a permit has been issued under this section, an owner may change the category of the vessels's Atlantic tunas permit to another category by application on the appropriate form to NMFS or by dialing 1–888–USA-TUNA before the specified deadline. After the deadline, the vessel's permit category may not be changed to another category for the remainder of the calendar year, regardless of any change in the vessel's ownership. For 1997, the deadline is July 28, 1997. In years after 1997, the deadline for category changes is May 15.

* * * * *

4. In § 285.31, paragraph (a)(40) is added to read as follows:

§ 285.31 Prohibitions.

* * * * *

(a) * * *

(40) Fish for, catch, possess or retain, or attempt to fish for, catch, possess or retain Atlantic bluefin tuna by means, aid, or use of any aircraft, unless holding a valid permit in the Harpoon or Purse Seine category under § 285.21.

* * * * *

5. In § 285.33, the heading is revised, the existing paragraph is designated as paragraph (a), and paragraph (b) is added to read as follows:

§ 285.33 Gear restrictions.

* * * * *

(b) *Aircraft*. Other than for a vessel holding a valid permit in the Harpoon or Purse Seine category under § 285.21(a), locating, fishing for, catching, taking, retaining or possessing ABT by means, aid, or use of any aircraft is prohibited.

[FR Doc. 97–18912 Filed 7–14–97; 4:13 pm]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 62, No. 138
Friday, July 18, 1997

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

7 CFR Part 800

RIN 0580–AA56

Fees for Official Inspection and Official Weighing Services

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Grain Inspection, Packers and Stockyards Administration (GIPSA) is proposing a 12.5 percent increase in the administrative service fee for official inspection and weighing services performed in the United States under the United States Grain Standards Act (USGSA), as amended. The fee adjustment is necessary to cover indirect field office and headquarters operational costs and to maintain a 3-month operational reserve. GIPSA is also proposing to delete from the fee schedule the unit fees for submitted samples and factor only analysis performed online at an applicant's facility.

DATES: Written comments must be submitted on or before August 18, 1997.

ADDRESSES: Written comments must be submitted to George Wollam, USDA, GIPSA, ART, Stop 3649, Washington, DC 20250–3649, or FAX them to (202) 720–4628. All comments received will be made available for public inspection during regular business hours in Room 0623, South Building, USDA, 1400 Independence Avenue, SW, Washington, DC 20250–3649 (7 CFR 1.27 (b)). Comments may also be sent by electronic mail or Internet to: gwollam@fgisdc.usda.gov.

FOR FURTHER INFORMATION CONTACT: George Wollam at the above address or telephone (202) 720–0292.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule has been determined to be nonsignificant for the purpose of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This action is not intended to have a retroactive effect. The USGSA provides in section 87g that no subdivision may require or impose any requirements or restrictions concerning the inspection, weighing, or description of grain under the Act. Otherwise, this proposed rule will not preempt any State or local laws, regulations, or policies unless they present irreconcilable conflict with this proposed rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to provisions of this proposed rule.

Effects on Small Entities

James R. Baker, Administrator, GIPSA, has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Most users of the official inspection and weighing services do not meet the requirements for small entities. FGIS is required by statute to make services available and to recover costs of providing such services, as nearly as practicable.

The proposed fee revision applies to entities engaged in the export of grain. Under provisions of the USGSA, most grain exported from U.S. export port locations must be officially inspected and weighed. Mandatory inspection and weighing services are provided by FGIS on a fee basis at 37 export facilities. All of the export facilities are owned and managed by multi-national corporations, large cooperatives, or public entities that do not meet the criteria for small entities as defined under the Regulatory Flexibility Act and the regulations issued thereunder. A 3-percent increase in hourly and certain unit fees went into effect June 15, 1997, and will recover the increased operational costs caused by mandated cost-of-living increases to Federal salaries. That increase is anticipated to generate $218,100 in additional revenue, bringing to $22.21 million the projected total revenue for fiscal year 1997. This proposed 12.5 percent increase in the administrative fee (which was not addressed in an earlier June 15, 1997, increase) is designed to generate sufficient revenue to cover indirect costs associated with field office and headquarters operations and to maintain the retained earnings at a 3-month operating reserve for the inspection and weighing program. Additional revenue estimated for fiscal year 1998 is projected to be $440,000 at an 85.6 million metric ton level. The 12.5 percent increase will not have a significant economic impact on small entities.

Information Collection and Recordkeeping Requirements

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the previously approved information collection and recordkeeping requirements have been approved by the Office of Management and Budget under control number 0580–0013.

Background

The USGSA requires GIPSA to charge and collect reasonable fees for performing official inspection and weighing services. The fees are to cover, as nearly as practicable, FGIS's costs for performing these services, including related administrative and supervisory costs.

Effective October 1, 1996, GIPSA changed the methodology it uses for fees charged for its inspection and weighing services. The current fee structure for these services consists of three basic components: (1) An hourly rate charged to recover the direct labor costs of providing service; (2) a unit test or service rate; and (3) a per metric ton administrative charge to recover the indirect costs, such as salaries and benefits for office management and support staff and rent, incurred both at field offices and headquarters. Fees charged in the first two components of the structure were increased by approximately 3 percent effective June 15, 1997 (62 FR 31701, June 11, 1997, corrected at 62 FR 34342, June 25, 1997), to cover increased costs due to mandated Federal cost-of-living increases. At that time, GIPSA noted

that a further adjustment of fees, including an adjustment to the administrative fee to recover the indirect costs of field offices and headquarters and to replenish the operating reserve, would be addressed in future rulemaking.

The current USGSA administrative fee was published in the August 22, 1996, **Federal Register** (61 FR 43301) and became effective on October 1, 1996. The per metric ton administrative charge recovers the indirect costs and administrative costs of FGIS field offices and headquarters such as the salaries and benefits for office management and support staff, Departmental charges, Animal and Plant Health Inspection Service and Agricultural Marketing Service charges, management of computers and software, utilities, and rent. The 3-percent increase that became effective June 15, 1997, was intended to recover only increases to the salaries of service personnel responsible for inspection and weighing of grain. The administrative fee is assessed on all outbound grain inspected and/or weighed at an applicant's facility.

Six levels of fees exist, ranging from 1 metric ton or less to over 7,000,001 metric tons, with fees decreasing as the number of metric tons inspected increases. The charge is assessed in addition to the hourly rate. At the beginning of each fiscal year (October 1), all applicants pay the same per metric-ton-fee. Once a level has been reached, the fee for additional metric tons is reduced until the maximum volume is reached.

COMPARISON OF CURRENT AND PROPOSED ADMINISTRATIVE FEES

Metric tons	Current fees	Proposed fees
1–1,000,000	$0.090	$0.1013
1,000,001–1,500,000	.082	.0923
1,500,001–2,000,000	.042	.0473
2,000,001–5,000,000	.032	.0360
5,000,001–7,000,000	.017	.0192
7,000,001+	.002	.0023

GIPSA is now proposing a 12.5 percent increase in the administrative fee. This increase is designed to generate additional revenue to cover the indirect costs associated with field office and headquarters operations and maintain the retained earnings at a 3-month operating reserve for the inspection and weighing program.

GIPSA estimates collecting $22.2 million in revenue for fiscal year 1997 under the current fee schedule. This is $1 million less than the $23.2 million estimated cost of operations for fiscal year 1997. Similar losses have occurred for the past 3 years, with $753,000 in fiscal year 1994; $630,000 in fiscal year 1995; and $1,273,000 in fiscal year 1996. These losses resulted in a retained earning balance of only $922,000 at the beginning of fiscal year 1997, significantly below a desired 3-month operating reserve of $6 million.

Indirect costs for the inspection and weighing program are estimated at $4.68 million, or 20 percent of the total $23.2 obligation for the program. Because of a down-turn in metric tons exported, the current administrative fee will generate only an estimated $3.5 million for fiscal year 1997, resulting in an estimated loss of $1.18 million.

The administrative fee must be increased to ensure sufficient revenue is collected to recover indirect costs for an average export volume year. This will permit any excess revenue collected during high volume years, such as 89.9 million metric tons in FY 1996, to offset low volume years such as this year estimated at 76 million metric tons.

The current administrative fee generates an estimated $4.09 million at the 5-year average export volume of 85.6 million metric tons. The proposed fee increase of 12.5 percent will generate an estimated $4.53 million at the 85.6 million metric ton level, or increase actual revenue by $440,000 or 10.75 percent.

It is further proposed that fees for submitted samples and factor only analysis performed online at an applicant's facility (7 CFR 800.71, Table 1 (3)(ii)) be deleted because these services are covered under the hourly rate and should not be charged as a separate test.

Proposed Action

The Agency proposes, effective October 1, 1997, to apply a 12.5 percent increase to Administrative Fees in 7 CFR 800.71, Table 1 (3), and to delete fees for Additional Service (assessed in addition to all other fees) in Table 1 (3)(ii).

List of Subjects in 7 CFR Part 800

Administrative practice and procedure, Grain.

For the reasons set out in the preamble, 7 CFR part 800 is proposed to be amended as follows:

PART 800—GENERAL REGULATIONS

1. The authority citation for Part 800 continues to read as follows:

Authority: Pub. L. 94–582, 90 Stat. 2867, as amended (7 U.S.C. 71 *et seq.*)

2. Section 800.71 paragraph (a), Schedule A, is amended by revising Table 1 (3) to read as follows:

§ 800.71 Fees assessed by the Service.

(a) * * *

SCHEDULE A.—Fees for Official Inspection and Weighing Services Performed in the United States

TABLE 1.—FEES FOR OFFICIAL SERVICES PERFORMED AT AN APPLICANT'S FACILITY IN AN ONSITE FGIS LABORATORY [1]

* * * * * * *

(3) Administrative Fee (assessed in addition to all other applicable fees, only one administrative fee will be assessed when inspection and weighing services are performed on the same carrier).

(i) All outbound carriers (per-metric-ton): [4]	
(a) 1—1,000,000	$0.1013
(b) 1,000,001—1,500,000	0.0923
(c) 1,500,001—2,000,000	0.0473
(d) 2,000,001—5,000,000	0.0360
(e) 5,000,001—7,000,000	0.0192
(f) 7,000,001—	0.0023

[1] Fees for original inspection and weighing, reinspection, and appeal inspection service include, but are not limited to, sampling, grading, weighing, prior to loading stowage examinations, and certifying results performed within 25 miles of an employee's assigned duty station. Travel and related expenses will be charged for service outside 25 miles as found in § 800.72 (a).

* * * * *

[4] The administrative fee is assessed on an accumulated basis beginning at the start of the Service's fiscal year (October 1 each year).

* * * * * * *

Dated: July 14, 1997.

James R. Baker,

Administrator.

[FR Doc. 97–18943 Filed 7–17–97; 8:45 am]

BILLING CODE 3410–EN–P

FEDERAL RESERVE SYSTEM

12 CFR Part 226

[Regulation Z; Docket No. R–0979]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 3500

[Regulation X; Docket No. FR–4257–N–01]

Truth in Lending Act and Real Estate Settlement Procedures Act; Simplification and Improvement of Consumer Disclosures

AGENCIES: Office of the Assistant Secretary for Housing-Federal Housing Commissioner (HUD); Board of

Governors of the Federal Reserve System (the Board) (collectively, the Agencies).

ACTION: Advance notice of proposed rulemaking; public forum.

SUMMARY: The Board and HUD will hold a public forum concerning the streamlining and reform of the Truth in Lending Act (TILA) and the Real Estate Settlement Procedures Act (RESPA). The Economic Growth and Regulatory Paperwork Reduction Act of 1996 directs the Agencies to submit legislative recommendations to the Congress on how to simplify and improve consumer disclosures under RESPA and TILA if the disclosures cannot be simplified through regulatory change. The Agencies have concluded that meaningful simplification of the disclosures can only come about through statutory revisions. In addition, some have suggested that more effective protection of consumers from adverse steering and unnecessary costs, as well as greater certainty about permitted and prohibited behavior, might be achieved through reform of other provisions of RESPA. The public forum is intended to give interested parties an opportunity to discuss their views on statutory reform with the Agencies.

DATES: *Public Forum.* Wednesday, July 30, 1997, 8:15 a.m. to 4:30 p.m.

Comments: Persons unable to attend the forum or wishing to provide written views on the issues raised in this notice may submit comments by August 15, 1997.

ADDRESSES: *Public Forum.* Terrace Level, Room E of the Federal Reserve Board's Martin Building, C Street Northwest, between 20th and 21st Streets, Washington, DC

Comments: Comments may be submitted to either agency.

Board: Comments submitted to the Board should refer to Docket No. R–0979, and may be mailed to William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW, Washington, DC 20551. Comments also may be delivered to Room B–2222 of the Eccles Building between 8:45 a.m. and 5:15 p.m. weekdays, or to the guard station in the Eccles building courtyard on 20th Street, NW (between Constitution Avenue and C Street) at any time. When possible, comment letters should use a standard courier typeface with a type size of 10 or 12 characters per inch. This will enable the Board to convert the text into machine-readable form through electronic scanning, and will facilitate automated retrieval of comments for review. Also, if accompanied by an original document in paper form, comments may be submitted on 3½ inch or 5¼ inch computer diskettes in any IBM-compatible DOS-based format. Comments may be inspected in Room MP–500 of the Martin Building between 9:00 a.m. and 5:00 p.m. weekdays, except as provided in 12 CFR 261.8 of the Board's Rules Regarding Availability of Information.

HUD: Comments to HUD should be addressed to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410–0500. Communications should refer to the above docket number and title. Facsimile (FAX) comments are not acceptable. Comments received will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT:

Board: Sheilah A. Goodman or Kyung Cho-Miller, Staff Attorneys, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, at (202) 452–3667 or (202) 452–2412; for the hearing impaired *only,* Diane Jenkins, Telecommunications Device for the Deaf (TDD), at (202) 452–3544.

HUD: David R. Williamson, Director, Officer of Consumer and Regulatory Affairs, Room 9146, (202) 708–4560; or for legal questions, Kenneth A. Markison, Assistant General Counsel for GSE/RESPA, Grant E. Mitchell, Senior Attorney for RESPA, or Rodrigo J. Alba, Attorney, Office of General Counsel, Room 9262, (202) 708–1550. For hearing- and speech-impaired persons, these numbers may be accessed via TTY (text telephone) by calling the Federal Information Relay Service at 1–800–877–8339. The address for the above-listed persons is: Department of Housing and Urban Development, 451 Seventh Street, SW Washington, D.C. 20410. The telephone numbers for the Agencies are not toll-free.

SUPPLEMENTARY INFORMATION:

I. Background

On September 30, 1996, the Economic Growth and Regulatory Paperwork Reduction Act of 1996 (Pub. L. 104–208, 110 Stat. 3009) became law. Section 2101 of that act directs the Board and HUD to simplify and improve the disclosures given in a home mortgage transaction subject to TILA and RESPA, and to create a single disclosure that will satisfy the requirements of both statutes, if possible. If legislation is necessary to accomplish this objective, the Agencies are directed to submit legislative recommendations to the Congress.

TILA is a comprehensive statute that covers all types of consumer credit transactions. The act's goal is to help consumers understand credit terms and shop for credit by requiring creditors to provide uniform credit disclosures. TILA is primarily a disclosure statute, though it contains some substantive provisions. TILA disclosures focus primarily on the costs imposed by a creditor and the terms of a credit obligation. The law requires the disclosure of two terms thought to be key in aiding consumers in comparison shopping for credit—the finance charge and the annual percentage rate (APR). The finance charge is intended to reflect the dollar amount of the cost of credit; the APR is the cost of the credit expressed as a yearly rate. TILA also requires, among other things, the disclosure of a payment schedule, whether a creditor will impose a penalty if a loan is prepaid, whether a loan may be assumed, and the fee for a late payment. Finally, TILA provides substantive protections for certain home-secured loans such as prohibitions on certain contract terms, and the right to cancel the transaction.

RESPA was enacted in large measure to ensure that the home-buying public is afforded timely and effective information about the costs of settlement in mortgage transactions, and to eliminate kickbacks and referral fees that tend to increase unnecessarily the cost of settlement services. To achieve these goals, RESPA mandates disclosures at various points in the home financing process for transactions involving ''federally related mortgage loans,'' which include most financial transactions creating a lien on owner-occupied residential structures. RESPA disclosures focus on the fees for services required in home mortgage transactions and require an itemization of all costs associated with settlement. RESPA also imposes certain restrictions on payments among settlement service providers (such as lenders, appraisers, and title companies). Section 8(a) of RESPA prohibits compensation for the referral of settlement service business; section 8(b) prohibits unearned fees and fee splitting arrangements. Section 8(c)(2) of RESPA, however, provides that payment may be made for ''* * * goods or facilities actually furnished or for services actually performed * * *.''

In December 1996, the Board and HUD jointly published for comment an advance notice of proposed rulemaking on the issue of simplifying and

combining the disclosure requirements of RESPA and TILA (61 FR 69055, Dec. 31, 1996). The notice requested comment on both regulatory and statutory changes to improve the current disclosure scheme. The comments that were received covered a wide range of issues. Nearly all of the recommendations for reconciling the two regulations require legislative action (e.g. changes to the timing of disclosures under the two statutes). The remainder of the recommendations generally involved small changes that could produce only minor improvements that likely would not be worth the corresponding compliance costs for creditors associated with reprinting forms or retraining personnel. HUD is separately considering whether to propose minor simplification amendments to various RESPA-required forms. HUD will also weigh the merits of proposing such changes in light of the associated costs.

On April 2, 1997, the Board published a second notice summarizing the comments and reopening the comment period to allow interested parties more time to comment on potential legislative action. (62 FR 15624) The Board determined, in consultation with HUD, that beyond the revisions that have been made over the past several years, without legislative action any additional regulatory changes would be inadequate to achieve the goal of harmonizing TILA and RESPA to any significant degree. The notice stated that the Agencies would consider holding public meetings, as was suggested by many of the commenters, to help in developing legislative recommendations.

II. Public Forum

Although TILA and RESPA both regulate mortgage transactions, they differ in fundamental ways. In crafting legislative recommendations, the Board and HUD believe that it is important to examine the goals of RESPA and TILA, and what problems this dual—but not identical—statutory scheme presents. Therefore, the Board and HUD will hold a joint public forum on July 30, 1997, to help the Agencies in their consideration of issues to be addressed in the legislative recommendations. The forum will be held at the Board's offices in Washington, D.C. The Agencies have invited speakers representing industry and consumer interests to participate in the discussion, which will be followed by an open session for other members of the public to express their views.

At the forum, the Board's staff will present preliminary findings of a survey on consumer credit shopping that was commissioned by the Board. Each invited speaker will be given an opportunity to make a brief introductory statement. The invitees will be asked to discuss a number of topics, including (1) consumer credit shopping behavior, (2) the goals of TILA and RESPA, and whether the current statutory and regulatory scheme for home mortgage lending satisfies those goals, and (3) whether significant improvement can be made to the existing provisions of TILA and RESPA, or whether there is a need for more comprehensive reform.

There will be an opportunity during the open session for other attendees to offer the Agencies their views on these issues. Oral statements in this open session should be brief to allow as many speakers as possible to offer their views. Written statements of any length may be submitted for the record, and are due by August 15, 1997.

Dated: July 14, 1997.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

By order of the Board of Governors of the Federal Reserve System, July 14, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97–18940 Filed 7–17–97; 8:45 am]

BILLING CODE 6210–01–P (½)
BILLING CODE 4210–27–P (½)

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–NM–59–AD]

RIN 2120–AA64

Airworthiness Directives; Lockheed Model L–1011 Series Airplanes Equipped With Rolls Royce Model RB211–22B Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to certain Lockheed Model L–1011 series airplanes, that currently requires various modifications and corrective actions to prevent a potential fire hazard caused by heat damage to the flex fuel feed line from an undetected gearbox fire. In lieu of the various modifications and corrective actions, that AD also provides for an optional terminating action (i.e., installation of a vent air tube in the gear compartment and thickened gearbox housings) for another existing AD. For airplanes on which that optional terminating action has been accomplished, this action would require accomplishment of the various modifications and corrective actions. This proposal is prompted by a report indicating that, due to bearing failure, an in-flight fire occurred on an airplane on which a thickened gearbox housing was installed. The actions specified by the proposed AD are intended to detect and correct bearing failure, which could lead to a fire in the gearbox.

DATES: Comments must be received by August 25, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–59–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Lockheed Aeronautical Systems Support Company, Field Support Department, Dept. 693, Zone 0755, 2251 Lake Park Drive, Smyrna, Georgia 30080. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Atlanta Aircraft Certification Office, Campus Building, 1701 Columbia Avenue, Suite 2–160, College Park, Georgia.

FOR FURTHER INFORMATION CONTACT: Thomas B. Peters, Aerospace Engineer, Systems and Flight Test Branch, ACE–116A, FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, Campus Building, 1701 Columbia Avenue, Suite 2–160, College Park, Georgia 30337–2748; telephone (404) 305–7367; fax (404) 305–7348.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic,

environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 96–NM–59–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–59–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On March 25, 1987, the FAA issued AD 87–07–10, amendment 39–5597 (52 FR 10736, April 3, 1987), applicable to certain Lockheed Model L–1011 series airplanes, equipped with Rolls Royce Model RB211–22B engines. That AD currently requires various modifications and corrective actions that constitute terminating action for AD 85–09–03, amendment 39–5056 (50 FR 18553, May 3, 1985). (These various modifications include installation of: a fire detector segment, a modified gearbox breather duct, and a vent air tube in the gear compartment.) In lieu of the various modifications and corrective actions, that AD also provides for an optional terminating action (i.e., installation of a vent air tube in the gear compartment and installation of thickened gearbox housings) for the requirements of AD 85–09–03. AD 87–07–10 was prompted by reports of gearbox fires, which were caused by failed bearings. The requirements of that AD are intended to prevent a potential fire hazard, as a result of heat damage to the flex fuel feed line from an undetected gearbox fire.

At the time of issuance of AD 87–07–10, the FAA had not received any reports of bearing failure on Lockheed Model L–1011 series airplanes equipped with Rolls Royce Model RB211–524 series engines on which thickened gearbox housings were installed. Since Rolls Royce Model RB211–22B engines are similar in design to Model RB211–524 series engines, the FAA determined that installation of thickened housings on Model RB211–22B engines would prevent bearing failure that could cause a gearbox fire. Therefore, the FAA included the installation of such housings as optional terminating action in AD 87–07–10.

Actions Since Issuance of Previous AD

Since the issuance of that AD, the FAA has received a report indicating that an in-flight fire occurred in a thickened gearbox housing on a Rolls Royce Model RB211–524 series engine installed on a Lockheed Model L–1011 series airplane. (This housing was installed on Model L–1011 series airplanes equipped with Rolls Royce Model RB211–22B engines as an optional terminating action of AD 87–07–10.) In light of this report, the FAA has determined that the optional terminating action of AD 87–07–10 does not adequately preclude bearing failure, as previously believed. Bearing failure, if not detected and corrected, could lead to a fire in the gearbox.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 87–07–10 to continue to require various modifications and corrective actions, which constitute terminating action for AD 85–09–03. For airplanes on which the optional terminating action specified in AD 87–07–10 has been accomplished, this AD would add a requirement to accomplish the various modifications and corrective actions. The actions would be required to be accomplished in accordance with the service bulletins described previously in AD 87–07–10.

Other Relevant Rulemaking

The FAA has previously issued AD 94–03–10, amendment 39–8817 (59 FR 6535, February 11, 1994), which is applicable to certain Lockheed Model L–1011 series airplanes equipped with Rolls Royce Model RB211–524 series engines. That AD requires modification of the high speed gearbox of the engines. Operators should note that this proposed AD would not affect the current requirements of AD 94–03–10.

Cost Impact

There are approximately 130 Lockheed Model L–1011 series airplanes equipped with Rolls Royce Model RB211–22B engines of the affected design in the worldwide fleet. The FAA estimates that 76 airplanes of U.S. registry would be affected by this proposed AD.

The proposed installation of a fire detector segment would take approximately 3 work hours per engine (3 engines per airplane) to accomplish, at an average labor rate of $60 per work hour. Required parts for Walter-Kidde systems would cost approximately $2,100 per engine. Required parts for Graviner systems would cost approximately $8,100 per engine. Based on these figures, the cost impact on U.S. operators of the installation proposed by this AD is estimated to be $6,840 per airplane (for Walter-Kidde systems), or $24,840 per airplane (for Graviner systems).

The proposed modification would take approximately 6 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts would cost approximately $10,000 per airplane. Based on these figures, the cost impact on U.S. operators of the modification proposed by this AD is estimated to be $787,360, or $10,360 per airplane.

The proposed introduction of a vent air tube would take approximately 3 work hours per engine (3 engines per airplane) to accomplish, at an average labor rate of $60 per work hour. Required parts would cost approximately $500 per engine. Based on these figures, the cost impact on U.S. operators of the introduction of a vent air tube proposed by this AD is estimated to be $155,040, or $2,040 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the rules docket. A copy of it may be obtained by contacting the rules docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–5597 (52 FR 10736, April 3, 1987), and by adding a new airworthiness directive (AD), to read as follows:

Lockheed: Docket 96–NM–59–AD. Supersedes AD 87–07–10, Amendment 39–5597.

Applicability: Model L–1011 series airplanes equipped with Rolls Royce RB211–22B engines, certificated in any category.

Note 1: If an operator has accomplished the requirements of paragraphs (a) and (b) of this AD on any affected airplane and, subsequently, installs a different Model RB211–22B engine on that airplane, the airplane and all installed engines are still subject to the requirements of this AD.

Note 2: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To detect and correct bearing failure, which could lead to a fire in the gearbox, accomplish the following:

(a) Within 8,000 flight hours or 30 months after May 8, 1987 (the effective date of AD 87–07–10, amendment 39–5597), whichever occurs first, accomplish the procedures specified in the Accomplishment Instructions of the service bulletins listed in paragraphs (a)(1) and (a)(2) of this AD.

(1) Lockheed Service Bulletin 093–26–036, dated April 1, 1986, *Installation of Fire Detector Segment;* and

(2) Lockheed Service Bulletin 093–71–067, Revision 1, dated April 1, 1986, *Gearbox Breather Duct Modification*.

(b) Within 8,000 flight hours or 30 months after May 8, 1987, whichever occurs first, accomplish the procedures specified in the Accomplishment Instructions of the service bulletins listed in paragraphs (b)(1) and (b)(2) of this AD.

(1) Rolls Royce Service Bulletin RB.211–72–4666, Revision 3, dated October 14, 1977, *Introduction of Vent Air Tube in Gear Compartment;* and

(2) Rolls Royce Service Bulletin RB.211–72–8138, dated March 21, 1986, *Installation of Additional No. 7 Fire Sensor.*

(c) For airplanes on which Rolls Royce Service Bulletin RB.211–72–4666, Revision 3, dated October 14, 1977, and Rolls Royce Service Bulletin RB.211–72–3878, Revision 3, dated June 25, 1976, have been accomplished in accordance with paragraph C of AD 87–07–10: Within 48 months or 16,000 flight hours after the effective date of this AD, whichever occurs first, accomplish the actions specified in paragraphs (a) and (b) of this AD.

(d) Accomplishment of the requirements of paragraphs (a) and (b) of this AD; or accomplishment of the requirements of paragraph (c) of this AD; constitutes terminating action for the requirements of AD 85–09–03, amendment 39–5056. The AFM limitations required by AD 85–09–03 may be removed following accomplishment of the terminating action.

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Atlanta Aircraft Certification Office (ACO), FAA, Small Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on July 11, 1997.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–18935 Filed 7–17–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–03–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 727 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all Boeing Model 727 series airplanes. This proposal would require repetitive inspections to detect cracks in the forward flange of the vertical beam of the aft fuselage bulkhead at certain buttock lines, and installation of a splice repair, if necessary. The proposed AD also would require installation of a preventative modification on the door frames in certain cases. This proposal is prompted by reports of fatigue cracks found in the vertical beam web and forward flange of the aft fuselage bulkhead. The actions specified by the proposed AD are intended to detect and correct such fatigue cracking, which could result in the inability of the subject vertical beam to withstand the fail-safe loads, and consequent loss of cabin pressurization.

DATES: Comments must be received by August 25, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–03–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207.

This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Walter Sippel, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington; telephone (425) 227–2774; fax (425) 227–1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 97–NM–03–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–03–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received reports of fatigue cracks in the vertical beam web and forward flange of the aft fuselage bulkhead at body station 1183 at the left and right buttock lines 17.8. This cracking occurred on Boeing Model 727 series airplanes. These cracks were discovered during inspections conducted as part of the Supplemental Structural Inspection Document (SSID) program, required by AD 84–21–05, amendment 39–4920 (49 FR 38931, October 2, 1984). Investigation revealed that such cracking was caused by pressurization cycles. Such fatigue cracking, if not detected and corrected in a timely manner, could result in the inability of the subject vertical beam to withstand the fail-safe loads, and consequent loss of cabin pressurization.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Service Bulletin 727–53–0210, dated April 1, 1993, as revised by Notice of Status Change 727–53–0210 NSC 1, dated June 17, 1993, and Notice of Status Change 727–53–0210 NSC 2, dated September 21, 1995. The service bulletin describes procedures for repetitive close visual inspections and high frequency eddy current (HFEC) inspections to detect cracks in the forward flange of the vertical beam at left and right buttock lines 17.8 from water lines 265 through 288 inclusive, and installation of a splice repair, if necessary. The service bulletin also describes procedures for installation of a preventative modification on the door frames in certain cases. Accomplishment of the splice repair and the preventative modification will minimize the possibility of cracks in the vertical beam and forward flange of the aft fuselage bulkhead. (The service bulletin references Boeing Service Bulletin 727–53–0055 as an additional source of service information for identical procedures to repair and modify the affected area.)

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require repetitive close visual inspections and HFEC inspections to detect cracks in the forward flange of the vertical beam at left and right buttock lines 17.8 from water lines 265 through 288 inclusive, and installation of a splice repair, if necessary. The proposed AD also would require installation of a preventative modification on the door frames in certain cases. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Cost Impact

There are approximately 1,560 Boeing Model 727 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 1,054 airplanes of U.S. registry would be affected by this proposed AD.

It would take approximately 2 work hours per airplane to accomplish the proposed inspections, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the inspection proposed by this AD on U.S. operators is estimated to be $126,480, or $120 per airplane, per inspection cycle.

Should an operator be required to accomplish the proposed preventative modification, it would take approximately 100 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. The cost of required parts could range between $910 and $1,042 per preventative modification kit (2 kits per airplane). Based on these figures, the cost impact of the preventative modification proposed by this AD on U.S. operators is estimated to be between $7,820, and $8,084 per airplane.

Should an operator be required to accomplish the proposed splice repair, it would take approximately 148 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts would cost approximately $3,545 per airplane ($1,756 for the left side splice repair kit and $1,789 for the right side splice repair kit). Based on these figures, the cost impact of the proposed splice repair on U.S. operators is estimated to be $12,425 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the rules docket. A copy of it may be obtained by contacting the rules docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 97–NM–03–AD.

Applicability: All Model 727 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To detect and correct fatigue cracking in the forward flange of the vertical beam of the aft pressure bulkhead, which could result in the inability of the subject vertical beam to withstand the fail-safe loads, and consequent loss of cabin pressurization, accomplish the following:

(a) Perform a close visual inspection and a high frequency eddy current (HFEC) inspection to detect cracks in the forward flange of the vertical beam at left and right buttock line 17.8 from water lines 265 through 288 inclusive, in accordance with Boeing Service Bulletin 727–53–0210, dated April 1, 1993, as revised by Notice of Status Change 727–53–0210 NSC 1, dated June 17, 1993, and Notice of Status Change 727–53–0210 NSC 2, dated September 21, 1995; at the time specified in paragraph (a)(1) or (a)(2) of this AD, as applicable.

(1) For airplanes on which the preventative modification specified in Boeing Service Bulletin 727–53–0210, dated April 1, 1993; or Boeing Service Bulletin 727–53–0055, Revision 6, dated February 28, 1986, Revision 7, dated March 5, 1987, Revision 8, dated December 17, 1987, or Revision 9, dated August 3, 1989; has not been accomplished: Inspect prior to the accumulation of 18,500 total flight cycles, or within 1,500 flight cycles after the effective date of this AD, whichever occurs later.

(2) For airplanes on which the preventative modification specified in Boeing Service Bulletin 727–53–0210, dated April 1, 1993, or Boeing Service Bulletin 727–53–0055, Revision 6, dated February 28, 1986, Revision 7, dated March 5, 1987, Revision 8, dated December 17, 1987, or Revision 9, dated August 3, 1989, has been accomplished: Inspect prior to the accumulation of 40,000 flight cycles since installation of preventative modification, or with 1,500 flight cycles after the effective date of this AD, whichever occurs later. Repeat the close visual and HFEC inspections thereafter at intervals not to exceed 6,000 flight cycles.

Note 2: The compliance times specified in paragraphs (a)(1) or (a)(2) of this AD remain the same regardless of whether any splice repair has or has not been accomplished in accordance with any service bulletin specified in those paragraphs.

(b) If no crack is detected during any inspection required by paragraph (a)(1) or (a)(2) of this AD, accomplish paragraph (b)(1) or (b)(2) of this AD.

(1) Prior to further flight, install the preventative modification on the door frames in accordance with Boeing Service Bulletin 727–53–0210, dated April 1, 1993, as revised by Notice of Status Change 727–53–0210 NSC 1, dated June 17, 1993, and Notice of Status Change 727–53–0210 NSC 2, dated September 21, 1995. Prior to the accumulation of 40,000 flight cycles following accomplishment of the preventative modification, accomplish the close visual and HFEC inspections specified in paragraph (a) of this AD. Repeat those inspections thereafter at intervals not to exceed 6,000 flight cycles. Or

(2) Repeat the close visual and HFEC inspections required by paragraph (a) of this AD thereafter at the intervals not to exceed 3,000 flight cycles.

(c) If any crack is detected during any inspection required by paragraph (a)(1), (a)(2), or (a)(3) of this AD, prior to further flight, install the splice repair kits in accordance with Boeing Service Bulletin 727–53–0210, dated April 1, 1993, as revised by Notice of Status Change 727–53–0210 NSC 1, dated June 17, 1993, and Notice of Status Change 727–53–0210 NSC 2, dated September 21, 1995. Prior to further flight following accomplishment of the splice repair, install the splice repair with the preventative modification on the door frames in accordance with the service bulletin. Prior to the accumulation of 40,000 flight cycles following accomplishment of the preventative modification, accomplish the close visual and HFEC inspections specified in paragraph (a) of this AD. Repeat those inspections thereafter at intervals not to exceed 6,000 flight cycles.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on July 11, 1997.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–18936 Filed 7–17–97; 8:45 am]

BILLING CODE 4910–13–U

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 202, 230, 232, 239, 270, and 274

[Release Nos. 33–7430, IC–22747, File No. S7–19–97]

RIN 3235–AG73

Registration Under the Securities Act of 1933 of Certain Investment Company Securities

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rules.

SUMMARY: The Commission is proposing amendments to the rule and the form under the Investment Company Act of 1940 that prescribe the method by which certain investment companies calculate and pay registration fees under the Securities Act of 1933. The proposed amendments are designed to implement the provisions of the National Securities Markets Improvement Act of 1996 that simplify the method of determining the amount of these fees.

DATES: Comments must be received on or before August 18, 1997.

ADDRESSES: Comments should be submitted in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Stop 6–9, Washington, DC 20549. Comments also may be submitted electronically at the following E-mail address: rule-comments@sec.gov. All comment letters should refer to File No. S7–19–97; this file number should be included on the subject line if E-mail is used. Comment letters will be available for public inspection and copying in the Commission's Public Reference Room,

450 Fifth Street, NW., Washington, DC 20549. Electronically submitted comment letters also will be posted on the Commission's Internet web site (http://www.sec.gov).

FOR FURTHER INFORMATION CONTACT: Robin S. Gross, Staff Attorney, or Nadya B. Roytblat, Assistant Office Chief, at (202) 942–0690, Office of Regulatory Policy, Division of Investment Management, Stop 10–2, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The Commission is requesting public comment on amendments to rule 24f–2 (17 CFR 270.24f–2) and Form 24F–2 (17 CFR 274.24) under the Investment Company Act of 1940 (15 U.S.C. 80a) (the ''Investment Company Act''). In addition, the Commission is proposing conforming amendments to rule 485 (17 CFR 230.485) under the Securities Act of 1933 (15 U.S.C. 77a) (the ''Securities Act''); Form N–1A (17 CFR 274.11A and 239.15A), Form N–3 (17 CFR 274.11b and 239.17a), and Form N–4 (17 CFR 274.11c and 239.17b), the registration forms used by certain types of investment companies to register under the Investment Company Act and to register their securities under the Securities Act; Form S–6 (17 CFR 239.16), the form used by unit investment trusts to register their securities under the Securities Act; Form N–14 (17 CFR 239.23), the form used by investment companies to register under the Securities Act securities issued in business combination transactions; rule 24e–1 under the Investment Company Act (17 CFR 270.24e–1); rule 13 of Regulation S–T (17 CFR 232.13); and rule 3a of Informal and Other Procedures (17 CFR 202.3a). The Commission is also proposing to rescind rules 24e–2 and 24f–1 under the Investment Company Act (17 CFR 270.24e–2 and 270.24f–1).

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Executive Summary

The Commission is proposing amendments to rule 24f–2 and Form 24F–2 under the Investment Company Act that prescribe the methods by which certain investment companies calculate and pay registration fees under the Securities Act. The proposed amendments are designed to implement a provision of the National Securities Markets Improvement Act of 1996 (''Improvement Act'') that amended sections 24 (e) and (f) of the Investment Company Act to simplify the current system for registering investment company securities. The proposed amendments to rule 24f–2 and Form 24F–2 would streamline the rule and Form to make them consistent with amended section 24.

I. Background

The Securities Act generally requires issuers that wish to offer their securities publicly to register the securities with the Commission and pay a registration fee.[1] The application of these provisions has presented operational problems for certain types of investment companies. Unlike other issuers, open-end management investment companies, unit investment trusts and face-amount certificate companies (collectively, ''funds'') sell and redeem their securities on a continuous basis. A fund often cannot predict the number of securities it will sell at the time it files its registration statement under the Securities Act. In addition, funds often experience a high turnover in their outstanding securities, as a substantial number of securities that are sold replace securities that recently have been redeemed or repurchased.[2]

Section 24 of the Investment Company Act modifies the Securities Act registration provisions for funds.[3] Section 24 and related rules were designed to address the problem of inadvertent ''over sales'' (*i.e.*, sales in excess of securities registered) that easily could occur with a fund that continually issues securities.[4] Section 24(e) permits a fund to register additional securities by a post-effective amendment to a registration statement.[5] Section 24(f) permits a fund to register securities within six months after their sale, but requires that the fund pay three times the registration fee that otherwise would be due under section 6(c) of the Securities Act.[6]

Section 24(f) also authorizes the Commission to adopt rules to permit funds to register an indefinite number of securities. In 1977, the Commission exercised this authority and adopted rule 24f–2.[7] Rule 24f–2 permits a fund to declare that it is registering an indefinite number of securities (''rule 24f–2 declaration'').[8] After the end of each of its fiscal years, the fund must file a notice on Form 24F–2 to make the registration of securities it sold during the fiscal year ''definite'' and pay a registration fee with respect to those securities.[9] Under certain circumstances, the fund may offset, or ''net,'' sales made during the fiscal year against redemptions effected during the fiscal year for the purpose of calculating the fund's Securities Act registration fee.[10]

These statutory provisions and rules, taken together, have provided funds with significant flexibility to avoid over sales and to reduce their registration fees. These provisions, however, are highly complex. Funds are presented with a number of options for registering their securities and using redemptions to offset sales. Inadvertent non-compliance with, failure to understand the interrelationship of, or a late filing

[1] Section 5(a) of the Securities Act (15 U.S.C. 77e(a)) makes it unlawful to sell a security through the mails or in interstate commerce unless a registration statement is in effect as to that security. Section 6(a) (15 U.S.C.77f(a)) sets forth certain requirements for registration statements. Section 6(b) (15 U.S.C. 77f(b)) specifies the fees that must be paid in connection with registering securities with the Commission under the Securities Act.

[2] *See* Computation of Filing Fees for Securities Registered by Open-End Management Companies, Investment Company Act Rel. No. 9677 (Mar. 15, 1977) (42 FR 15922 (Mar. 24, 1977)) (adopting amendments to rule 24e–2).

[3] 15 U.S.C. 80a–24.

[4] *See* Investment Company Act Rel. No. 15611 (Mar. 9, 1987) (52 FR 8302 (Mar. 17, 1987)) (proposing amendments to rule 24f–2 relating to certain unit investment trusts).

[5] 15 U.S.C. 80a–24(e).

[6] 15 U.S.C. 80a–24(f).

[7] Registration of an Indefinite Number of Investment Company Shares, Investment Company Act Rel. No. 9989 (Nov. 3, 1977) (42 FR 58400 (Nov. 9, 1977)).

[8] Rule 24f–2(a)(1) (17 CFR 270.24f–2(a)(1)).

[9] Rule 24f–2(b)(1) (17 CFR 270.24f–2(b)(1)).

[10] Rule 24f–2(c) (17 CFR 270.24f–2(c)). The rule that governs the computation of fees for registering securities by post-effective amendment, rule 24e–2, allows a fund to take a credit for securities redeemed during the previous fiscal year. Thus, a fund that has had redemptions in excess of sales in one fiscal year can apply the unused redemptions to reduce registration fees that it would pay under rule 24e–2 in the next fiscal year (in effect, preserving the unused redemptions).

pursuant to these provisions can result in a fund facing significant adverse consequences.[11]

The Improvement Act amended sections 24 (e) and (f) of the Investment Company Act, among other things, to create a new, simpler system for the registration of fund securities under the Securities Act.[12] Amended section 24(f) of the Investment Company Act, when effective, will provide that a fund will be deemed to have registered an indefinite amount of securities upon the effective date of its registration statement under the Securities Act.[13] The fund then will pay a fee within 90 days after the end of each of its fiscal years based upon the sale price of the fund securities sold during that fiscal year (including securities issued pursuant to a dividend reinvestment plan (''DRIP securities'')) reduced by (i) the aggregate redemption price of the securities redeemed during that year and (ii) the aggregate redemption price of the securities redeemed during any prior fiscal year ending on or after October 11, 1995 that were not used previously by the fund to reduce its registration fees. Section 24(f) will provide the exclusive means for registering fund securities.[14]

The Improvement Act also will replace the current provisions for late payment of registration fees with an interest payment requirement. A fund will not be deemed to have sold unregistered securities or lose the ability to net sales against redemptions solely because its registration fee was paid late. Instead, to compensate the U.S. Treasury for any delay in the receipt of revenues from a late payment of registration fees, amended section 24(f) will require the fund to pay interest charges on late payments.[15]

The Commission is proposing amendments to several rules and forms under the Investment Company Act and the Securities Act to implement the Improvement Act's amendments to section 24. The Commission also is proposing to rescind two rules under the Investment Company Act relating to the registration of fund securities that will no longer be necessary when the amendments to section 24 become effective.

II. Discussion

A. Amendments to Rule 24f-2

Rule 24f-2 currently contains detailed technical provisions setting out when Securities Act registration fees must be paid, the calculation of registration fees, and the circumstances under which a fund may net sales against redemptions in calculating its fee. As a result of the amendments to section 24(f), many of these provisions can be eliminated and the rule can be simplified significantly.[16]

1. Form Filing Requirements

The rule, as proposed to be amended, generally would require a fund to file a Form 24F–2 within 90 days after the end of each of its fiscal years.[17] The amended rule also would specify that any fund that pays the fee more than 90 days after the end of its fiscal year will be required to pay interest in the manner specified in amended section 24(f) and in Form 24F–2.

The Commission is proposing to eliminate the provision in current rule 24f-2 that a Form 24F–2 is deemed timely filed, regardless of when it reaches the Commission, if the fund establishes that it timely transmitted the Form to a third party that guaranteed delivery no later than the filing date.[18] This provision was adopted in 1995 in response to a series of late filings made by certain funds that would have resulted in these funds losing the ability to net redemptions against sales without exemptive relief from the Commission.[19] This provision appears inconsistent with one of the reasons for the interest payment requirement in amended section 24(f)—to compensate the U.S. Treasury for any delay in the timely receipt of revenue.[20]

The Commission is proposing to eliminate the requirement in current rule 24f-2 that a fund's Form 24F–2 be accompanied by an opinion of counsel stating that the securities which Form 24F–2 ''makes definite in number,'' were legally issued, fully paid, and non-assessable.[21] This opinion requirement no longer seems necessary in light of amended section 24(f)'s providing for the registration of an indefinite number of securities in all cases. In addition, the relevant registration forms require funds to file an opinion of counsel to address the legality of the securities being registered.[22]

Comment is requested on the general approach of the proposed amendments. Should any provisions that would be eliminated from the rule be retained? Comment also is requested whether the opinion requirement should be retained in order to provide additional assurance that fund securities are legally issued.

2. Fund Mergers and Reorganizations

Like the current rule, the amended rule would specify that the date on which a fund ceases operations would be deemed to be the end of the fund's fiscal year.[23] As under the current rule, a fund that ceases operations because it is merged into an operating fund would file a Form 24F–2 with respect to its final fiscal year. The acquiring fund would not assume the redemptions

[11] Under rule 24f–2, failure to pay the registration fee within 60 days after the end of the fund's fiscal year precludes the fund's netting sales against redemptions for purposes of fee calculations, resulting in a significantly higher registration fee. Failure to pay the fee within 180 days could result in the fund being deemed to have sold unregistered securities. These penalties were not designed to protect the interests of fund shareholders; rather, they reflected a mismatch of the fee payment structure of the Securities Act and the reality of fund operations. *See The Securities Investment Promotion Act of 1996: Hearing on S. 1815 Before the Senate Comm. on Banking, Housing, and Urban Affairs*, 104th Cong., 2d Sess. 39 (1996) (testimony of Arthur Levitt, Chairman, SEC).

[12] Section 203 of the Improvement Act, Pub. L. 104–290 (1996).

[13] Section 24(f)(1), as amended. Amended section 24(f) becomes effective on the earlier of October 11, 1997 or the effective date of Commission rulemaking implementing amended section 24(f). *See* 15 U.S.C. 80a–24 note. For purposes of convenience, section 24, as it will be amended when section 203 of the Improvement Act becomes effective, is referred to in this Release as ''amended section 24'' or ''section 24, as amended.''

[14] Section 203 of the Improvement Act will rescind the provisions of sections 24 (e) and (f) that allow for post-effective amendment and post-sale registration of securities. *See supra* notes 5–6 and accompanying text.

[15] Section 24(f)(3), as amended. *See also*, H.R. Rep. No. 622, 104th Cong., 2d Sess. 44 (1996) [hereinafter ''House Report'']. Payment of interest will not preclude the Commission from bringing an action to enforce the requirements of section 24(f). Section 24(f)(3), as amended.

[16] For example, the current rule requires a fund to *elect* to register an unlimited number of securities. Rule 24f-2(a) (17 CFR 24f-2(a)). This provision can be eliminated because, under section 24(f) as amended, all funds will be deemed to have registered an indefinite number of securities upon the effective date of their Securities Act registration statement. Similarly, the rule's netting provision can be eliminated because amended section 24(f) includes a netting provision. Finally, because funds are required to file Form 24F–2 with the Commission electronically using the Commission's Electronic Data Gathering, Analysis, and Retrieval system, the amended rule would not contain any provisions that suggest that the Form can be filed on paper.

[17] The current rule has a provision explaining how to calculate the relevant time periods under the rule. Rule 24f-2(e) (17 CFR 270.24f-2(e)). The amended rule would retain this provision, as well as the explanatory note that provides an example of how to determine the filing date. Proposed rule 24f–2(c).

[18] Rule 24f-2(f) (17 CFR 24f-2(f)).

[19] *See* Registration Fees for Certain Investment Companies, Investment Company Act Release No. 21332 (Sept. 1, 1995) (60 FR 47041 (Sept. 11, 1995)) (''1995 Adopting Release'') at nn.7–10 and accompanying text.

[20] *See supra* note 15 and accompanying text.

[21] Rule 24f-2(b)(1) (17 CFR 24f-2(b)(1)).

[22] *See, e.g.*, item 24(b)(10) of Form N–1A (requiring an opinion of counsel stating that the securities registered will, when sold, be legally issued, fully paid and non-assessable).

[23] Rule 24f–2(b)(3) (17 CFR 270.24f–2(b)(3)); proposed rule 24f–2(b).

(''redemption credits'') of the acquired fund to reduce its registration fees.

Rule 24f–2 provides two exceptions to this provision that would continue to be available under the amendment (''reorganization exceptions''). The first exception is a reorganization undertaken for the purpose of changing the state of incorporation or form of organization of a fund (''predecessor fund''), that satisfies the requirements of rule 414 of Regulation C under the Securities Act.[24] In such a reorganization, the fund that remains after the transaction (''successor fund''), may assume any remaining redemption credits of the predecessor fund. The other exception involves the merger of the predecessor fund into a newly-created series of a ''series company'' as defined in rule 18f–2 under the Investment Company Act.[25] In each case, the successor fund assumes the assets and liabilities of the predecessor fund, continues the predecessor fund's business, and each shareholder of the predecessor fund, following the transaction, owns the same *pro rata* interest in the same portfolio of securities as the shareholder owned before the transaction occurred. In both instances, therefore, the predecessor fund is not being acquired by an operating fund.

The proposed amendments would simplify the reorganization exceptions by deleting the references to rules 414 and 18f–2. The amended rule would permit the successor fund to assume the redemption credits of the predecessor fund if the successor fund (i) had no assets or liabilities, other than nominal assets or liabilities, and no operating history prior to the merger; and (ii) acquired all of the assets and assumed all of the liabilities and obligations of the predecessor fund.[26] Satisfying these conditions, which are derived from rule 414, demonstrates that the transaction was effected solely to change the form of organization of the predecessor fund. Comment is requested whether the proposed amendments would simplify the rule or whether the terminology of the current rule should be retained.

The proposed amendments would clarify that the reorganization exceptions are not available in a transaction designed to result in the predecessor fund merging with a fund that was not a shell prior to the merger.[27] This clarification is intended to prevent redemption credits from being preserved in instances when the ultimate purpose of the transaction is to merge the predecessor fund into an operating fund.

B. Amendments to Form 24F–2

Form 24F–2 was adopted by the Commission in 1995 to provide a standard format for the annual registration fee filings required by rule 24f-2.[28] The Commission is proposing amendments to Form 24F–2 to reflect the changes made by the Improvement Act. Form 24F–2, as proposed to be amended, would consist of 8 Items and Instructions for completing and filing the Form.[29] The proposed Items include identifying information about the fund, a worksheet for calculating the registration fee, and provisions regarding paying the fee and any interest that may be due.

1. General Information (Proposed Items 1–4)

Like the current Form, the amended Form would require certain identifying information concerning the fund and the class or series of securities to which the filing relates.[30] Unlike the current Form, the amended Form would not require information about securities registered other than pursuant to rule 24f–2.[31] This information is not directly relevant to the calculation of the registration fee; rather the Items requiring this information were designed to assist funds in determining that all their securities were registered. The need to determine this information will be substantially reduced as funds sell shares that were previously registered. Comment is requested whether the Form should continue to require this information to assist fund compliance personnel in determining whether securities sold by the fund have been appropriately registered.

2. The Worksheet

The proposed worksheet in Form 24F–2 would be less complex than the one in the current Form, reflecting the simplified registration system of amended section 24(f). It would consist of eight line items.

a. Sales Information (Proposed Item 5(i)).

Section 24(f)(2), as amended, will require that a fund calculate its fee based *only* on the number of securities sold during the fiscal year pursuant to an indefinite registration of securities under section 24(f). In this way, section 24(f) will avoid imposing a fee on securities that were registered pursuant to section 24(e) prior to the effective date of the amendments to section 24(f) and on which a registration fee had already been paid.[32]

Reflecting the statutory provision, proposed Item 5(i) of the worksheet would require the aggregate sale price of securities sold during the fiscal year pursuant to section 24(f). Proposed Instruction to the amended Form would remind funds to include in this Item DRIP securities, as required by amended section 24(f), but not to include previously registered shares.[33]

b. Redemption Information (Proposed Items 5(ii)—5(iv)). Section 24(f)(2), as amended, will provide that in calculating its registration fee a fund may reduce the amount of securities sold during the fiscal year by (i) the aggregate price of securities redeemed during the fiscal year, and (ii) the aggregate price of the securities redeemed during any prior fiscal year ending on or after October 11, 1995 that were not used previously to reduce fees. In this way, amended section 24(f) will

[24] Rule 24f–2(b)(3)(i) (17 CFR 270.24f–2(b)(3)(i)); rule 414 ([17 CFR 230.414). Rule 414 generally provides that the registration statement of a predecessor company will be deemed to be the registration statement of the successor company when the purpose of the reorganization is to change the company's domicile or form of organization, provided certain conditions are satisfied.

[25] Rule 24f–2(b)(3)(ii) (17 CFR 270.24f–2(b)(3)(ii)); rule 18f–2 (17 CFR 270.18f–2). A series company is a fund that issues two or more series of securities, each of which is preferred over all other series with respect to a specific portfolio of assets. A merger into a series of another fund generally would not satisfy the requirements of rule 414 because the successor series would be part of a separately registered series company and would not necessarily adopt the predecessor fund's registration statement as its own, as required by rule 414.

[26] Proposed rule 24f–2(b). The proposed amendments would make clear that the successor fund may be a series of a series company.

[27] Proposed rule 24f–2(b)(3).

[28] *See* 1995 Adopting Release, *supra* note 19, at nn. 33–43 and accompanying text.

[29] Reflecting current practice, the proposed amendments would require a fund choosing to calculate registration fees on a class-by-class or series-by-series basis to make one filing, consisting of a separate Form 24F–2 for each class or series. *See* Instruction A.1 to Form 24F–2 as proposed to be amended.

[30] Items 1, 2, 3 and 4 of Form 24F–2 as proposed to be amended. Proposed Item 4, which requires the fund to provide the date of its fiscal year-end also would require the fund to indicate whether the Form was being filed late. This requirement is designed to facilitate Commission processing of a late filing that would require the payment of interest. Proposed Item 4 also would include a box to be checked if the filing is the last time the fund will be filing the Form (for example, if the fund is ceasing operations). This Item would replace current Item 6, which requires a fund to indicate if it is terminating its rule 24f–-2 declaration.

[31] Items 7, 8 and 9 of Form 24F–2.

[32] As discussed above, after the effective date of the amendments to section 24(f), all funds will be deemed to have registered an indefinite number of securities and no fund will have reason to register a definite number of securities and pay a registration fee on the securities at the time of their registration. In addition, with the repeal of section 24(e)(1), funds may not register additional securities on a post-effective amendment.

[33] Instruction C.4 to Form 24F–2, as proposed to be amended.

permit funds to net redemptions during the fiscal year or earlier fiscal years against sales without having to ''preserve'' those redemption credits through filing periodic post-effective amendments pursuant to section 24(e).[34]

Reflecting the statutory provision, proposed Item 5(ii) would require the aggregate price of securities redeemed or repurchased during the fiscal year, and proposed Item 5(iii) would require the aggregate price of securities redeemed or repurchased during any *prior* fiscal year ending no earlier than October 11, 1995.[35] The total amount of available redemption credits would be set forth in proposed Item 5(iv).

c. Registration Fee Calculation (Proposed Items 5(v)–5(viii)).

In order to determine the fund's net aggregate sale price of securities for purposes of calculating the registration fee, the fund's aggregate redemptions (proposed Item 5(iv)) would be subtracted from the fund's aggregate sales (proposed Item 5(i)). If sales exceeded redemptions, the result would be set forth in proposed Item 5(v). This amount would be used to calculate the fund's registration fee.

If the fund's aggregate redemptions exceeded the fund's aggregate sales, the amount would be set forth in proposed Item 5(vi). In this case, the fund would not be required to pay a registration fee. As provided by amended section 24(f), these redemption credits could be used by the fund in future years to reduce registration fees.

Proposed Item 5(vii) would require the fund to set forth the multiplier for determining the registration fee.[36] The registration fee due would be set forth in proposed Item 5(viii).[37]

3. Interest and Other Payment Information (Proposed Items 6–8)

Proposed Item 6 would be completed only by funds that filed the Form late. It would require the fund to report the amount of interest due (if any).[38] The total of the registration fee and interest payment would be reported in proposed Item 7. Proposed Item 8 would contain information about when and how the fund's payment was sent to the Commission's lockbox depository.

4. Request for Comment

Comment is requested on the proposed amendments to Form 24F–2. Will the amended Form assist funds in calculating their registration fees? Should any additional information be required or is any of the information proposed to be set forth on the Form unnecessary? Do the proposed Instructions to the amended Form adequately address the procedures for completing and filing the Form?

C. Conforming Amendments

1. Rule Rescissions

The Improvement Act will, when effective, eliminate the provisions of the Investment Company Act that relate to the registration of fund securities by post-effective amendment.[39] As a result of those changes, rule 24e–2, the rule that addresses the computation of fees on securities registered by post-effective amendment, will be extraneous, and the Commission is proposing that it be rescinded. Similarly, because the Improvement Act will eliminate the provision of section 24(f) of the Investment Company Act that allows for post-sale registration, the Commission is proposing to rescind rule 24f–1, which details the procedures for post-sale registration.

2. Conforming Amendments to Forms and Rules

The forms used by funds to register securities under the Securities Act contain provisions on their cover pages and related instructions concerning the calculation and payment of registration fees and the registration of an indefinite number of securities under current rule 24f–2.[40] The Commission is proposing to modify these forms to delete these provisions or to conform them to amended section 24(f).

The Commission also is proposing a conforming amendment to rule 485 under the Securities Act, the rule that permits post-effective amendments to certain fund registration statements to become effective automatically. Currently, rule 485 permits a fund's registration statement filed to increase the number of securities registered or to register an indefinite number of securities to become effective immediately.[41] These provisions would be eliminated. In addition, the Commission is proposing to amend certain rules relating to registration fee payments to reflect amended section 24.[42] Finally, cross-references to section 24(e)(3) of the Investment Company Act in rule 24e–1 under the Investment Company Act would be changed to reflect that that section will become section 24(e).

D. General Request for Comment

Any interested persons wishing to submit written comments on the proposed rule and form changes that are the subject of this Release, to suggest additional changes (including changes to provisions of the rules that the Commission is not proposing to amend), or to submit comments on other matters that might have an effect on the proposals described above, are requested to do so. Commenters suggesting alternative approaches are encouraged to submit proposed rule text.

III. Cost/Benefit Analysis

The Commission is sensitive to the costs and benefits imposed by its rules. The Commission notes that the proposed amendments implement the changes mandated by the Improvement Act to the system for registering fund securities under the Securities Act. The proposed amendments reflect the requirements of amended section 24 of the Investment Company Act and do not impose any additional requirements. The proposed amendments to Form 24F–2 should assist funds in calculating their registration fees and interest, if any, under amended section 24(f). Based on its experience with Form 24F–2, the Commission believes that the benefits to funds and the Commission of having a standardized format for registration fee

[34] Had Congress not included a ''cut-off'' date (*i.e.*, fiscal years ended on or after October 11, 1995), funds arguably could have used as credits securities redeemed before rule 24f–2 was adopted in 1977. Since redemptions occurring before October 11, 1995 would have to have been ''preserved'' by registering securities pursuant to rule 24e–2 before the effective date of the amendments, and since such newly registered securities would not have been registered pursuant to an indefinite registration pursuant to amended section 24(f), the provision should not result in the loss of any redemption credits of any fund that is entitled to use them to reduce registration fees. *See* House Report, *supra* note 15, at 44. *See also supra* note 10.

[35] In each case, proposed Instructions C.5 and C.6 to the amended Form would remind funds not to include redemptions that were previously used to reduce registration fees payable to the Commission.

[36] The multiplier for calculation of the registration fee is determined by the Commission in accordance with section 6(b) of the Securities Act. As of October 1, 1996, the multiplier was 1/3300. This multiplier is subject to change from time to time, without notice, by act of Congress. The Commission staff has found that most mistakes in Form 24F–2 filings arise from the use of the wrong multiplier. Having the fund set forth the multiplier it used often enables the staff to quickly determine and notify the fund of the source of the error. Proposed Instruction C.3 to the Form would remind funds to determine the current fee rate prior to filing. Changes in the multiplier are generally posted on the Commission's web site.

[37] A fund that showed net redemptions in proposed Item 5(vi) would enter ''0'' in Item 5(viii).

[38] The manner in which interest should be calculated would be set forth in proposed Instruction D.

[39] *See* 15 USC 80a–24(e) (1) and (2).

[40] Form S–6, Form N–1A, Form N–3, Form N–4, and Form N–14.

[41] Rule 485(b) (i) and (ii) [17 CFR 230.485(b) (i) and (ii)].

[42] Rule 3a of Informal and Other Procedures and rule 13 of Regulation S–T.

filings and the guidance provided by the Form should outweigh any burdens associated with filing the Form. Form 24F–2 has made it easier for funds to calculate registration fees and reduced errors in fee calculations. The Form as proposed to be amended would continue these benefits. The Commission does not believe that the amended Form would impose any significant one-time or ongoing costs on funds. The proposed amendments to funds' registration forms also are designed to reflect amended section 24 and would not require funds to obtain or provide any information that is not currently required by these forms.

The Commission requests comment on any of these matters.

IV. Paperwork Reduction Act

Certain provisions of the proposed amendments contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995,[43] and the Commission has submitted them to the Office of Management and Budget (''OMB'') for review in accordance with 44 USC 3507(d) and 5 CFR 1320.11. The title for the collection of information is ''Proposed Amendments to Forms 24F–2, N–1A, N–3, N–4, N–14 and S–6.'' The Forms contain currently approved collections of information under OMB control numbers 3235–0456, 3235–0307, 3235–0316, 3235–0318, 3235–0336 and 3235–0184, respectively. The proposed amendments to these collections of information are necessary to implement the changes to section 24 of the Investment Company Act made by the Improvement Act. An agency may not sponsor, conduct, or require response to an information collection unless a currently valid OMB control number is displayed.

Form 24F–2 provides a standardized format for funds' annual registration fee filings and assists funds in calculating the fees. Form N–1A is used by open-end management investment companies to register with the Commission as investment companies under the Investment Company Act and to register their offerings of securities under the Securities Act. Form N–3 is used by insurance company separate accounts organized as management investment companies to register with the Commission as investment companies under the Investment Company Act and to register their offerings of securities under the Securities Act. Form N–4 is used by insurance company separate accounts organized as unit investment trusts (''UITs'') to register with the Commission as investment companies under the Investment Company Act and to register their offerings of securities under the Securities Act. Form S–6 is used by UITs to register their securities under the Securities Act (UITs register as investment companies on a separate Form N–8B–2). Form N–14 is used by investment companies to register under the Securities Act securities issued in business combination transactions. The primary purpose of the registration process and registration forms is to provide disclosure of financial and other information to investors and potential investors for the purpose of evaluating an investment in a security.

Form 24F–2 is required to be filed annually. Forms N–1A, N–3, and N–4 are filed annually and updated on occasion. Form N–14 is filed on occasion. Form S–6 is filed annually. It is estimated that approximately 6681 funds file Form 24F–2, 7500 funds file Form N–1A, 53 funds file Form N–3, 288 funds file Form N–4, 95 funds file Form N–14, and 3263 funds file Form S–6. The average annual burden per respondent for Form 24F–2 is estimated to be 1.9 hours, for Form N–1A, 213 hours, for Form N–3, 512.3 hours, for Form N–4, 138.35 hours, for Form N–14, 620 hours, and for Form S–6, 35 hours. The total annual burden for all respondents for Form 24F–2 is estimated to be 12,694 hours, for Form N–1A, 990,000 hours, for Form N–3, 27,499 hours, for Form N–4, 40,562 hours, for Form N–14, 58,900 hours, and for Form S–6, 114,205 hours. The proposed amendments would reduce the annual burden per respondent for Form 24F–2 from 1.9 hours to 1 hour. The proposed amendments would not result in any change in the burden hours for the registration forms.

The information collection requirements imposed by Form 24F–2 and the registration forms are mandatory. Responses to the collection of information will not be kept confidential.

Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments to (i) evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (ii) evaluate the accuracy of the agency's estimate of the burden of the proposed collections of information; (iii) enhance the quality, utility, and clarity of the information to be collected; (iv) minimize the burden of the collections of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Persons desiring to submit comments on the collection of information requirements should direct them to the Office of Management and Budget, Attention: Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Washington, D.C. 20503, and should also send a copy of their comments to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Stop 6–9, Washington, DC 20549 with reference to File No. S7–19–97. OMB is required to make a decision concerning the collections of information between 30 and 60 days after publication, so a comment to OMB is best assured of having its full affect if OMB receives it within 30 days of publication.

V. Summary of Regulatory Flexibility Analysis

The Commission has prepared an Initial Regulatory Flexibility Analysis (''IRFA'') in accordance with 5 U.S.C. 603 regarding the proposed rule and form amendments. The IRFA states that the proposed amendments to rule 24f–2 and Form 24F–2 would implement the provisions of the Improvement Act governing registration of fund securities under the Securities Act. The IRFA further states that the proposed conforming amendments to rules and forms would conform the relevant provisions of these rules and forms to the requirements of amended section 24 of the Investment Company Act. The IRFA indicates that the proposed amendments are designed to make it easier for funds to comply with the new statutory provisions and provide guidance on calculating registration fees on fund securities.

The IRFA sets forth the statutory authority for the proposed amendments. The IRFA also discusses the effect of the proposed amendments on funds that are small entities. For purposes of the proposed amendments, small entities are funds with assets of $50 million or less at the end of their most recent fiscal year. Based on a review of data filed by funds with the Commission, it is estimated that approximately 948 funds may be considered small entities. The IRFA states that the proposed amendments would assist small entities in complying with the new statutory requirements.

The IRFA states that the proposed amendments would not impose any new reporting, recordkeeping or other compliance requirements, and that the Commission believes that there are no

[43] 44 USC 3501.

rules that duplicate, overlap or conflict with the proposed amendments.

The IRFA discusses the various alternatives considered by the Commission in connection with the proposed amendments that might minimize the effect on small entities, including: (a) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (b) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for small entities; (c) the use of performance rather than design standards; and (d) an exemption from coverage of the rule, or any part of the rule, for small entities. Performance, rather than design, standards are incorporated in amended section 24(f) of the Act, and are therefore incorporated into the proposed rule and form amendments, to the extent that (i) registration fees on fund shares are based on sales less redemptions, and (ii) a fund is required to pay interest if the registration fee is paid late.

The Commission believes that it would be inconsistent with the purposes of amended section 24 of the Investment Company Act to exempt small entities from the proposed amendments. The Commission considered not having a standardized form to accompany the funds' annual registration fee filings. Based on the Commission's and funds' experience prior to the adoption of Form 24F–2, and the comments received when Form 24F–2 was proposed, however, the Commission believes that Form 24F–2 has been beneficial. Form 24F–2 has made it easier for funds to calculate registration fees and reduced errors in fee calculations.

Different compliance or reporting requirements for small entities are not necessary because the proposed amendments do not establish any new reporting, recordkeeping or compliance requirements. The Commission has determined that it is not feasible to further clarify, consolidate or simplify the proposed amendments for small entities.

The IRFA includes information concerning the solicitation of comments with respect to the IRFA. Cost-benefit information reflected in the ''Cost-Benefit Analysis'' section of this Release also is reflected in the IRFA. A copy of the IRFA may be obtained by contacting Robin S. Gross, Securities and Exchange Commission, 450 5th Street, NW., Mail Stop 10–2, Washington, DC. 20549.

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996, the Commission also requests information regarding the potential impact of the proposed amendments on an annual basis. Commenters should provide empirical data to support their views.

VI. Statutory Authority

The Commission is proposing to rescind rules 24e–2 and 24f–1, and amend rules 24e–1 and 24f–2 and Form 24F–2, pursuant to the authority set forth in sections 24 and 38(a) of the Investment Company Act (15 U.S.C. 80a–24, –37(a). The Commission is proposing to amend rule 485 pursuant to the authority set forth in sections 6, 7, 8, 10 and 19(a) of the Securities Act (15 U.S.C. 77f, 77h, 77j, 77s(a)) and section 38 of the Investment Company Act. The authority citations for the proposed amendments to Forms N–1A, N–3, N–4, N–14 and S–6, and rule 13 of Regulation S–T and rule 3a of Informal and Other Procedures precede the text of the amendments.

Text of Proposed Rule and Form Amendments

List of Subjects

17 CFR Part 202

Administrative practice and procedure, Securities.

17 CFR Parts 230, 270 and 274

Investment companies, Reporting and recordkeeping requirements, Securities.

17 CFR Part 232

Administrative practice and procedure, Reporting and recordkeeping requirements, Securities.

17 CFR Part 239

Reporting and recordkeeping requirements, Securities.

For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is proposed to be amended as follows:

PART 202—INFORMAL AND OTHER PROCEDURES

1. The authority citation for part 202 continues to read in part as follows:

Authority: 15 U.S.C. 77s, 77t, 78d–1, 78u, 78w, 78*ll*(d), 79r, 79t, 77sss, 77uuu, 80a–37, 80a–41, 80b–9, and 80b–11, unless otherwise noted.

* * * * *

§ 202.3a [Amended]

2. In § 202.3a, the seventh sentence of the introductory text is amended by adding the phrase '', including fees paid pursuant to section 24(f) of the Investment Company Act of 1940 (15 U.S.C. 80a–24(f))'' after the phrase ''Section 6(b) of the Securities Act of 1933''.

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

3. The authority citation for part 230 continues to read in part as follows:

Authority: 15 U.S.C. 77b, 77f, 77g, 77h, 77j, 77s, 77sss, 78c, 78d, 78*l*, 78m, 78n, 78o, 78w, 78*ll*(d), 78t, 80a–8, 80a–29, 80a–30, and 80a–37, unless otherwise noted.

* * * * *

§ 230.485 [Amended]

4. Section 230.485 is amended by removing paragraphs (b)(1) (i) and (ii) and redesignating paragraphs (b)(1) (iii) through (ix) as paragraphs (b)(1) (i) through (vii), revising the reference to ''paragraph (b)(1)(ix)'' in the introductory text of paragraph (b)(2) to read ''paragraph (b)(1)(vii)'' and the two references to ''paragraph (b)(1)(v)'' in paragraph (d)(2)(ii)(B) and the undesignated paragraph that follows to read ''paragraph (b)(1)(iii)''.

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

5. The authority citation for part 232 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77sss(a), 78c(b), 78*l*, 78m, 78n, 78o(d), 78w(a), 78*ll*(d), 79t(a), 80a–8, 80a–29, 80a–30 and 80a–37.

§ 232.13 [Amended]

6. Section 232.13 is amended in paragraph (a)(1)(iii) by adding after the words ''Securities Act filings'' the phrase '', including filings under section 24(f) of the Investment Company Act (15 U.S.C. 80a–24(f))''.

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

7. The authority citation for part 239 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77z–2, 77sss, 78c, 78*l*, 78m, 78n, 78o(d), 78u–5, 78w(a), 78*ll*(d), 79e, 79f, 79g, 79j, 79l, 79m, 79n, 79q, 79t, 80a–8, 80a–29, 80a–30 and 80a–37, unless otherwise noted.

* * * * *

§ 239.16 [Form S–6 Amended]

8. Form S–6 (referenced in § 239.16) is amended on the cover page by removing the words ''and amount'' in Item E, removing Items F and G, and redesignating Item H as Item F.

Note: Form S–6 does not and the amendment will not appear in the Code of Federal Regulations.

Note: Form N–14 does not and the amendments will not appear in the Code of Federal Regulations.

§ 239.23 [Form N–14 Amended]

9. Form N–14 (referenced in § 239.23) is amended on the cover page by revising the Instruction to the table ''Calculation of Registration Fee under the Securities Act of 1933'' to read as follows:

Form N–14

* * * * *

Calculation of Registration Fee under the Securities Act of 1933

* * * * *

Instruction

Registrants relying on section 24(f) of the Investment Company Act, which permits registration of an indefinite number of securities, need not include the Securities Act registration fee table, but must provide the ''Title of Securities Being Registered'' and state that no filing fee is due because of reliance on section 24(f).

* * * * *

§ 239.23 [Form N–14 amended]

10. Form N–14 (referenced in § 239.23) is amended by revising General Instruction B to read as follows:

Form N–14

* * * * *

General Instructions

* * * * *

B. Registration Fee

Section 6(b) of the 1933 Act and Rule 457 (17 CFR 230.457) thereunder set forth the fee requirements under the 1933 Act. Registrants relying on section 24(f) of the 1940 Act, which permits registration of an indefinite number of shares, are directed to rule 24f–2 under the 1940 Act (17 CFR 270.24f–2) regarding payment of the registration fee. If, contemporaneous with a filing on Form N–14, an open-end management company is offering its securities to the public by means of a current prospectus under an effective registration statement, the prospectus included in a registration statement filed on Form N–14 may be used, under Rule 429(a) (17 CFR 230.429(a)), in connection with the securities covered by the earlier registration statement.

* * * * *

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

11. The authority citation for part 270 is amended by adding the following citation to read as follows:

Authority: 15 U.S.C. 80a–1 *et seq.*, 80a–37, 80a–39 unless otherwise noted;

* * * * *

Section 270.24f–2 also issued under 15 U.S.C. 80a–24(f)(4).

§ 270.24e–1 [Amended]

12. Section 270.24e–1 is amended by removing the reference ''24(e)(3)'' each time it appears and adding the reference ''24(e)''.

§ 270.24e–2 [Removed]

13. Section 270.24e–2 is removed.

§ 270.24f–1 [Removed]

14. Section 270.24f–1 is removed.

15. Section 270.24f–2 is revised to read as follows:

§ 270.24f–2. Registration under the Securities Act of 1933 of certain investment company securities.

(a) *General.* Any face-amount certificate company, open-end management company or unit investment trust (''issuer'') that is deemed to have registered an indefinite amount of securities pursuant to section 24(f) of the Act (15 U.S.C. 80a–24(f)) shall, not later than 90 days after the end of any fiscal year during which it has publicly offered such securities, file Form 24F–2 (17 CFR 274.24) with the Commission. Form 24F–2 shall be prepared in accordance with the requirements of that Form, and shall be accompanied by the payment of a registration fee with respect to the securities sold during the fiscal year in reliance upon registration pursuant to section 24(f) of the Act calculated in the manner specified in section 24(f) of the Act and such Form. An issuer that pays the registration fee more than 90 days after the end of its fiscal year shall pay interest in the manner specified in section 24(f) of the Act and in Form 24F–2.

(b) *Issuer ceasing operations; mergers and other transactions.* For purposes of this section, if an issuer ceases operations, the date the issuer ceases operations shall be deemed to be the end of its fiscal year. In the case of a liquidation, merger, or sale of all or substantially all of the assets (''merger'') of the issuer, the issuer shall be deemed to have ceased operations for purposes of this section on the date the merger is consummated; *provided, however,* that in the case of a merger of an issuer or a series of an issuer (''Predecessor Issuer'') with another issuer or a series of that issuer (''Successor Issuer''), the Predecessor Issuer shall not be deemed to have ceased operations and the Successor Issuer shall assume the obligations, fees, and redemption credits of the Predecessor Issuer incurred pursuant to section 24(f) of the Act and § 270.24e–2 (as in effect prior to the effective date of its rescission) if the Successor Issuer:

(1) Had no assets or liabilities, other than nominal assets or liabilities, and no operating history immediately prior to the merger;

(2) Acquired all of the assets and assumed all of the liabilities and obligations of the Predecessor Issuer; and

(3) The merger is not designed to result in the Predecessor Issuer merging with, or substantially all of its assets being acquired by, an issuer (or a series of that issuer) that would not meet the conditions of paragraph (b)(1) of this section.

(c) *Counting days.* To determine the date on which Form 24F–2 must be filed with the Commission under paragraph (a) of this section, the first day of the 90 day period shall be the first calendar day of the fiscal year following the fiscal year for which the Form is to be filed. If the last day of the 90 day period falls on a Saturday, Sunday or Federal holiday, the period shall end on the first business day thereafter.

Note to paragraph (c): For example, a Form 24F–2 for a fiscal year ending on June 30 must be filed no later than September 28. If September 28 falls on a Saturday or Sunday, the Form must be filed on the following Monday.

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

16. The authority citation for part 274 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78*l*, 78m, 78n, 78o(d), 80a–8, 80a–24, and 80a–29, unless otherwise noted.

Note: Form N–1A does not and the amendments will not appear in the Code of Federal Regulations.

§§ 239.15A and 274.11A [Form N–1A Amended]

17. Form N–1A (referenced in § 239.15A and § 274.11A) is amended on the cover page by removing the words ''Calculation of Registration Fee Under the Securities Act of 1933'' and the accompanying chart and note, and adding the following:

''Title of Securities Being Registered . . . . .

Omit from the facing sheet reference to the other Act if the Registration Statement or amendment is filed under only one of the Acts. Include the ''Approximate Date of Proposed Public Offering'' and ''Title of Securities Being Registered'' only where securities are being registered under the Securities Act of 1933.''

§§ 239.15A and 274.11A [Form N–1A Amended]

18. Form N–1A (referenced in § 239.15A and § 274.11A) is amended by

revising General Instruction B to read as follows:

Form N–1A

* * * * *

General Instructions

* * * * *

B. Registration Fees

Registration fees should not be paid when filing this form. *See* section 24(f) of the Investment Company Act and rule 24f–2 thereunder.

* * * * *

§§ 239.15A and 274.11A [Form N–1A Amended]

19. Form N–1A (referenced in § 239.15A and § 274.11A) is amended by revising General Instruction F.2 to read as follows:

Note: Form N–1A does not and the amendments will not appear in the Code of Federal Regulations.

Form N–1A

* * * * *

General Instructions

* * * * *

F. Documents Comprising Registration Statement or Amendment

* * * * *

2. A registration statement or an amendment thereto which is filed under only the 1933 Act shall contain all the information and documents specified in paragraph 1 of this Instruction F.

* * * * *

§§ 239.15A and 274.11A [Form N–1A Amended]

20. Form N–1A (referenced in § 239.15A and § 274.11A) is amended by removing General Instruction F.3 and redesignating General Instruction F.4 as General Instruction F.3.

Note: Form N–1A does not and the amendments will not appear in the Code of Federal Regulations.

§§ 239.17a and 274.11b [Form N–3 Amended]

21. Form N–3 (referenced in § 239.17a and § 274.11b) is amended on the cover page by removing the words ''Calculation of Registration Fee Under the Securities Act of 1933'' and the accompanying chart and note, and adding the following:

''Title of Securities Being Registered . . . . .

Omit from the facing sheet reference to the other Act if the Registration Statement or amendment is filed under only one of the Acts. Include the ''Approximate Date of Proposed Public Offering'' and ''Title of Securities Being Registered'' only where securities are being registered under the Securities Act of 1933.

Note: Form N–3 does not and the amendments will not appear in the Code of Federal Regulations.

§§ 239.17a and 274.11b [Form N–3 Amended]

22. Form N–3 (referenced in § 239.17a and § 274.11b) is amended by revising General Instruction B to read as follows:

Note: Form N–3 does not and the amendments will not appear in the Code of Federal Regulations.

Form N–3

* * * * *

General Instructions

* * * * *

B. Registration Fees

Registration fees should not be paid when filing this form. *See* section 24(f) of the Investment Company Act and rule 24f–2 thereunder.

* * * * *

§§ 239.17a and 274.11b [Form N–3 Amended]

23. Form N–3 (referenced in § 239.17a and § 274.11b) is amended by revising General Instruction H.2 to read as follows:

Note: Form N–3 does not and the amendments will not appear in the Code of Federal Regulations.

Form N–3

* * * * *

General Instructions

* * * * *

H. Documents Comprising Registration Statement or Amendment

* * * * *

2. A registration statement or an amendment to it which is filed under only the 1933 Act shall contain all the information and documents specified in paragraph 1 of this Instruction H.

* * * * *

§§ 239.17a and 274.11b [Form N–3 Amended]

24. Form N–3 (referenced in § 239.17a and § 274.11b) is amended by removing General Instruction H.3 and redesignating General Instructions H.4 and H.5 as General Instructions H.3 and H.4.

Note: Form N–3 does not and the amendments will not appear in the Code of Federal Regulations.

§§ 239.17b and 274.11c [Form N–4 Amended]

25. Form N–4 (referenced in § 239.17b and § 274.11c) is amended on the cover page by removing the words ''Calculation of Registration Fee Under the Securities Act of 1933'' and the accompanying chart and note, and adding the following:

''Title of Securities Being Registered . . .

Omit from the facing sheet reference to the other Act if the Registration Statement or amendment is filed under only one of the Acts. Include the ''Approximate Date of Proposed Public Offering'' and ''Title of Securities Being Registered'' only where securities are being registered under the Securities Act of 1933.''

Note: Form N–4 does not and the amendments will not appear in the Code of Federal Regulations.

§§ 239.17b and 274.11c [Form N–4 Amended]

26. Form N–4 (referenced in § 239.17b and § 274.11c) is amended by revising General Instruction B to read as follows:

Note: Form N–4 does not and the amendments will not appear in the Code of Federal Regulations.

Form N–4

* * * * *

General Instructions

* * * * *

B. Registration Fees

Registration fees should not be paid when filing this form. *See* section 24(f) of the Investment Company Act and rule 24f–2 thereunder.

* * * * *

§§ 239.17b and 274.11c [Form N–4 Amended]

27. Form N–4 (referenced in § 239.17b and § 274.11c) is amended by revising General Instruction H.2 to read as follows:

Note: Form N–4 does not and the amendments will not appear in the Code of Federal Regulations.

Form N–4

* * * * *

General Instructions

* * * * *

H. Documents Comprising Registration Statement or Amendment

* * * * *

2. A registration statement or an amendment to it which is filed under only the 1933 Act shall contain all the information and documents specified in paragraph 1 of this Instruction H.

* * * * *

§§ 239.17b and 274.11c [Form N–4 Amended]

28. Form N–4 (referenced in § 239.17b and § 274.11c) is amended by removing General Instruction H.3 and redesignating General Instructions H.4 and H.5 as General Instructions H.3 and H.4.

29. Section 274.24 and Form 24F–2 are revised to read as follows:

§ 274.24 Form 24F–2, annual notice of securities sold pursuant to registration of certain investment company securities.

Form 24F–2 shall be used as the annual report filed by face amount certificate companies, open-end management companies, and unit investment trusts pursuant to § 270.24f–2 of this chapter for reporting securities sold during the fiscal year.

Note: Form 24F–2 does not and the amendments will not appear in the Code of Federal Regulations. A copy of Form 24F–2 as proposed to be revised is attached as Appendix I to this document.

Dated: July 14, 1997.

By the Commission.

Margaret H. McFarland

Deputy Secretary.

BILLING CODE 8010–01–U

APPENDIX I

OMB APPROVAL
OMB Number: 3235-0456
Expires:
Estimated average burden hours per response: 1

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 24F-2
Annual Filing under Rule 24f-2 of the Investment Company Act of 1940

Read instructions at end of Form before preparing Form.
Please print or type.

1. Name and address of issuer:
2. The name of each series or class of securities for which this Form is filed (leave this item blank if the Form is being filed for all series and classes of securities of the issuer):
3. Investment Company Act File Number: _____ Securities Act File Number: _____
4(a). Last day of fiscal year for which this Form is filed: _____
4(b). [ ] Check box if this Form is being filed late (*i.e.*, more than 90 days after the end of the issuer's fiscal year). *Note: If the Form is being filed more than 90 days after the end of the issuer's fiscal year, interest must be paid on the registration fee due.*
4(c). [ ] Check box if this is the last time the issuer will be filing this Form.

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5. Calculation of registration fee:

(i)	Aggregate sale price of securities sold during the fiscal year pursuant to section 24(f):		$ _____
(ii)	Aggregate price of securities redeemed or repurchased during the fiscal year:	$ _____	
(iii)	Aggregate price of securities redeemed or repurchased during any *prior* fiscal year ending no earlier than October 11, 1995 that were not previously used to reduce registration fees payable to the Commission:	$ _____	
(iv)	Total available redemption credits [add Items 5(ii) and 5(iii)]:		--$ _____
(v)	Net sales -- if Item 5(i) is greater than Item 5(iv) [subtract Item 5(iv) from Item 5(i)]:		$ _____
(vi)	Redemption credits available for use in future years -- if Item 5(i) is less than Item 5(iv) [subtract Item 5(iv) from Item 5(i)]:	$ ( )	
(vii)	Multiplier for determining registration fee (See Instruction C.8):		x _____
(viii)	Registration fee due [multiply Item 5(v) by Item 5(vii)] (enter "0" if no fee is due):		= $ _____

6. Interest due -- if this Form is being filed more than 90 days after the end of the issuer's fiscal year (see Instruction D):

+ $ _____

7. Total of the amount of the registration fee due plus any interest due [Item 5(vii) plus Item 6]:

= $ _____

8. Date the registration fee and any interest payment was sent to the Commission's lockbox depository: _____

Account Number: _____

Method of Delivery:

[ ] Wire Transfer
[ ] Mail or other means

SIGNATURES

This Form has been signed below by the following persons on behalf of the issuer and in the capacities and on the dates indicated.

By (Signature and Title)* _____

_____

Date _____

* Please print the name and title of the signing officer below the signature.

BILLING CODE 8010–01–C

Form 24F–2

Annual Filing Under Rule 24f–2 of the Investment Company Act of 1940

Instructions

A. General

1. This Form should be used by an open-end management investment company, face amount certificate company, or unit investment trust (''issuer'') for annual notices required by rule 24f–2 under the Investment Company Act of 1940 [15 U.S.C. 80a *et seq.*] (''Investment Company Act''). If the issuer has registered more than one class or series of securities on the same registration statement under the Securities Act of 1933 [15 U.S.C. 77a *et seq.*] (''Securities Act''), the issuer may file a single Form 24F–2 for those classes or series that have the same fiscal year end. An issuer choosing to calculate registration fees on a class-by-class or series-by-series basis should make a single filing consisting of a separate Form 24F–2 for each class or series.

2. This Form must be filed within 90 days after the end of the issuer's fiscal year. See Instruction B.4.

3. Pursuant to rule 101(a)(1)(i) of Regulation S–T [17 CFR 232.101(a)(1)(i)] this Form must be submitted in electronic format using Commission's Electronic Data Gathering, Analysis, and Retrieval (''EDGAR'') system. Consult the EDGAR Filer Manual and Appendices for instructions on how to properly construct the submission header for an electronic 24F–2 EDGAR filing.

4. This Form must be accompanied by the appropriate registration fee. If the Form is being filed late, interest must be paid. See Instruction D.

5. This Form will be deemed filed with the Commission on the date on which it is received by the Commission. The Commission will not accept for filing any Form accompanied by insufficient payment of the registration fee. A Form accompanied by insufficient payment of the registration fee will be returned to the issuer for proper payment and will not be deemed filed until receipt by the Commission of proper payment of the registration fee. No part of the registration fee is refundable. Issuers should refer to rule 0–8 under the Investment Company Act [17 CFR 270.0–8], rule 3a of the Commission's Rules of Informal and Other Procedures [17 CFR 202.3a], and rule 13(c) under Regulation S–T [17 CFR 232.13(c)] for instructions on payment of fees to the Commission.

B. Identifying Information

1. Item 1—Provide the name of the issuer as it appears on the cover of the issuer's most recent Securities Act registration statement or post-effective amendment.

2. Item 2—If the Form is being filed for all classes and series of securities of the issuer, Item 2 may be left blank.

3. Item 3—The Investment Company Act file number should be the number assigned to the issuer's registration statement filed under the Investment Company Act (beginning with ''811–''). The Securities Act file number in Item 3 is the number of the registrant's most recent Securities Act registration statement (beginning with ''2–'', ''33–'' or ''333–'').

4. Item 4(a)—In the case of an issuer that ceases operations, the date it ceases operations is deemed the last day of its fiscal year for purposes of section 24(f) of the Investment Company Act.

5. Item 4(b)—Check the box if the Form is filed late. If the issuer files the Form late, the issuer is required under section 24(f) to pay interest on unpaid amounts at the average investment rate for Treasury and tax loan accounts. See Instruction D.

6. Item 4(c)—Check the box if this is the last time the issuer will be filing Form 24F–2 (i.e., if the issuer has discontinued operations).

C. Computation of Registration Fee

1. Item 5 is a work sheet for calculating the registration fee due. An issuer must aggregate prices within each class or series for which the Form is being filed. If the issuer charges a front-end sales load on its securities, the aggregate sale price must include the sales load.

2. Special Rule for Separate Accounts—The sale price of securities sold to an unmanaged separate account that offers interests that are registered under the Securities Act and on which a registration fee has been or will be paid may be excluded from the sale price of securities reported in Item 5(i). If the issuer chooses to exclude the sale price of these securities from Item 5(i), the issuer may not use securities redeemed or repurchased from those unmanaged separate accounts for purposes of determining the redemption or repurchase price of securities in Items 5(ii) and 5(iii).

3. EDGAR—Report responses for Item 5 under the following EDGAR header-tags:

Item 5(i)—<SALE-PROCEEDS>
Item 5(iv)—<REDEEMED-VALUE>
Item 5(viii)—<FEE-PAID>

The <SALE-PROCEEDS> and <REDEEMED-VALUE> tags are located immediately after the <SHARES> tag in the 24F–2 submission header.

4. Item 5(i)—Report the total sale price of securities sold during the fiscal year in reliance upon registration under section 24(f). Include securities issued pursuant to dividend reinvestment plans (''DRIP shares'') whether or not they are required to be registered under the Securities Act. Do not include the sale price of securities, if any, which were registered under the Securities Act other than pursuant to section 24(f), such as securities registered by post-effective amendment pursuant to rule 24e–2 under the Investment Company Act as in effect before [effective date of rescission of rule 24e–2]. Example: An issuer sold 1,000,000 shares, and 250,000 shares had previously been registered pursuant to rule 24e–2. Item 5(i) should show the aggregate sale price of 750,000 shares.

5. Item 5(ii)—Report the aggregate redemption or repurchase price of securities redeemed or repurchased during the fiscal year. Do not include securities that have been redeemed or repurchased and previously applied as a reduction to registration fees pursuant to rule 24e–2 as in effect before [effective date of rescission of rule 24e–2]. Example: An issuer with an August 30, 1997 fiscal year end registered shares pursuant to rule 24e–2 in September 1997. The issuer applied securities redeemed during its 1997 fiscal year to reduce its registration fees payable under rule 24e–2. The redemption price of these securities should not be included in Item 5(ii).

6. Item 5(iii)—Report the aggregate redemption or repurchase price of securities redeemed or repurchased during any prior fiscal year ending no earlier than October 11, 1995, that were not used previously to reduce registration fees payable to the Commission. Do not include securities that have been redeemed or repurchased and previously applied as a reduction to registration fees pursuant to rule 24e-2 as in effect before [effective date of rescission of rule 24e-2]. See the Example to Item 5(ii).

7. Items 5(iv) through 5(vi)—Report the sum of Items 5(ii) and 5(iii) in Item 5(iv). Subtract Item 5(iv) from Item 5(i). If Item 5(iv) is less than Item 5(i), report the result in Item 5(v) (net sales). If Item 5(iv) is greater than Item 5(i), report the resulting negative number in parentheses in Item 5(vi) (net redemptions or repurchases). The amount of redemptions or repurchases reported in Item 5(vi) may be used by the issuer in future years to offset sales (by including it in response to Item 5(iii) of Form 24F–2 filed for the next fiscal year).

8. Item 5(vii)—The multiplier for calculation of the registration fee is determined by the Commission in accordance with Section 6(b) of the Securities Act [15 U.S.C. 77f(b)]. As of October 1, 1996, the multiplier was 1/3300. Use of a decimal factor or some other method to calculate registration fees may result in payment of an incorrect amount. This multiplier is subject to change from time to time, without notice, by act of Congress through appropriations for the Commission or other laws. Issuers should determine the current fee rate prior to the time of filing by reference to Section 6(b) and any law or regulation affecting Section 6(b). The Commission generally makes available information concerning changes in the fee rate on its Internet site at http://www.sec.gov/news/press. Unless otherwise specified by act of Congress, the fee rate in effect at the time of filing applies to all securities sold during the fiscal year, regardless of whether the fee rate changed during the year.

9. Item 5(viii)—If the issuer reports net redemptions or repurchases in Item 5(vi), report ''0'' in Item 5(viii).

D. Computation of Interest Due if Form is Filed Late

1. Item 6—Section 24(f) requires any issuer that pays its registration fee more than 90 days after the end of its fiscal year to pay interest to the Commission on unpaid amounts. The payment of interest does not preclude the Commission from bringing an action to enforce the requirements of section 24(f). Pursuant to section 11 of the Debt Collection Act [31 USC 3717], that rate is published by the Secretary of the Treasury. The rate is subject to quarterly revisions if the annual average of investment rates changes by two percent. Otherwise, the rate

is computed each year for the 12 month period ending September 30 for applicability effective January 1 of the following year. The rate in effect for calendar year 1997 is 5 percent. As noted above, however, that rate is subject to change and filers owing interest should verify the current interest rate.

2. The interest is assessed only on the amount of the registration fee due, and begins to accrue on the 91st day following the end of the issuer's fiscal year. The amount of interest due should be calculated based on the interest rate in effect at the time the interest payment is made using the following formula:

I = (X) (Y) (Z/365)

Where:

I = Amount of interest due
X = Amount of registration fee due
Y = Applicable interest rate, expressed as a percentage
Z = Number of days by which the registration fee payment is late

E. Payment and Signature

1. Item 8—Identify which SEC account number (payor's CIK number) was designated to receive the payment.

2. The Form must be signed on behalf of the issuer by an authorized officer of the issuer. See rule 302 of Regulation S–T [17 CFR 232.302] regarding signatures on forms filed electronically.

[FR Doc. 97–18857 Filed 7–17–8:45 am]

BILLING CODE 8010–01–U

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 202, 206, and 211

RIN 1010–AC02

Amendments to Gas Valuation Regulations for Federal Leases

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of further extension of public comment period.

SUMMARY: The Minerals Management Service (MMS) hereby gives notice that it is extending the public comment period for a notice requesting comments on supplemental information which was published in the **Federal Register** on April 22, 1997, (62 FR 19536). In this notice MMS withdrew its proposed rulemaking to amend the regulations for valuing natural gas produced from Federal leases and requested comments on supplemental options for natural gas valuation.

In response to requests for additional time, MMS will further extend the comment period from July 23, 1997, to September 22, 1997.

DATES: Comments must be submitted on or before September 22, 1997.

ADDRESSES: Written comments or suggestions should be sent to the following addresses.

For comments sent via the U.S. Postal Service use: Minerals Management Service, Royalty Management Program, Rules and Publications Staff, P.O. Box 25165, MS 3021, Denver, Colorado 80225–0165.

For comments via courier or overnight delivery service use: Minerals Management Service, Royalty Management Program, Rules and Publications Staff, MS 3021, Building 85, Denver Federal Center, Room A–613, Denver, Colorado 80225–0165.

FOR FURTHER INFORMATION CONTACT: David S. Guzy, Chief, Rules and Publications Staff, phone: (303) 231–3432, FAX: (303) 231–3385 or(303) 231–3194, e-Mail: David__Guzy@ mms.gov.

SUPPLEMENTARY INFORMATION: MMS received requests from representatives of the oil and gas industry to extend the comment period of this notice. This time extension is in response to these requests in order to provide commentors with adequate time to provide detailed comments.

Dated: July 15, 1997.

Lucy Querques Denett,

Associate Director for Royalty Management.

[FR Doc. 97–18998 Filed 7–17–97; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

[OH–241–FOR, #74]

Ohio Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: OSM is reopening the public comment period on a proposed amendment to the Ohio permanent regulatory program (hereinafter referred to as the ''Ohio program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of revisions to section 150:13–6–03 of the Ohio Administrative Code (OAC) dealing with the Small Operator Assistance Program (SOAP). The amendment is intended to revise the Ohio program to be consistent with the corresponding Federal regulations.

DATES: Written comments must be received by 4:00 p.m., [E.D.T.] August 4, 1997.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to George Rieger, Field Branch Chief, at the address listed below.

Copies of the Ohio program, the proposed amendment, a listing of any scheduled public hearings, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Appalachian Regional Coordinating Center.

George Rieger, Field Branch Chief, Appalachian Regional Coordinating Center, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh PA 15220, Telephone: (412) 937–2153

Ohio Division of Mines and Reclamation, 1855 Fountain Square Court, Columbus, Ohio 43244, Telephone: (614) 265–1076.

FOR FURTHER INFORMATION CONTACT: George Rieger, Field Branch Chief, Appalachian Regional Coordinating Center, Telephone: (412) 937–2153.

SUPPLEMENTARY INFORMATION:

I. Background on the Ohio Program

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. Background information on the Ohio program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the August 10, 1982, **Federal Register** (47 FR 34688). Subsequent actions concerning conditions of approval and program amendments can be found at 30 CFR 935.11, 935.15, and 935.16.

II. Description of the Proposed Amendment

By letter dated October 3, 1996, (Administrative Record No. OH–2170–00) Ohio submitted a proposed amendment to its program regarding its SOAP pursuant to SMCRA. Ohio submitted the proposed amendment at its own initiative. OSM announced receipt of the proposed amendment in the October 18, 1996, **Federal Register** (61 FR 54373) and in the same document opened the public comment period and provided an opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on November

18, 1996. (At the time of announcement, the proposed amendment was identified as [OH–240; Amendment Number 74]. Please note that the amendment is now identified as [OH–241; Amendment Number 74].) However, there was no requirement that historical information be collected, as well as certain cross-reference contained in the proposed amendments were incorrect or inadvertently omitted in that notice. These were conveyed to Ohio in a document dated April 14, 1997, Administrative Record No. OH–2170–07. Also, Ohio had already corrected some of the cross-reference errors and submitted corrections to its proposed amendments in a facsimile document dated April 1, 1997. It agreed to make additional corrections in a letter dated May 27, 1997. On June 24, 1997, Ohio submitted its revisions in response to the April 14, 1997 document. (Administrative Record Nos. OH–2170-06, OH–2170–08, and OH–2170–09 respectively). Therefore, OSM is reopening the public comment period only on the following proposed amendments:

OAC 1501:13–6–03 Small Operator Assistance Program

1. OAC 1501:13–6–03(D)(10)—The cited cross-reference regarding the scale of topographic maps is revised from OAC 1501:13–9–04 to OAC 1501:13–4–09.

2. OAC 1501:13–6–03(F)(2)(c)—The cited cross-reference are revised to ORC 1513.07(B)(2)(n)(i), OAC 1501:13–4–04(J), (J)(18) through (J)(26) and OAC 1501:13–4–13(J), (J)(18) through (J)(26).

3. OAC 1501:13–6–03(F)(2)(d)—The cited cross-reference are revised to include OAC 1501:13–4–05(K) and 1501:13–4 14(J) in addition to those already referenced, i.e. 1513.07(B)(2)(m), OAC 1501:13–4–04(A) and 1501:13–4–13(A).

4. OAC 1501:13–6–03(A)(1)(D) and OAC 1501:13–6–03(F)(2)(d) are revised to include the words ''and historical'' after the opening phrase ''The collection of archaeological''.

5. OAC 1501:13–6–03(A)(1)(C) and OAC 1501:13–6–03(F)(2)(C)—The cross-references in the statement ''The development of cross-section maps and plans required under (B)(2) of section 1513. of the Revised Code.'' are revised to (B)(2)(n)(i) of section 1513.07.

6. OAC 1501:13–6–03(A)(1)(D) and OAC 1501:13–6–03(F)(2)(D)—The cross-references in the statement ''The collection of archaeological information required under division (B)(2) of section 1513. of the Revised Code. . . .'' are revised to (B)(2)(m) of section 1513.07 of the Revised Code.

7. OAC 1501:13–6–03(D)(9) is the same as (D)(12), therefore (D)(9) has been deleted.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. Specifically, OSM is seeking comments on the revisions to the State's regulations that were submitted on June 24, 1997 (Administrative Record No. OH–2170–09), with the corrections and additions as noted above. Comments should address whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Ohio program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Appalachian Regional Coordinating Center will not necessarily be considered in the final rulemaking or included in the Administrative Record.

IV. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to Whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Unfunded Mandates

This rule will not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 10, 1997.

Allen D. Klein,

Regional Director, Appalachian Regional Coordinating Center.

[FR Doc. 97–19000 Filed 7–17–97; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF THE TREASURY

31 CFR Part 103

RIN 1506–AA09, 1506–AA19, 1506–AA20

Financial Crimes Enforcement Network; Bank Secrecy Act Regulations; Money Services Businesses—Money Transmitters; Open Working Meeting

AGENCY: Financial Crimes Enforcement Network, Treasury.

ACTION: Meeting on proposed rules.

SUMMARY: The Financial Crimes Enforcement Network (''FinCEN'') will hold a working meeting to give interested persons the opportunity to discuss with FinCEN officials issues arising under the proposed rules for money services businesses published May 21, 1997. This meeting, which along with three additional meetings, was first announced in the **Federal Register** on July 8, 1997, will specifically deal with money transmitters.

DATES: July 28, 1997, 9:30 a.m. to 5:00 p.m., New York, NY.

ADDRESSES: New York Hilton & Towers, Rendezvous Trianon Room, 1335 Avenue of the Americas, New York, New York 10019.

FOR FURTHER INFORMATION CONTACT:

Legal or Technical: Eileen Dolan, Legal Assistant, Office of Legal Counsel, FinCEN, at (703) 905–3590, or Charles Klingman, Financial Institutions Policy Specialist, FinCEN, at (703) 905–3602.

Attendance: Camille Steele, at (703) 905–3819, or Karen Robb, at (703) 905–3770.

General: FinCEN's Information telephone line, at (703) 905–3848, or www.ustreas.gov/treasury/bureaus/fincen (''What's New'' section).

SUPPLEMENTARY INFORMATION: On May 21, 1997, FinCEN issued three proposed regulations relating to money services businesses. The first proposed regulation (62 FR 27890) would define money services businesses and require the businesses to register with the Department of the Treasury and to maintain a current list of their agents. The second proposed regulation (62 FR 27900) would require money transmitters, and issuers, sellers, and redeemers, of money orders and traveler's checks, to report suspicious transactions involving at least $500 in funds or other assets. The third proposed regulation (62 FR 27909) would require money transmitters and their agents to report and retain records of transactions in currency or monetary instruments of at least $750 but not more than $10,000 in connection with the transmission or other transfer of funds to any person outside the United States, and to verify the identity of senders of such transmissions or transfers.

On July 8, 1997 (62 FR 36475), FinCEN announced that it would hold four working meetings to give interested persons the opportunity to discuss with FinCEN officials issues arising under the proposed regulations. At that time, only the specific time and address of the first meeting, scheduled for July 22, 1997, dealing specifically with the definition and registration of money services businesses, had been determined. FinCEN indicated that the specific time and address of the remaining meetings would be announced later.

FinCEN is announcing today the time and address of the second meeting, which is scheduled for July 28, 1997. This meeting is being held specifically to discuss issues arising under the regulations as they relate to money transmitters. The meeting is not intended as a substitute for FinCEN's request for written comments in the notice of proposed rulemaking published May 21, 1997. Rather, the meeting is intended to help make the comment process as productive and interactive as possible by providing a forum between the industry and FinCEN concerning the issues arising under the proposed regulation. The meeting will be open to the public and will be recorded. A transcript of the meeting will be available for public inspection and copying; prepared statements will be accepted for inclusion in the record. Accordingly, oral or written material not intended to be disclosed to the public should not be raised at the meeting.

In the interest of providing as broad and convenient an opportunity as possible for persons to discuss these regulatory measures, FinCEN will provide time (approximately midafternoon) during this meeting to discuss issues relating to any of the three rules published May 21, 1997. Thus, persons wishing to discuss aspects of the rules other than those for which a particular meeting is called may wish to participate in one or more of the meetings.

Persons wishing to attend or to participate in this second meeting should inform either Camille Steele or Karen Robb as listed under the **FOR FURTHER INFORMATION CONTACT** section.

Dated: July 15, 1997.

Eileen P. Dolan,

Federal Register Liaison Officer, Financial Crimes Enforcement Network.

[FR Doc. 97–19001 Filed 7–17–97; 8:45 am]

BILLING CODE 4820–03–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 110

[CGD01–97–017]

RIN 2115–AA98

Special Anchorage Area: Special Anchorage, Hudson River, at Hyde Park, NY

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to disestablish the special anchorage located at Hyde Park, NY. The Poughkeepsie Yacht Club has requested the diseastablishement of this special anchorage because it is unsuitable for its intended purpose. Once disestablished, any vessels seeking to anchor in this area will be required to exhibit anchorage lights in accordance with the rules of the road.

DATES: Comments must be received on or before September 16, 1997.

ADDRESSES: Comments should be mailed to Lieutenant Junior Grade David D. Gefell, Waterways Oversight Branch, Coast Guard Activities New York, 212 Coast Guard Drive, Staten Island, NY 10305. The telephone number is 718–354–4195.

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade David D. Gefell, (718) 354–4195.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and address, identify this rulemaking (CGD01–97–017) and the specific section of the proposal to which their comments apply, and give reasons for each comment. Persons wanting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments. The Coast Guard plans no public hearing; however, persons may request a pubic hearing by

writing to the Waterways Oversight Branch at the address under **ADDRESSES**. The request should include the reasons why a hearing would be beneficial. If it is determined that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Poughkeepsie Yacht Club has requested the disestablishment of the special anchorage located at mile 72.7 on the east bank of the Hudson River, at Hyde Park, NY. This special anchorage is described in 33 CFR § 110.60, paragraph (p–3). Special anchorages are areas of water in which vessels of not more than 65 feet in length may anchor without exhibiting anchor lights. The Poughkeepsie Yacht Club lies adjacent to this special anchorage and is its principal user. However, the Poughkeepsie Yacht Club has requested disestablishment for the following reasons:

(1) The special anchorage is a hindrance to yacht club activities, many of which occur within the limited area available which is not encumbered by the seasonal weed bed or the shallow water depth at mean low water;

(2) The special anchorage is not used in the winter. All yacht club moorings and docks must be removed annually in this reach of the Hudson River due to the substantial ice build up; and

(3) Transient vessels anchor approximately 1500 feet north of the special anchorage to use Esopus Island as a breakwater to block wake action caused by commercial shipping which transits west of the island.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary. The principal users of this special anchorage are the members of the Poughkeepsie Yacht Club who fully understand the impact of their request. Additionally, the Coast Guard is unaware of any boaters other than the members of the Poughkeepsie Yacht Club who anchor or use moorings in this special anchorage.

Small Entities

The Coast Guard has considered the economic impact of this rule under the Regulatory Flexibility Act (5 U.S.C. 601–612). For the reasons discussed in the Regulatory Evaluation section, the Coast Guard expects that the proposed rule, if adopted, will not have a significant economic impact on a substantial number of small entities. If, however, you think that your business or organization qualifies as a small entity and that this rule will have significant economic impact on your business or organization, please submit a comment explaining why you think it qualifies and in what way and to what degree this rule will economically affect it.

Collection of Information

This proposal contains no collection-of-information requirements under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that since this rule disestablishes a special anchorage, under 2.B.2.e.(34)(f) of Commandant Instruction M16475.1B (as reviewed by 59 FR 38654, July 29, 1994), it is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 110

Anchorage grounds.

Proposed Regulation

For reasons set out in the preamble, the Coast Guard proposes to amend 33 CFR part 110.60 as follows:

PART 110—[AMENDED]

1. The authority citation for Part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 2071; 49 CFR 1.46 and 33 CFR 1.05–1(g). Section 110.1a and each section listed in it are also issued under 33 U.S.C. 1223 and 1231.

§ 110.60 [Amended]

2. In section 110.60, paragraph (p–3) is removed.

Dated: June 16, 1997.

J.L. Linnon,

Rear Admiral, Coast Guard, Commander, First Coast Guard District.

[FR Doc. 97–18991 Filed 7–17–97; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[FRL–5860–7]

Proposed Rule to Withdraw From Federal Regulations the Applicability to Alaska's Waters of Arsenic Human Health Criteria

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; re-opening of comment period.

SUMMARY: The purpose of this document is to re-open the public comment period on this proposed rule for an additional two weeks period.

DATES: EPA will now accept public comments on its proposed withdrawal of the human health criteria for arsenic applicable to Alaska until August 4, 1997. Comments postmarked after this date may not be considered.

ADDRESSES: An original plus 2 copies, and if possible an electronic version of the comments either in WordPerfect or ASCII format, should be addressed to Sally Brough, U. S. EPA Region 10, Office of Water, 1200 Sixth Avenue, Seattle, Washington 98101.

FOR FURTHER INFORMATION CONTACT: Fred Leutner at EPA Headquarters, Office of Water (4305), 401 M Street, SW, Washington, D.C. 20460 (telephone: 202–260–1542), or Sally Brough in EPA's Region 10 (telephone: 206–553–1295).

SUPPLEMENTARY INFORMATION: This proposed rule appeared in the **Federal Register** on May 21, 1997 (62 FR 27707) and provided for a public comment period of 45 days which closed on July 7, 1997. Shortly before that closing date, officials of several groups in Alaska contacted the Environmental Protection Agency (EPA) and requested an extension of the comment period. These officials cited difficulty in obtaining certain documents in the administrative record within the short comment period provided by EPA. To be fair to all parties who may want to provide comments, EPA is re-opening the comment period for an additional 2 weeks from the date of publication of this Notice.

List of Subjects in 40 CFR Part 131

Environmental protection, Water pollution, Water quality standards.

Robert Perciasepe,

Assistant Administrator for Water.

[FR Doc. 97–18970 Filed 7–17–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300505; FRL–5717–8]

Corn Gluten; Proposed Exemption From the Requirement of a Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: EPA is proposing to establish an exemption from the requirement of a tolerance for residues of the biochemical pesticide corn gluten, also known as corn gluten meal, when used as a herbicide in or on various food commodities. The exemption from the requirement of a tolerance is being proposed by the Agency on its own initiative.

DATES: Comments, identified by the docket control number [OPP–300505], must be received on or before September 16, 1997.

ADDRESSES: By mail, submit written comments to: Information and Records Integrity Branch, Public Information and Services Divison (7506C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Freshteh Toghrol, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 5th Floor, Crystal Station 1, 2805 Crystal Drive, Arlington, VA; Telephone number (703) 308–7014, e-mail: toghrol.freshteh@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA) and 21 U.S.C. 346a(d), EPA proposes to amend 40 CFR 180.1164 by establishing an exemption from the requirement of a tolerance for residues of the biochemical pesticide corn gluten, also known as corn gluten meal, when applied in accordance with good agricultural practices in or on all food commodities. Pursuant to section 408(d)(2)(a)(i) of the FFDCA, as amended, the Agency is issuing this proposed exemption on its own initiative.

I. Corn Gluten

Corn gluten is classified by Food and Drug Administration as GRAS (Direct Food Substances Affirmed As Generally Recognized As Safe, 21 CFR 184.1321).

A. Proposed Use Practices

Corn gluten, also known as corn gluten meal, is proposed to be used as an herbicide in or on all food commodities. The rate of application and number of applications will not be limited because corn gluten is a protein (food-by product) obtained from corn.

B. Product Identity/Chemistry

1. *Corn gluten*. Corn gluten (Cas Reg. No. 66071–96–3), also known as corn gluten meal, is the principal protein component of corn endosperm. It consists mainly of zein and glutelin, and is a by-product of the wet milling of corn for starch. The gluten fraction is washed to remove residual water soluble proteins. Corn gluten is also produced as a by-product during the conversion of the starch in whole or various fractions of dry milled corn to corn syrups.

a. The ingredient is used as a nutrient supplement as defined in 21 CFR 170.3(o)(20) and a texturizer as defined in 21 CFR 170.3(o)(32).

b. The ingredient is used in food at levels not to exceed current good manufacturing practice.

c. Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Corn gluten is also classified by EPA as a pesticide not requiring Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulation (Exemptions For Pesticides of a Character Not Requiring FIFRA Regulation, 40 CFR 152.25). Corn gluten is listed under 40 CFR 152.25(g)(1):

§ 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation.

* * * * *

(g) *Minimum risk pesticides*—(1) *Exempted products.* Products containing the following active ingredients are exempt from the requirements of FIFRA, alone or in combination with other substances listed in this paragraph, provided that all of the criteria of this section are met.

* * * * *

(2) *Permitted inerts.* A pesticide product exempt under paragraph (g)(1) of this section may only include inert ingredients listed in the most current List 4A * * *.

(3) *Other conditions of exemption.* All of the following conditions must be met for products to be exempted under this section:

(i) Each product containing the substance must bear a label identifying the name and percentage (by weight) of each active ingredient and the name of each inert ingredient.

(ii) The product must not bear claims either to control or mitigate microorganisms that pose a threat to human health, including but not limited to disease transmitting bacteria or viruses, or claim to control insects or rodents carrying specific diseases, including, but not limited to ticks that carry Lyme disease.

(iii) The product must not include any false and misleading labeling statements, including those listed in 40 CFR 156.10 (a)(5)(i) through (viii).

Based upon the information provided above, EPA has found that when corn gluten is used in accordance with good agricultural practice, the ingredient is useful and a tolerance is not necessary to protect public health. Therefore, EPA proposes that an exemption from the requirement of a tolerance be established for residues of the herbicide corn gluten, when used as an active ingredient for end-use formulations.

2. *Magnitude of Residue.* The Agency believes that corn gluten residues are non-toxic since corn gluten occurs naturally in food and the environment.

3. *Analytical method.* The analytical method is not needed because corn gluten residues consist of proteins, which will not be distinguishable from those proteins present in the crop.

C. Mammalian Toxicological Profile

Corn gluten is a protein found in food consumed by humans, and animals, and

is non-toxic to humans, and animals. The Agency therefore, supports the exemption from the requirement of a tolerance for corn gluten.

D. Aggregate Exposure

1. *Dietary exposure.* Under this proposed tolerance exemption, oral exposure to crops containing corn gluten may occur; however, due to the product's lack of mammalian toxicity, such exposure will not be harmful to humans.

2. *Drinking water and non dietary exposure.* Corn gluten is a food by-product and its use in residential, home garden, or lawn care situations, as well as other potential sources of dietary and non-dietary exposure to the general population such as drinking water and non-occupational exposures, are not expected to be significant or harmful to human health.

E. Cumulative Effects

Since corn gluten is not toxic to mammals, it is unlikely that it will have any cumulative toxic effects when used with other pesticides or substances.

F. Safety Determination

1. *Population in general.* Corn gluten is a non-toxic protein, isolated from corn, a plant used as food by humans and as feed by animals. Corn has been used as food and feed as long as corn has been known to and used by humankind, with no reported adverse effects. Based on this, the Agency believes that the aggregate exposure to corn gluten over a lifetime will not pose appreciable risks to human health. The Agency also concludes that there is a reasonable certainty that no harm will result from aggregate exposure to corn gluten residues and that exempting corn gluten from the requirement of a tolerance is safe.

2. *Infants and children.* Residues of corn gluten pose no potential toxicity to infants and children. Due to the lack of adverse effects and negligible exposure, the Agency concludes with reasonable certainty, that no harm will result to infants and children from aggregate exposure to corn gluten.

G. Existing Tolerances

No tolerances or exemptions from requirements of tolerances have been issued in the United States or internationally for corn gluten.

II. Public Record

The official record for this rulemaking, as well as the public version, has been established for this notice of filing under docket control number [OPP–300505] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP–300505]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

III. Regulatory Assessment Requirements

This action proposes to establish an exemption from the tolerance requirement under FFDCA section 408(e). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). In addition, this proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub.L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require special OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 40 CFR Part 180

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 7, 1997.

Janet L. Andersen.

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I, part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1164 is amended by adding new paragraph (c) to read as follows:

§ 180.1164 Food and food by-products; exemption from the requirement of a tolerance.

* * * * *

(c) Corn gluten is exempt from the requirement of a tolerance on all food commodities when used as an herbicide in accordance with good agricultural practice.

[FR Doc. 97–18973 Filed 7–17–97; 8:45 am]

BILLING CODE 6560–50–F

Notices

Federal Register
Vol. 62, No. 138
Friday, July 18, 1997

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food and Consumer Service

Agency Information Collection Activities: Proposed Collection; Comment Request; Form FCS–250, Food Coupon Accountability Report

AGENCY: Food and Consumer Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on the proposed information collection. This notice announces the Food and Consumer Service's (FCS) intention to request that the Office of Management and Budget (OMB) review of the agency's proposal to continue requiring information collection on Form FCS–250, Food Coupon Accountability Report. Section 4(c) of the Food Stamp Act of 1977 (the Act) provides that the Secretary issue regulations deemed necessary or appropriate for the effective and efficient administration of the Food Stamp Program (FSP). Requirements in section 7 of the Act authorize the Secretary to prescribe procedures for the accountability of food stamp coupons including delivery, monitoring the level of inventories, documentation, and security as requirements for coupon issuers and bulk storage points. Further, section 7(f) of the Act provides that State agencies shall be strictly liable to the Secretary for any financial losses involved in the acceptance, storage, and issuance of food stamp benefits. The information collected on Form FCS–250 provides data which is used in the preparation of State agency liability billings for coupon losses.

DATES: Written comments must be submitted on or before September 16, 1997.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to James I. Porter, Assistant Branch Chief, State Administration Branch, Food Stamp Program, Food and Consumer Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, VA 22302.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information regarding this information collection should be directed to James I. Porter, (703) 305–2385.

SUPPLEMENTARY INFORMATION:

Title: Food Coupon Accountability Report.

OMB Number: 0584–0009.

Form Number: FCS–250.

Expiration Date: October 31, 1997.

Type of Request: Extension of a currently approved information collection.

Abstract: Pursuant to the Act, Part 274.4(b)(1) of the FSP regulations requires the completion and submission of Form FCS–250, Food Coupon Accountability Report, including supporting documentation, by coupon issuers and bulk storage points the State agencies. The monthly FCS–250 report shall reflect the beginning and end-of-month inventories, receipt and transfer of coupon shipments, coupons returned to inventory, and credits.

Affected Public: State and local governments, individuals and FSP participants.

Estimated Number of Respondents: 1,587.

Number of Responses Per Respondent: 12.

Estimated Total Annual Burden: 57,132.

Dated: July 10, 1997.

William E. Ludwig,

Administrator, Food and Consumer Service.

[FR Doc. 97–18960 Filed 7–17–97; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food and Consumer Service

Agency Information Collection Activities: Proposed Collection; Comment Request; Form FCS–135, Affidavit of Return or Exchange of Food Coupons

AGENCY: Food and Consumer Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on proposed information collections. This notice announces the Food and Consumer Service's (FCS) intention to request that the Office of Management and Budget (OMB) review and approve the agency's proposal to continue requiring the use of Form FCS–135, Affidavit of Return or Exchange of Food Coupons, for another three years. Section 4(c) of the Food Stamp Act of 1977 (the Act) provides that the Secretary issue regulations deemed necessary or appropriate for the effective and efficient administration of the Food Stamp Program (FSP). Requirements in section 7 of the Act authorize the Secretary to prescribe procedures for food stamp benefit issuance, use, and accountability. Section 13 of the Act authorizes the Secretary to delegate to the State agencies the responsibility for establishment and collection of overissuance claims against households.

DATES: Written comments must be submitted on or before September 16, 1997.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the

accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to James I. Porter, Assistant Branch Chief, State Administration Branch, Food Stamp Program, Food and Consumer Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, VA 22302.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information regarding this information collection should be directed to James I Porter, (703) 305–2385.

SUPPLEMENTARY INFORMATION:

Title: Affidavit of Returned or Exchange of Food Coupons.

OMB Number: 0584–0052.

Form Number: FCS–135.

Expiration Date: 11/30/97.

Type of Request: Extension of a currently approved information collection.

Abstract: Pursuant to the Act, Part 274.6(f) of the FSP regulations provides that delivered Authorization To Participate (ATP) cards and food stamp coupons that are improperly manufactured or partially mutilated may be returned for replacement. If identifiable, such returned ATP cards and food stamp coupons shall be exchanged. Loose or intact books of food stamp coupons may be returned by participants and other individuals for a variety of circumstances: Because the coupons were found; death of a participant; overissuance; termination of participation; payment of a claim; etc. Part 273.18(j) of the FSP regulations provides that if coupon books collected from households as payment for claims are returned intact and in usable form, the coupon books may be returned to inventory. Coupon return activity, who made the return and the amount, why, and the exchange of coupons, if appropriate, are documented on Form FCS–135, Affidavit of Return or Exchange of Food Coupons. A copy of the completed form is retained by the servicing office, a copy is provided as a receipt for the returned and exchanged coupons, and a copy is used to transmit unusable food stamp coupons to the destruction point.

Affected Public: State and local governments, individuals and FSP participants.

Estimated Number of Respondents: 5,861.

Number of Responses Per Respondent: 7.26.

Estimated Total Annual Burden: 11,642.

July 10, 1997.

William E. Ludwig,

Administrator, Food and Consumer Service.

[FR Doc. 97–18961 Filed 7–17–97; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food and Consumer Service

Agency Information Collection Activities: Proposed Collection; Comment Request; Form FCS–46, Issuance Reconciliation Report

AGENCY: Food and Consumer Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on the proposed information collection. This notice announces the Food and Consumer Service's (FCS) intention to request that the Office of Management and Budget (OMB) review of the agency's proposal to continue requiring information collection on Form FCS–46, Issuance Reconciliation Report. Section 4(c) of the Food Stamp Act of 1977 (the Act) provides that the Secretary issue regulations deemed necessary or appropriate for the effective and efficient administration of the Food Stamp Program (FSP). Requirements in section 7 of the Act authorize the Secretary to prescribe procedures for food stamp benefit issuance, use, and accountability. Further, section 7(f) of the Act provides that State agencies shall be strictly liable to the Secretary for any financial losses involved in the acceptance, storage, and issuance of food stamp benefits. Form FCS–46 requires that State agencies report the reconciliation results from all issuance systems, for liability assessment and billing purposes.

DATES: Written comments must be submitted on or before September 16, 1997.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to James I. Porter, Assistant Branch Chief, State Administration Branch, Food Stamp Program, Food and Consumer Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, VA 22302.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information regarding this information collection should be directed to James I. Porter, (703) 305–2385.

SUPPLEMENTARY INFORMATION:

Title: Issuance Reconciliation Report.

OMB Number: 0584–0080.

Form Number: FCS–46.

Expiration Date: 11/30/97.

Type of Request: Extension of a currently approved information collection.

Abstract: Pursuant to the Act, Part 274.4(b)(2) of the FSP regulations requires the completion and submission of Form FCS–46, Issuance Reconciliation Report, by the State agencies. The report shall identify and report the number and value of all benefit issuances that reconcile and those that do not reconcile with the record-for-issuance and/or the master issuance file. Additionally, the report shall reflect the benefits that are returned, accountable issuance documents that are stolen and transacted for benefits, replacement benefits, and obligations from the exchange of coupons.

Affected Public: State and local governments, individuals and FSP participants.

Estimated Number of Respondents: 445.

Number of Responses Per Respondent: 12.

Estimated Total Annual Burden: 42,720.

Dated: July 10, 1997.

William E. Ludwig,

Administrator, Food and Consumer Service.

[FR Doc. 97–18962 Filed 7–17–97; 8:45 am]

BILLING CODE 3410–30–U

DEPARTMENT OF AGRICULTURE

Forest Service

California Spotted Owl Federal Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The California Spotted Owl Federal Advisory Committee will meet on August 5–7, 1997 in Sacramento, California. This is the second meeting of the committee. The meeting on August 5 is for discussions with invited experts on key issues, review of sub-committee reports and general Committee business. Public testimony will be taken on August 6 from 8:30 a.m. to 4:00 pm. The Committee will be taking testimony addressing the relationship between the RDEIS and the Sierra Nevada Ecosystem Project reports and any significant technical concerns about the RDEIS. The meeting on August 7 is reserved for additional Committee discussions with invited experts and invited representatives of interest groups on specific aspects of Sierra Nevada resource management.

Those needing California Spotted Owl RDEIS documents for meeting participation should contact Mike Skinner at (415) 705–1870.

DATES: The meeting will be held August 5–7, 1997: August 5: 9:00 a.m.–4:00 p.m.; August 6: 8:30 a.m.–4:00 p.m.; and August 7: 9:00 a.m.–4:00 p.m.

ADDRESSES: The meeting will be held at the Sacramento Convention at 1400 J Street, Room 304–5, Sacramento, California 95814.

FOR FURTHER INFORMATION CONTACT: Charles Philpot, Committee Chair, (503) 625–5758; or Johathan Stephens, Forest Service, (202) 205–0948; or Katherine Clement, (415) 705–1834.

Dated: July 11, 1997.

Katherine Clement,

Assistant Regional Forester, Ecosystem Conservation.

[FR Doc. 97–18930 Filed 7–17–97; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Associated Electric Cooperative; Finding of No Significant Impact

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of Finding of No Significant Impact.

SUMMARY: Notice is hereby given that the Rural Utilities Service (RUS) has made a finding of no significant impact with respect to its action related to the construction of a 250 megawatt (MW) combined cycle electric generation plant and associated facilities in Southeast Missouri by Associated Electric Cooperative (Associated). The finding of no significant impact is the conclusion of an environmental assessment prepared by RUS. The environmental assessment is based on a environmental analysis submitted to RUS by Associated. RUS conducted an independent evaluation of the environmental analysis and concurs with its scope and content. The environmental analysis has been incorporated by reference in the environmental assessment.

FOR FURTHER INFORMATION CONTACT: Bob Quigel, Environmental Protection Specialist, Engineering and Environmental Staff, RUS, Stop 1571, 1400 Independence Avenue, SW., Washington, DC 20250, telephone (202) 720–0468, E-mail bquigel@rus.usda.gov.

SUPPLEMENTARY INFORMATION: The preferred site for the plant is located in Dunklin County, Missouri, approximately 1 mile west of Glennonville. As proposed, the 250 MW combined-cycle plant consists of a 180 MW combustion turbine connected to a heat recovery steam generator designed to recover waste heat from the combustion turbine exhaust. The waste heat from the combustion turbine would be used to convert water to steam which would drive a conventional steam turbine to add about 70 MW to the plant's capacity. A single-shaft electrical generator would connect both combustion and steam turbines. Primary fuel for the combustion turbine would be natural gas which would be supplied via a 24-inch diameter gas line which passes through the southwest corner to the northeast corner of the site. Back-up fuel would be low-sulfur oil. The entire combined-cycle plant would occupy an area of approximately 10 acres. An additional 2 acres on or adjacent to the plant site would be required for a switchyard to connect the plant to Associated's electric transmission system. The power output from the plant would be connected to Associated's transmission grid via its 161 kilovolt (kV) transmission line that crosses the St. Francis site. A new 1.5 mile, 69 kV transmission line would be constructed from the plant to the nearest existing 69 kV transmission line. Power from the transmission line would be used for lighting and other electrical needs as well as for power to start-up the combustion turbine.

Alternatives considered to constructing the project as proposed include no action, load management and conservation, power purchases, alternative generation technologies, and alternative site locations.

Copies of the environmental assessment and finding of no significant impact along with the environmental analysis are available for review at, or can be obtained from, RUS at the address provided herein or from Duane Helderlein, Environmental Specialist, Associated Electric Cooperative, P.O. Box 754, Springfield, Missouri, 65801–0754 telephone (417) 885–9360. Duane's E-mail address is dhelder@dialnet.net. These documents are also available at the public libraries in Dexter, Kennett, New Madrid, and Sikeston, and Poplar Bluff, Missouri, and Piggott Arkansas. Interested parties wishing to comment on the adequacy of the environmental assessment should do so within 30 days of the publication of this notice. RUS will take no action that would approve clearing or construction activities related to proposed combined cycle power plant prior to the expiration of the 30-day comment period.

Dated: July 11, 1997.

Adam M. Golodner,

Deputy Administrator, Program Operations.

[FR Doc. 97–18941 Filed 7–17–97; 8:45 am]

BILLING CODE 3410–15–U

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to Procurement List.

SUMMARY: The Committee has received proposals to add to the Procurement List a commodity and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: August 18, 1997.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodity and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity and services to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodity and services.

3. The action will result in authorizing small entities to furnish the commodity and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity and services proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodity and services have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodity

Plug Assembly, Drain
2590–00–299–0739
NPA: Goodwill Industries—Knoxville, Inc., Knoxville, Tennessee

Services

Grounds Maintenance
U.S. Department of Energy
Western Area Power Administration
Phoenix, Arizona
NPA: Mesa ARC, Mesa, Arizona

Janitorial/Custodial

U.S. Department of Energy
Western Area Power Administration
Phoenix, Arizona
NPA: Mesa ARC, Mesa, Arizona

Order Processing Service

GSA, Northeast Distribution Center
Burlington, New Jersey
NPA: Bestwork Industries for the Blind, Inc., Westmont, New Jersey

Beverly L. Milkman,

Executive Director.

[FR Doc. 97–18963 Filed 7–17–97; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Addition

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to the Procurement List.

SUMMARY: This action adds to the Procurement List a commodity to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: August 18, 1997.

ADDRESS: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: On April 4, 1997, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (62 F.R. 16134) of proposed addition to the Procurement List. Comments were received from a current contractor for this plastic postal tray, a contractor for the paper version of the tray, and the mayor of the city and a U.S. Senator from the state where the first contractor's plant is located. The first contractor objected to the Committee's regulation requiring consideration of impact on the entire corporate entity of a current contractor, including the parent corporation, as it stated its parent corporation would not subsidize any losses the contractor sustains if the trays are added to the Procurement List. The contractor also claimed that the addition would have a severe impact on the contractor's sales and would require layoffs having a dramatic impact on the local economy which has a high unemployment rate and a largely minority population. The mayor and Senator seconded these contentions about the local economy. The contractor claimed that addition of another postal tray to the Procurement List has raised prices and stopped development on the tray by eliminating competition, and predicted the same thing would happen with this tray. The contractor also claimed there would be impacts on its suppliers and subcontractors, and objected to being relegated to six-month contracts as a supplier of raw materials to the nonprofit agencies producing the trays as the short-term arrangement made business planning impossible.

The Committee's assessment of impact on a contractor's entire corporate structure, rather than just the corporate division holding the contract for the commodity or service being added to the Procurement List, reflects the ability of large corporations to shift assets between divisions to minimize the impact of adverse developments in a way that smaller entities cannot do. Under these circumstances, any impact on the division is the result of the parent corporation's decision not to help its division, not the Committee's action.

The contractor will continue to have the opportunity to supply raw materials to the nonprofit agencies producing the other tray and the portion of the Government requirement for this tray which is already on the Procurement List, as well as the opportunity to supply materials for the portion currently being added. Since the materials the contractor will continue to have the opportunity to supply constitute a substantial majority of the value of the contract, this fact should significantly mitigate the impact of this addition on the contractor, its suppliers, and the local economy. Moreover, approximately 25% of the requirements for this tray continues to be available for procurement outside the Committee's Program.

The prices the nonprofit agencies charge are set by the Committee, which is required to establish a fair market price for each commodity and service on the Procurement List. The price established for this tray is within the Committee's guidelines. The United States Postal Service (USPS) and the nonprofit agencies are working to improve features of both trays, so it is not correct to say development ceased when the trays were added to the Procurement List. The Committee has been informed that raw material

suppliers, including the contractor and its competitors, not the nonprofit agencies, have insisted the supply contracts be only six months long.

The second contractor produces only the paper version of the tray, not the plastic version being added to the Procurement List. The firm would like the opportunity to produce the plastic tray, which is replacing the paper version, and is taking steps to be ready to produce the plastic tray.

However, the contractor's plastic tray has not been approved by USPS, which has also advised that the transition from paper to plastic will be a long-term process. Accordingly, the contractor is only losing an opportunity to compete for further contracts, if its product is approved, and the Committee has long taken the position that loss of an opportunity to compete is not severe adverse impact on a contractor without current Government sales of the item being added to the Procurement List. In addition, as noted above, no contractor is completely losing the opportunity to compete for future plastic tray business because approximately one-quarter of the USPS requirements for the tray will be available for procurement outside the JWOD Program.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodity and impact of the addition on the current or most recent contractors, the Committee has determined that the commodity listed below is suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity to the Government.

2. The action will not have a severe economic impact on current contractors for the commodity.

3. The action will result in authorizing small entities to furnish the commodity to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity proposed for addition to the Procurement List.

Accordingly, the following commodity is hereby added to the Procurement List:

Corrugated Plastic MM Tray
P.S. Item 3925
(U.S. Postal Service requirements for East Hartford, CT; Somerville, NJ and Baltimore, MD)

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 97–18964 Filed 7–17–97; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to Procurement List.

SUMMARY: The Committee has received a proposal to add to the Procurement List commodities to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: August 18, 1997.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed addition, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities to the Government.

2. The action will result in authorizing small entities to furnish the commodities to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodities have been proposed for addition to Procurement List for production by the nonprofit agency listed:

Box, Shipping, Fiberboard
8115–00–559–9998
8115–00–559–9999
8115–00–576–8407
8115–00–579–8461
8115–00–559–5516
8115–00–616–9151
8115–00–616–9154
8115–00–993–2790
8115–00–993–2791
8115–00–579–8406
8115–00–616–9147
8115–00–616–9150
8115–00–616–9152
8115–00–774–6562
8115–00–559–9996
8115–00–782–1695
8115–00–926–4887
8115–00–926–4888
8115–00–953–0276
8115–00–935–1140
8115–00–926–4886
8115–00–142–9594
8115–00–901–6434
8115–00–901–6428
8115–00–901–6435
8115–00–935–5904
8115–00–935–5905
8115–00–935–5906
8115–00–935–5907
8115–00–935–6510
8115–00–753–4690
8115–00–753–4691
(50% of the Government's requirement)
NPA: Orange County Rehabilitation Center—Occupations Incorporated, Middletown, New York.

Beverly L. Milkman,

Executive Director.

[FR Doc. 97–18966 Filed 7–17–97; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

ENVIRONMENTAL PROTECTION AGENCY

Coastal Nonpoint Pollution Control Program: Proposed Findings Documents, Environmental Assessments, and Findings of No Significant Impact

AGENCY: National Oceanic and Atmospheric Administration, U.S. Department of Commerce, and the U.S. Environmental Protection Agency.

ACTION: Notice of Availability of Proposed Findings Documents, Environmental Assessments, and Findings of No Significant Impact on Approval of Coastal Nonpoint Pollution Control Programs for Louisiana and Puerto Rico.

SUMMARY: Notice is hereby given of the availability of the Proposed Findings Documents, Environmental Assessments (EA's), and Findings of No Significant Impact for Louisiana and Puerto Rico. Coastal states and territories were required to submit their coastal nonpoint programs to the National Oceanic and Atmospheric Administration (NOAA) and the U.S. Environmental Protection Agency (EPA) for approval in July 1995. The Findings documents were prepared by NOAA and EPA to provide the rationale for the agencies' decision to approve each state and territory coastal nonpoint pollution control program. Section 6217 of the Coastal Zone Act Reauthorization Amendments (CZARA), 16 U.S.C. section 1455b, requires states and territories with coastal zone management programs that have received approval under section 306 of the Coastal Zone Management Act to develop and implement coastal nonpoint pollution control programs. The EA's were prepared by NOAA, pursuant to the National Environmental Policy Act (NEPA), 42 U.S.C. sections 4321 *et seq.*, to assess the environmental impacts associated with the approval of the coastal nonpoint pollution control programs submitted to NOAA and EPA by Louisiana and Puerto Rico.

NOAA and EPA have proposed to approve, with conditions, the coastal nonpoint pollution control programs submitted by Louisiana and Puerto Rico. The requirements of 40 CFR Parts 1500–1508 (Council on Environmental Quality (CEQ) regulations to implement the National Environmental Policy Act) apply to the preparation of the Environmental Assessments. Specifically, 40 CFR section 1506.6 requires agencies to provide public notice of the availability of environmental documents. This notice is part of NOAA's action to comply with this requirement.

Copies of the Proposed Findings Documents, Environmental Assessments, and Findings of No Significant Impact may be obtained upon request from: Joseph P. Flanagan, Coastal Programs Division (N/ORM3), Office of Ocean and Coastal Resource Management, NOS, NOAA, 1305 East-West Highway, Silver Spring, Maryland, 20910, tel. (301) 713–3121, ext. 201.

DATES: Individuals or organizations wishing to submit comments on the proposed Findings or Environmental Assessments should do so by August 18, 1997.

ADDRESSES: Comments should be made to: Joseph A. Uravitch, Coastal Programs Division (N/ORM3), Office of Ocean and Coastal Resource Management, NOS, NOAA, 1305 East-West Highway, Silver Spring, Maryland, 20910, tel. (301) 713–3155, ext. 195.

(Federal Domestic Assistance Catalog 11.419 Coastal Zone Management Program Administration)

Dated: Dated July 15, 1997.

Nancy Foster,

Assistant Administrator for Ocean Services and Coastal Zone Management, National Oceanic and Atmospheric Administration.

Robert H. Wayland, III,

Director, Office of Wetlands, Oceans and Watersheds, Environmental Protection Agency.

[FR Doc. 97–19005 Filed 7–17–97; 8:45 am]

BILLING CODE 3510–12–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

National Estuarine Research Reserve System

AGENCY: Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Notice of Public Meeting and Intent to Prepare a Draft Environmental Impact Statement.

SUMMARY: In accordance with the National Environmental Policy Act and with section 315 of the Coastal Zone Management Act of 1972, as amended, the State of Mississippi and the National Oceanic and Atmospheric Administration (NOAA) intend to conduct a public scoping meeting on the proposed Mississippi National Estuarine Research Reserve (NERR) to solicit comments on significant issues related to the preparation of a Draft Environmental Impact Statement (DEIS) and Draft Management Plan (DMP). The DEIS and DMP will address research, monitoring, education and resource protection needs for the reserve.

DATE AND TIME: Wednesday, August 6, 1997 at 6:00 p.m.

ADDRESS: East Jackson County Community Center, 9313 Old Stage Road, Pascagoula, Mississippi 39581.

FOR FURTHER INFORMATION CONTACT: Jerry Mitchell, Coastal Ecology Division, Mississippi Department of Marine Resources, at (601) 385–5860; Mark W. LaSalle, Mississippi State University Coastal Research and Extension Center (601) 388–4710; or Nathalie Peter, Sanctuaries and Reserves Division, Office of Ocean and Coastal Resource Management, NOAA, at (301) 713–3132, ext. 119.

SUPPLEMENTARY INFORMATION: In June 1997, NOAA approved the nomination of Grand Bay/Bangs Lake estuary complex as a proposed National Estuarine Research Reserve. Research reserves provide natural coastal habitats as field laboratories for baseline ecological studies and education programs. Research and monitoring programs are designed to enhance scientific understanding of the coastal environment and aid in resource management decision making.

The proposed Mississippi NERR is the Grand Bay/Bangs Lake estuary complex located in southeast Jackson County Mississippi. It encompasses approximately 15,000 acres of estuarine tidal marsh, shallow-water open bay, wet pine savanna, and coastal swamp habitats. Approximately 9,600 acres are state-owned estuarine marsh and shallow-bay bottoms that are currently recognized as the Grand Bay Estuarine Preserve. The remaining 5,400 acres are largely wet pine savanna that are part of the U.S. Fish and Wildlife Service (USFWS) Grand Bay Savanna National Wildlife Refuge.

The Department of Marine Resources (DMR) and the Mississippi State University Coastal Research and Extension Center (MSU) have developed a preliminary draft management plan outline for the NERR which will identify specific needs and priorities related to research, monitoring, education, and resource protection at the proposed site. It also outlines an administrative plan, volunteer program and facilities development needs, public access, and visitor use policies.

At the public meetings, DMR, MSU, and NOAA will provide a synopsis of the process for developing a DMP and will solicit comments on significant environmental issues that will be incorporated into a DEIS.

The public meeting will be held in Pascagoula, Mississippi, at the East Jackson County Community Center, 9313 Old Stage Road, on August 6, 1997, from 6:00 p.m. to 8:00 p.m.

Interested parties who wish to submit suggestions, comments or substantive information regarding the scope or content of the proposed DEIS/DMP are invited to attend the above meeting. Parties who wish to respond in writing should do so by August 21, 1997, to Jerry Mitchell, Coastal Ecology Division, Mississippi Department of Marine Resources, 192 Gateway Drive, Biloxi, MS 39531, or Nathalie Peter, NOAA Sanctuaries and Reserves Division, 1305 East-West Highway N/ORM2, Silver Spring, MD 20910.

Dated: July 11, 1997.

Federal Domestic Assistance Catalog Number 11.420 (Coastal Zone Management) Research Reserves

Jeffrey R. Benoit,

Director, Office of Ocean and Coastal Resource Management.

[FR Doc. 97–18999 Filed 7–17–97; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 071497B]

Marine Mammals; Scientific Research Permit (PHF# 872–1397)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Receipt of application.

SUMMARY: Notice is hereby given that Ann E. Bowles, Ph.D., Senior Research Biologist, Hubbs-Sea World Research Institute, 2595 Ingraham Street, San Diego, California 92109, has applied in due form for a permit to take northern elephant seals (*Mirounga angustirostris*) Pacific harbor seals (*Phoca vitulina richardsi*), and California sea lions (*Zalophus californianus*) for purposes of scientific research.

DATES: Written comments must be received on or before August 18, 1997.

ADDRESSES: The application and related documents are available for review upon written request or by appointment in the following office(s):

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713–2289); and

Regional Administrator, Southwest Region, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802-4213 (310/980-4001).

Written data or views, or requests for a public hearing on this request, should be submitted to the Director, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this application would be appropriate.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216).

The purpose of the proposed research is to study the effects of sonic boom simulation tests on pinniped hearing and physiological response. Up to 10 beached rehabilitated animals of each of the above species will be taken annually (i.e., physically and/or chemically restrained, instrumented with electrodes for physiological measurements, and exposed to sonic boom noise and other brief transients). Of these numbers, up to 3 of each species will be trained to respond behaviorally to low-intensity tone bursts, and up to 2 of each species will be exposed to brief startling stimuli to determine the threshold for startle. The proposed research will be conducted over a five year period.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: July 11, 1997.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 97–18914 Filed 7–17–97; 8:45 am]

BILLING CODE 3510–22–F

COMMODITY FUTURES TRADING COMMISSION

Chicago Mercantile Exchange Proposed Futures and Option Contracts on Cheddar Cheese Blocks

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of availability of the terms and conditions of proposed commodity futures and option contracts.

SUMMARY: The Chicago Mercantile Exchange (CME or Exchange) has applied for designation as a contract market in futures and futures options on cheddar cheese blocks. The Acting Director of the Division of Economic Analysis (Division) of the Commission, acting pursuant to the authority delegated by Commission Regulation 140.96, has determined that publication of the proposal for comment is in the public interest, will assist the Commission in considering the views of interested persons, and is consistent with the purposes of the Commodity Exchange Act.

DATES: Comments must be received on or before August 4, 1997.

ADDRESSES: Interested persons should submit their views and comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St., NW, Washington, DC 20581. In addition, comments may be sent by facsimile transmission to (202) 418–5521 or by electronic mail to secretary@cftc.gov. Reference should be made to the Chicago Mercantile Exchange cheddar cheese blocks futures and option contracts.

FOR FURTHER INFORMATION CONTACT: Please contact Fred Linse of the Division of Economic Analysis, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St., NW, Washington, DC 20581, telephone 202–418–5273. Facsimile number (202) 418–5527. Electronic mail flinse@cftc.gov.

SUPPLEMENTARY INFORMATION: The contracts were submitted pursuant to the Commission's Fast Track procedures for streamlining the review of applications for contract market designation (62 FR 10434). Under those procedures, the contracts, absent any contrary action by the Commission, may be deemed approved on August 25, 1997, 45 days after receipt of the applications. In view of the limited review period provided under the Fast Track procedures, the Commission has determined to publish for public

comment notice of the availability of the terms and conditions for 15 days, rather than 30 days as provided for applications submitted under the regular review procedures.

Copies of the terms and conditions will be available for inspection at the Office of the Secretariat, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St., NW, Washington, D.C. 20581. Copies of the terms and conditions can be obtained through the Office of the Secretariat by mail at the above address, by phone at (202) 418–5100, or via the Internet on the CFTC website at www.cftc.gov under ''What's Pending.'' .

Other materials submitted by the CME in support of the application for contract market designation may be available upon request pursuant to the Freedom of Information Act (5 U.S.C. 552) and the Commission's regulations thereunder (17 CFR Part 145 (1987)), except to the extent they are entitled to confidential treatment as set forth in 17 CFR 145.5 and 145.9. Requests for copies of such materials should be made to the FOI, Privacy and Sunshine Act Compliance Staff of the Office of the Secretariat at the Commission's headquarters in accordance with 17 CFR 145.7 and 145.8.

Any person interested in submitting written data, views, or arguments on the proposed terms and conditions, or with respect to other materials submitted by the CME, should send such comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st St., NW, Washington, DC 20581 by the specified date.

Issued in Washington, DC, on July 14, 1997.

John R. Mielke,

Acting Director.

[FR Doc. 97–18957 Filed 7–17–97; 8:45 am]

BILLING CODE 6351–01–P

DEPATMENT OF DEFENSE

Office of the Secretary

Meeting of the Historical Records Declassification Advisory Panel

AGENCY: Department of Defense, Historical Advisory Committee.

ACTION: Notice.

SUMMARY: Notice is hereby given of the forthcoming meeting of the Historical Records Declassification Advisory Panel. The purpose of this meeting is to discuss recommendations to the Department of Defense on topical areas of interest that, from a historical perspective, would be of the greatest benefit if declassified. Two public sessions will be held in 1997. The OSD Historian will chair these meetings.

DATES: Thursday, September 18, 1997.

TIME: The meeting is scheduled 9:00 a.m. until 2:00 p.m.

ADDRESSES: The National Archives Building, Room 410, 7th and Pennsylvania Avenue, NW., Washington, DC 20408.

FOR FURTHER INFORMATION CONTACT: Cynthia Kloss, Room 3C281, Office of the Deputy Assistant Secretary of Defense (Intelligence & Security), Office of the Assistant Secretary of Defense (Command, Control, Communications and Intelligence), 6000 Defense Pentagon, Washington, DC 20301–6000, telephone (703) 695–2289/2686.

Dated: July 14, 1997.

Patricia L. Toppings,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 97–18886 Filed 7–17–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Membership of the Defense Contract Audit Agency (DCAA) Performance Review Boards

AGENCY: Defense Contract Audit Agency, DoD.

ACTION: Notice of Membership of the Defense Contract Audit Agency Performance Review Boards.

SUMMARY: This notice announces the appointment of the members of the Performance Review Boards (PRBs) of the Defense Contract Audit Agency (DCAA). The publication of PRB membership is required by 5 U.S.C. 4314(c)(4). The Performance Review Boards provide fair and impartial review of Senior Executive Service (SES) performance appraisals and make recommendations to the Director, DCAA, regarding final performance ratings and performance awards for DCAA SES members.

EFFECTIVE DATE: July 18, 1997.

FOR FURTHER INFORMATION CONTACT: Dale R. Collins, Director, Human Resources Management, Defense Contract Audit Agency, Department of Defense, Ft. Belvoir, Virginia 22060–6219, 703–767–1236.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 4314(c)(4), the following are the names and titles of the executives who have been appointed to serve as members of the DCAA Performance Review Boards. They will serve one-year terms, effective upon publication of this notice.

Headquarters Performance Review Board

Mr. Lawrence Uhlfelder, Assistant Director, Policy and Plans, Defense Contract Audit Agency, Chairperson.

Mr. Russell Richards, Assistant Director, Operations, Defense Contract Audit Agency member.

Mr. Kirk Moberley, General Counsel, Defense Contract Audit Agency, member.

Regional Performance Review Board

Mr. Robert Matter, Regional Director, Western, Defense Contract Audit Agency Chairperson.

Mr. Francis Summers, Regional Director, Northeastern, Defense Contract Audit Agency, member.

Mr. James Lovelace, Deputy Regional Director, Central, Defense Contract Audit Agency, member.

Dated: July 14, 1997.

Patricia L. Toppings,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 97–18887 Filed 7–17–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Revised Non-Foreign Overseas Per Diem Rates

AGENCY: DoD, Per Diem, Travel and Transportation Allowance Committee.

ACTION: Notice of revised non-foreign overseas per diem rates.

SUMMARY: The Per Diem, Travel and Transportation Allowance Committee is publishing Civilian Personnel Per Diem Bulletin Number 196. This bulletin lists revisions in per diem rates prescribed for U.S. Government employees for official travel in Alaska, Hawaii, Puerto Rico, the Northern Mariana Islands and Possessions of the United States. Bulletin Number 196 is being published in the **Federal Register** to assure that travelers are paid per diem at the most current rates .

EFFECTIVE DATE: August 1, 1997.

SUPPLEMENTARY INFORMATION: This document gives notice of revisions in per diem rates prescribed by the Per Diem Travel and Transportation Allowance Committee for non-foreign areas outside the continental United States. It supersedes Civilian Personnel Per Diem Bulletin Number 195. Distribution of Civilian Personnel Per

Diem Bulletins by mail was discontinued. Per Diem Bulletins published periodically in the **Federal Register** now constitute the only notification of revisions in per diem rates to agencies and establishments outside the Department of Defense. For more information or questions about per diem rates, please contact your local travel office.

The text of the Bulletin follows:

BILLING CODE 5000–04–M

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
ALASKA:				
ANCHORAGE				
05/01 -- 09/30	147	66	213	02/01/97
10/01 -- 04/30	81	60	141	02/01/97
ANCHORAGE NAVAL RESERVE CENTER				
05/01 -- 09/30	147	66	213	02/01/97
10/01 -- 04/30	81	60	141	02/01/97
BARROW	110	76	186	03/01/96
BETHEL	93	61	154	02/01/97
CORDOVA	74	72	146	02/01/97
CRAIG				
05/01 -- 08/31	95	66	161	05/01/97
09/01 -- 04/30	79	64	143	05/01/97
DELTA JUNCTION	75	64	139	02/01/97
DUTCH HARBOR-UNALASKA	110	75	185	02/01/97
EARECKSON AIR STATION	75	60	135	02/01/97
EIELSON AFB				
05/16 -- 09/14	121	60	181	02/01/97
09/15 -- 05/15	75	55	130	02/01/97
ELMENDORF AFB				
05/01 -- 09/30	147	66	213	02/01/97
10/01 -- 04/30	81	60	141	02/01/97
FAIRBANKS				
05/16 -- 09/14	121	60	181	02/01/97
09/15 -- 05/15	75	55	130	02/01/97
FT. GREELY	75	64	139	02/01/97
FT. RICHARDSON				
05/01 -- 09/30	147	66	213	02/01/97
10/01 -- 04/30	81	60	141	02/01/97
FT. WAINWRIGHT				
05/16 -- 09/14	121	60	181	02/01/97
09/15 -- 05/15	75	55	130	02/01/97
GLENNALLEN	86	53	139	08/01/97
HOMER				
05/01 -- 09/30	116	64	180	02/01/97
10/01 -- 04/30	90	61	151	02/01/97
JUNEAU	89	79	168	02/01/97
KENAI-SOLDOTNA				
05/01 -- 09/30	94	61	155	02/01/97
10/01 -- 04/30	74	59	133	02/01/97

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
KENNICOTT	149	84	233	08/01/97
KETCHIKAN				
05/01 -- 09/30	99	77	176	02/01/97
10/01 -- 04/30	83	75	158	02/01/97
KING COVE	85	69	154	03/01/96
KING SALMON	77	68	145	03/01/96
KLAWOCK				
05/01 -- 08/31	95	66	161	05/01/97
09/01 -- 04/30	79	64	143	05/01/97
KODIAK	88	72	160	02/01/97
KOTZEBUE				
05/16 -- 09/15	101	81	182	04/01/97
09/16 -- 05/15	90	80	170	04/01/97
KULIS AGS				
05/01 -- 09/30	147	66	213	02/01/97
10/01 -- 04/30	81	60	141	02/01/97
MCCARTHY	149	84	233	08/01/97
MURPHY DOME				
05/16 -- 09/14	121	60	181	02/01/97
09/15 -- 05/15	75	55	130	02/01/97
NOME	93	76	169	02/01/97
PETERSBURG	82	58	140	02/01/97
SEWARD				
05/01 -- 09/15	114	74	188	02/01/97
09/16 -- 04/30	78	71	149	02/01/97
SITKA-MT. EDGECOMBE				
04/01 -- 10/31	97	63	160	02/01/97
11/01 -- 03/31	86	62	148	02/01/97
SKAGWAY				
05/01 -- 09/30	99	77	176	02/01/97
10/01 -- 04/30	83	75	158	02/01/97
SPRUCE CAPE	88	72	160	02/01/97
TANANA	93	76	169	02/01/97
UMIAT	125	107	232	08/01/97
VALDEZ				
05/15 -- 09/15	105	65	170	02/01/97
09/16 -- 05/14	84	64	148	02/01/97
WASILLA	89	65	154	02/01/97
WRANGELL				
05/01 -- 09/30	99	77	176	02/01/97
10/01 -- 04/30	83	75	158	02/01/97
[OTHER]	75	60	135	02/01/97

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
AMERICAN SAMOA:				
AMERICAN SAMOA	73	53	126	03/01/97
GUAM:				
GUAM (INCL ALL MIL INSTAL)	185	90	275	05/01/97
HAWAII:				
CAMP H M SMITH	110	61	171	07/01/97
EASTPAC NAVAL COMP TELE AREA	110	61	171	07/01/97
FT. DERUSSEY	110	61	171	07/01/97
FT. SHAFTER	110	61	171	07/01/97
HICKAM AFB	110	61	171	07/01/97
HONOLULU NAV & MC RESERVE CTR	110	61	171	07/01/97
ISLE OF HAWAII: HILO	76	55	131	07/01/97
ISLE OF HAWAII: OTHER				
04/01 -- 12/18	137	53	190	07/01/97
12/19 -- 03/31	150	54	204	07/01/97
ISLE OF KAUAI				
05/01 -- 11/30	109	71	180	07/01/97
12/01 -- 04/30	133	73	206	07/01/97
ISLE OF KURE	60	41	101	07/01/97
ISLE OF MAUI				
04/16 -- 12/14	100	58	158	07/01/97
12/15 -- 04/15	113	59	172	07/01/97
ISLE OF OAHU	110	61	171	07/01/97
KANEOHE BAY MC BASE	110	61	171	07/01/97
KEKAHA PACIFIC MISSILE RANGE FAC				
05/01 -- 11/30	109	71	180	07/01/97
12/01 -- 04/30	133	73	206	07/01/97
KILAUEA MILITARY CAMP	76	55	131	07/01/97
LULUALEI NAVAL MAGAZINE	110	61	171	07/01/97
NAS BARBERS POINT	110	61	171	07/01/97
PEARL HARBOR AFLOAT TNG GRP, MIDDLE	110	61	171	07/01/97
PEARL HARBOR NAVAL COMPLEX	110	61	171	07/01/97
PEARL HARBOR NAVAL SUBMARINE BASE	110	61	171	07/01/97
PEARL HARBOR NAVY PUBLIC WORKS CTR	110	61	171	07/01/97
SCHOFIELD BARRACKS	110	61	171	07/01/97
WHEELER ARMY AIRFIELD	110	61	171	07/01/97
[OTHER]	79	62	141	06/01/93
JOHNSTON ATOLL:				
JOHNSTON ATOLL	13	9	22	07/01/97

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
MIDWAY ISLANDS:				
MIDWAY ISLAND NAVAL AIR FACILITY				
	60	41	101	07/01/97
MIDWAY ISLANDS	60	41	101	07/01/97
NORTHERN MARIANA ISLANDS:				
ROTA	105	71	176	05/01/97
SAIPAN	170	78	248	05/01/97
[OTHER]	61	53	114	05/01/97
PUERTO RICO:				
BAYAMON				
05/01 -- 12/14	102	60	162	10/01/96
12/15 -- 04/30	130	63	193	10/01/96
CAROLINA				
05/01 -- 12/14	102	60	162	10/01/96
12/15 -- 04/30	130	63	193	10/01/96
DORADO				
04/01 -- 12/21	164	83	247	10/01/96
12/22 -- 03/31	300	96	396	10/01/96
FAJARDO [INCL CEIBA, LUQUILLO & HUMACAO]				
05/01 -- 11/23	70	64	134	10/01/96
11/24 -- 04/30	114	68	182	10/01/96
FT. BUCHANAN [INCL GSA SVC CTR, GUAYNABO]				
05/01 -- 12/14	102	60	162	10/01/96
12/15 -- 04/30	130	63	193	10/01/96
LUIS MUNOZ MARIN IAP AGS				
05/01 -- 12/14	102	60	162	10/01/96
12/15 -- 04/30	130	63	193	10/01/96
MAYAGUEZ	90	58	148	02/01/97
PONCE	107	58	165	10/01/96
ROOSEVELT ROADS				
05/01 -- 11/23	70	64	134	10/01/96
11/24 -- 04/30	114	68	182	10/01/96
ROOSEVELT ROADS NAS 2/				
05/01 -- 11/23	70	64	134	10/01/96
11/24 -- 04/30	114	68	182	10/01/96
SABANA SECA				
05/01 -- 12/14	102	60	162	10/01/96
12/15 -- 04/30	130	63	193	10/01/96
SABANA SECA US NAVAL SEC GRP ACT				
05/01 -- 12/14	102	60	162	10/01/96
12/15 -- 04/30	130	63	193	10/01/96

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
SAN JUAN				
05/01 -- 12/14	102	60	162	10/01/96
12/15 -- 04/30	130	63	193	10/01/96
SAN JUAN US NAVAL RESERVE STATION				
05/01 -- 12/14	102	60	162	10/01/96
12/15 -- 04/30	130	63	193	10/01/96
[OTHER]	70	50	120	10/01/96
VIRGIN ISLANDS (U.S.):				
ST. CROIX				
04/15 -- 12/14	109	80	189	07/01/97
12/15 -- 04/14	129	82	211	07/01/97
ST. JOHN				
06/01 -- 12/15	228	79	307	07/01/97
12/16 -- 05/31	344	91	435	07/01/97
ST. THOMAS				
04/15 -- 12/18	215	76	291	07/01/97
12/19 -- 04/14	322	87	409	07/01/97
WAKE ISLAND:				
WAKE ISLAND	40	35	75	10/01/96

Signature for Civilian Personnel Per Diem Bulletin Number 196.

Dated: July 14, 1997.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–18888 Filed 7–17–97; 8:45 am]

BILLING CODE 5000–04–C

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Oak Ridge Reservation

AGENCY: Department of Energy.

ACTION: Notice of Open Meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) notice is hereby given of the following Advisory Committee meeting: Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge Reservation

DATES: Wednesday, August 6, 1997, 6:00 p.m.–9:30 p.m.

ADDRESSES: Ramada Inn, 420 South Illinois Avenue, Oak Ridge, Tennessee.

FOR FURTHER INFORMATION CONTACT: Sandy Perkins, Site-Specific Advisory Board Coordinator, Department of Energy Oak Ridge Operations Office, 105 Broadway, Oak Ridge, TN 37830, (423) 576–1590.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda: The meeting will feature a report from three Board members on their participation in an incineration conference.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Sandy Perkins at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9:00 a.m. and 4 p.m., Monday-Friday, except Federal holidays. Minutes will also be available at the Department of Energy's Information Resource Center at 105 Broadway, Oak Ridge, TN between 8:30 am and 5:00 pm on Monday, Wednesday, and Friday; 8:30 am and 7:00 pm on Tuesday and Thursday; and 9:00 am and 1:00 pm on Saturday, or by writing to Sandy Perkins, Department of Energy Oak Ridge Operations Office, 105 Broadway, Oak Ridge, TN 37830, or by calling her at (423) 576–1590.

Issued at Washington, DC on July 15, 1997.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 97–18967 Filed 7–17–97; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–1220–001]

Cleveland Electric Illuminating Company; Notice of Filing

July 14, 1997.

Take notice that on May 22, 1997, Cleveland Electric Illuminating Company tendered for filing an amendment in the above-referenced dockets.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before July 18, 1997. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–18926 Filed 7–17–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–617–000]

Kern River Gas Transmission Company; Notice of Request Under Blanket Authorization

July 14, 1997.

Take notice that on July 2, 1997, Kern River Gas Transmission Company (Kern River) 295 Chipeta Way, Salt Lake City, Utah 84108, filed in the above docket, a request pursuant to 18 CFR Sections 157.205 and 157.211 of the Commission's Regulations, for authorization to construct and operate a new meter station to provide transportation deliveries for Southwest Gas Corporation (Southwest) to new markets at the California/Nevada border in Clark County, Nevada, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Specifically, Kern River proposes to construct own and operate the new Primm Meter Station at Milepost 578.2 on Kern River's pipeline in Section 6, Township 27 South, Range 59 East, Clark County, Nevada. Kern River states that the new meter station will consist of a 4-inch tap, one 2-inch turbine meter and appurtenances with a daily design capacity of approximately 6,000 Mcf per day at 650 psig.

Kern River further states that the cost to construct the Primm Meter Station is estimated to cost approximately $230,000. Kern River indicates that pursuant to a Facilities Construction Agreement and the facilities reimbursement provisions of Kern River's tariff, Southwest will reimburse Kern River for the actual costs associated with the construction of the meter station.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no request is filed within the time allowed therefor, the proposed activity is deemed to be authorized effective on the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–18925 Filed 7–17–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP96–610–000]

Granite State Gas Transmission, Inc., Notice of Availability of the Final Environmental Impact Statement for the Proposed Granite State LNG Project

July 14, 1997.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a Final Environmental Impact Statement (FEIS) on the construction and operation of the liquefied natural gas (LNG) peak shaving facility proposed by Granite State Gas Transmission, Inc. in the above-referenced docket.

The FEIS was prepared to satisfy the requirements of the National Environmental Policy Act. The staff concludes that approval of the proposed project, with the mitigating measures we have recommended, including receipt of necessary permits and approvals, would have limited environmental impact and would be an environmentally acceptable action. The FEIS evaluates alternatives to the proposal, including system alternatives and alternative sites for the storage facility and the permanent access road. Solely from an environmental perspective, the use of capacity available in 1999 on proposed pipelines would be an environmentally preferable alternative to providing the proposed peak shaving capacity.

Granite State is seeking approval of a specific site in Wells, Maine to store LNG that would be transported by tanker trucks from Everett, Massachusetts. The LNG would be vaporized as needed and the natural gas delivered into Granite State's existing pipeline system or the Portland Natural Gas Transmission System. The proposed action involves construction of:

- A 580,000-barrel LNG storage tank (equivalent to 2 billion cubic feet of natural gas);
- Two truck unloading stations;
- Two 67 million cubic feet per day vaporizers;
- A vapor handling system;
- A 12-inch-diameter sendout pipeline; and
- A new 1.4-mile-long permanent access road to the storage facility site from State Route 9.

In addition, Granite State proposes to upgrade and temporarily use an existing 1.1-mile-long dirt road for access into the storage facility site during the initial stages of construction.

The purpose of the proposed facilities would be to provide a 134,000 million British thermal units per day peak shaving service.

The FEIS has been placed in the public files of the FERC and is available for public inspection at:

Federal Energy Regulatory Commission, Public Reference and Files Maintenance Branch, 888 First Street, N.E., Room 2A, Washington, DC 20426, (202) 208–1371

and

Town Manager's Office, Town Hall, Wells, ME 04090, (207) 646–5113.

Copies of the FEIS have been mailed to Federal, state and local agencies; public interest groups; interested individuals; newspapers; and parties to this proceeding. A limited number of copies of the FEIS are available from the Public Reference and Files Maintenance Branch identified above.

Additional information about the proposed project is available from Paul McKee in the Commission's Office of External Affairs at (202) 202–1888.

Lois D. Cashell,

Secretary.

[FR Doc. 97–18924 Filed 7–17–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Project No. 11393–001 Alaska]

City of Saxman; Notice of Availability of Draft Environmental Assessment

July 14, 1997.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR Part 380 (Order No. 486, 52 FR 47897), the Office of Hydropower Licensing has reviewed the application for an original license for the major, unconstructed, Mahoney Lake Hydroelectric Project. The project would be located on Upper Mahoney Lake and Upper Mahoney Creek near Ketchikan in Southeast Alaska. The Commission staff has prepared a Draft Environmental Assessment (DEA) on the project. The DEA contains the staff's analysis of the potential environmental impacts of the project and has concluded that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

Copies of the DEA are available for review in the Public Reference Room, Room 2A, of the Commission's offices at 888 First Street, N.E., Washington, D.C. 20426.

Any comments should be filed within 30 days from the date of this notice and should be addressed to Lois D. Cashell, Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. For further information, contact Vince Yearick, Environmental Coordinator, at (202) 219–3073.

Lois D. Cashell,

Secretary.

[FR Doc. 97–18927 Filed 7–17–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: July 15, 1997. 62 FR 37904.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: July 16, 1997, 10:00 a.m.

CHANGE IN THE MEETING: The following Docket Number has been added to the Agenda scheduled for the July 16, 1997 meeting.

Item No.	Docket No. and company
CAG–10 ...	RP95–197–000, Transcontinental Gas Pipe Line Corporation.

Lois D. Cashell,

Secretary.

[FR Doc. 97–19071 Filed 7–16–97; 11:08 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5860–5]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Registration of Fuels and Fuel Additives: Requirements for Manufacturers (40 CFR 79)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this notice announces that the following Information Collection

Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: Registration of Fuels and Fuel Additives: Requirements for Manufacturers (40 CFR 79) (OMB Control Number 2060–0150, expiration date: 9–30–97). The ICR describes the nature of the information collection and its expected burden and cost; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 18, 1997.

FOR FURTHER INFORMATION OR A COPY CALL: Sandy Farmer at EPA, (202) 260–2740, and refer to EPA ICR No. 309.09.

SUPPLEMENTARY INFORMATION:

Title: Registration of Fuels and Fuel Additives (OMB Control No. 2060–0150; EPA ICR No. 309.09) expiring 9/30/97.

This is a request for an extension of a currently approved collection.

Abstract: Manufacturers of gasoline, diesel fuel, and additives for gasoline and/or diesel fuel, are required to have these products registered by the EPA prior to their introduction into commerce. Registration involves providing a chemical description of the fuel or additive, certain technical and marketing information, and any health-effects information in possession of the manufacturer. The development of health-effects data, required by 40 CFR 79, subpart F, is not included in this ICR due to upcoming changes in the requirements. Manufacturers are also required to submit periodic reports (annually for additives, quarterly and annually for fuels) on production volume and related information. The information is used to identify products whose evaporative or combustion emissions may pose an unreasonable risk to public health. Manufacturers typically claim confidentiality for compositional and production information. In accordance with the Clean Air Act, the results of health-effects testing shall not be considered confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The **Federal Register** Notice required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on April 14, 1997 (62 FR 18114); two comments were received.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average six hours per each notification/supplemental notification response, one hour for each notification update response, and one hour for each periodic report. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review insructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Manufacturers of gasoline, diesel fuel, and fuel additives.

Estimated number of Respondents: 1,400.

Frequency of Response: On occasion, quarterly, annually.

Estimated Total Annual Hour Burden: 12,900.

Estimated Total Annualized Cost Burden: $722,000.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the following addresses. Please refer to EPA ICR No. 309.09 and OMB Control No. 2060–0150 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, OPPE Regulatory Information Division (2137), 401 M Street, SW, Washington, DC 20460

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

Dated: July 14, 1997.

Joseph Retzer,

Director, Regulatory Information Division.

[FR Doc. 97–18969 Filed 7–17–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–5482–3]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or (202) 564–7153.

Weekly receipt of Environmental Impact Statements Filed July 07, 1997 Through July 11, 1997 Pursuant to 40 CFR 1506.9.

EIS No. 970259, Final EIS, NRC, Generic EIS—10 CFR Part 20: Support of Rulemaking on Radiological Criteria for Decommissioning of NRC-Licensed Nuclear Facilities (NUREG–1496), Implementation, Due: August 18, 1997, Contact: Carl Feldman, (301) 415–6194.

EIS No. 970260, Draft EIS, BLM, NM, CO, Rio Grande Corridor Coordinated Resource Management Plan and Taos Management Plan Amendment, Activity-Level-Plans, Implementation, NM and CO, Due: October 01, 1997, Contact: Steve Henke, (505) 758–8851.

EIS No. 970261, Draft EIS, FRC, WA, Sullivan Creek Hydroelectric (FERC No. 2225) Project, An Application for Amendment of License, Public Utility District No. 1, Sullivan Creek, Pend Oreille County, WA, Due: September 18, 1997, Contact: Rebecca Martin, (202) 219–2650.

EIS No. 970262, Draft EIS, IBR, CA, Central Valley Project, Municipal and Industrial Water Supply Contracts, Sacramento County Water Agency and San Juan Water District, City of Folsom, Sacramento County, CA, Due: September 05, 1997, Contact: Cecil Lesley, (916) 440–6851.

EIS No. 970263, Draft EIS, FRC, MS, AL, Destin Natural Gas Pipeline Project, Construction and Operation, Six Major Interstate Pipelines in the Gulf of Mexico, Southern Natural Gas, COE Sections 10 and 404 Permits, Right-of-Way and Special-Use Permits, Due: September 02, 1997, Contact: Paul McKee, (202) 208–1088.

EIS No. 970264, Draft EIS, AFS, CO, Dome Peak Timber Sale, Timber Harvesting and Road Construction, White River National Forest, Eagle Ranger District, Glenwood Spring, Eagle and Garfield Counties, CO, Due: September 02, 1997, Contact: David Van Norman, (970) 827–5715.

EIS No. 970265, Draft EIS, UMC, CA, Santa Margarita River Flood Control Project (MILCON P–010) and Basilone Road Bridge Replacement Project (MILCON P–030), Construction and Operation, COE Section 404 Permit, Camp Pendleton, CA, Due: September

05, 1997, Contact: Vicky K. Taylor, (619) 532–3007.

EIS No. 970266, Draft EIS, BLM, CA, Fourmile Hill Geothermal Development Project, Construction, Operation and Maintenance of a 49.9 megawatt (MW) Geothermal Power Plant, Federal Geothermal Leases CA–21924 and CA–21926, Glass Mountain Known Geothermal Resource Area, Klamath and Modoc National Forests, Siskiyou and Modoc Counties, CA, Due: September 16, 1997, Contact: Randall Sharp, (916) 233–5811.

EIS No. 970267, Final EIS, FRC, ME, Granite State Gas Transmission, Construction and Operation of a Liquefied Natural Gas Facility, Permits and Approvals, In the Town of Wells, York County, ME, Due: August 18, 1997, Contact: Paul McKee, (202) 208–1088.

EIS No. 970268, Draft EIS, IBR, NV, Clark County Wetlands Park Master Plan, Construction and Operation, Erosion Control Structures in Las Vegas Wash, COE Section 404 Permit, Right-of-Way Permit and Endangered Species Act Section 4, Clark County, NV, Due: September 17, 1997, Contact: Del Kidd, (702) 293–8698.

EIS No. 970269, Final EIS, FHW, WI, US 12 Whitewater Bypass, Improvements, Buckingham Road to Cox Road, Funding, Right-of-Way and COE Section 404 Permit, City of Whitewater, Jefferson, Rock and Walworth Counties, WI, Due: August 18, 1997, Contact: Richard C. Madzak, (608) 829–7510.

Dated: July 15, 1997.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 97–19003 Filed 7–17–97; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–5482–4]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared June 23, 1997 Through June 27, 1997 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 04, 1997 (62 FR 16154).

Draft EISs

ERP No. D–CGD–K50012–CA Rating EC2, A–92/San Mateo Hayward Bridge, Improvements to the East Approach and the Trestle Portion of the bridge, Coast Guard Bridge Permit and COE Section 404 Permit, Alameda and San Mateo Counties, CA.

Summary: EPA expressed environmental concerns with the alternatives, congestion impacts and CO hotspot analysis presented in the draft EIS.

ERP No. D–COE–K36121–CA Rating EC2, even Oaks Dam Water Conservation Feasibility Study, Establishing a Seasonal Water Conservation and Supply Pool, Flood Control and Flood Protection, Santa Ana River Basin, San Bernardino County, CA.

Summary: EPA expressed environmental concerns because the draft EIS did not consider ''end of pipe'' water conservation as an alternative to increasing the dam's water storage and did not sufficiently describe the proposed project's potential downstream impact.

ERP No. D–COE–L36110–WA Rating LO, Cedar River Section 205 Flood Damage Reduction Plan, Implementation, Renton, King County, WA.

Summary: EPA had no objection to the preferred alternative as described in the EIS.

ERP No. D–DOA–E39040–KY Rating LO, City of Albany's Cagle Water Expansion Project, To expand its Potable Water Treatment Plant, Funding and COE Section 404 Permit, Clinton and Wayne Counties, KY.

Summary: EPA had no objection to the proposed action.

ERP No. D–USN–E11039–FL Rating EC2, Cecil Field Naval Air Station, Disposal and Reuse, Implementation, City of Jacksonville, Duval and Clay Counties, FL.

Summary: EPA expressed environmental concerns regarding hazardous waste, air quality and noise issues for alternatives other than ARS 1. EPA had no objection to alternative ARS 1. Additional mitigation and discussion was requested for the other alternatives.

Final EISs

ERP No. F–DOE–A09824–00 Programmatic EIS—Waste Management, Managing Treatment, Storage and/or Disposal of Radioactive and Hazardous Waste for Five Types of Waste: Low-Level Radioactive; Low-Level Mixed; Transuranic Radioactive; High-Level Radioactive and Hazardous Waste, Site Selections Around the United States.

Summary: EPA's previous concerns have been resolved, therefore EPA had no objection with the proposed action.

ERP No. F–FHW–L40179–AK Third Street Widening Project, Improvement, Old Steese Highway and Hamilton Avenue, Funding and Right-of-Way Acquisition, Fairbanks North Star Borough, AK.

Summary: Review of the Final EIS was not deemed necessary. No formal comment letter was sent to the preparing agency.

ERP No. FR–USA–A21035–OR Umatilla Depot Activity, Revision to Disposal of Chemical Agents and Munitions Stored, Construction and Operation, Morrow and Umatilla Counties, OR.

Summary: Review of the Final EIS was not deemed necessary. No formal comment letter was sent to the preparing agency.

Dated: July 15, 1997.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 97–19004 Filed 7–17–97; 8:45 am]

BILLING CODE 6560–50–U

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 10:00 a.m. on Tuesday, July 22, 1997, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous Board of Directors' meetings.

Reports of actions taken pursuant to authority delegated by the Board of Directors.

Memorandum and resolution re: Statement of Policy Regarding the Federal Financial Institutions Examination Council Supervisory Policy—Securities Lending.

Memorandum and resolution re: Statement of Policy Regarding Improper and Illegal Payments by Banks and Bank Holding Companies.

Memorandum and resolution re: Statement of Policy Regarding the

Federal Financial Institutions Examination Council—Disclosure of Statutory Enforcement Actions.

Discussion Agenda:

Memorandum and resolution re: Part 325 Proposal to Revise the Regulatory Capital Treatment of Servicing Assets.

Memorandum and resolution re: Implementation of Deposit Shifting Statute.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550—17th Street, N.W., Washington, D. C.

The FDIC will provide attendees with auxiliary aids (e.g., sign language interpretation) required for this meeting. Those attendees needing such assistance should call (202) 416–2449 (Voice); (202) 416–2004 (TTY), to make necessary arrangements.

Requests for further information concerning the meeting may be directed to Ms. Valerie J. Best, Assistant Executive Secretary of the Corporation, at (202) 898–3812.

Dated: July 15, 1997.

Federal Deposit Insurance Corporation.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 97–19039 Filed 7–15–97; 4:22 pm]

BILLING CODE 6714–01–M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984.

Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, N.W., Room 962. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 232–011553–002.

Title: CSAV/Nacional Space Charter Agreement.

Parties:

Compania Sud Americana de Vapores (''CSAV'')

Companhia Maritima Nacional

Synopsis: The subject modification clarifies that CSAV's membership includes the CSAV/Braztrans Joint Service, a wholly-owned affiliate of CSAV. It also clarifies that the English language version of the Agreement will govern over versions in other languages.

Agreement No.: 224–201029.

Title: Jacksonville Port Authority/Autoliners, Inc. Wharfage Agreement.

Parties:

Jacksonville Port Authority (''Jaxport'')

Autoliners, Inc.

Synopsis: The proposed Agreement permits Jaxport to assess wharfage charges to Autoliners for automobiles crossing at the Port's facilities. The term of the Agreement is for one year.

Dated: July 15, 1997.

By Order of the Federal Maritime Commission.

Ronald D. Murphy,

Assistant Secretary.

[FR Doc. 97–19002 Filed 7–17–97; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR part 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.

JCC International, Inc., 944 Surrey Lane, Unit 2A, Schaumburg, IL 60193, Officer: John M. Guadagnoli, Jr., President

Chippey's Enterprises, Inc., d/b/a CEI Freight Forwarding, 744 NW. 107th Street, Miami, FL 33168–2101, Officers: Dwight A. Sheriff, President; Alan Grant, Vice President

World-Express, Inc., 8811 E. Garvey Ave., Suite #205, Rosemead, CA 91170, Officers: Andy Wu, President, Monica Chiu, Secretary

Zeal Cargo Corporation, 8525 N.W. 29 Street, Miami, FL 33122, Officer: Dario Bortnik, President.

Dated: July 14, 1997.

Joseph C. Polking,

Secretary.

[FR Doc. 97–18885 Filed 7–17–97; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 06/23/97 AND 07/04/97

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date terminated
TECO Energy, Inc., West Florida Gas, Inc., West Florida Gas, Inc	97–2351	06/23/97
Euramax International plc, Genstar Capital Corporation, Gentek Holdings, Inc	97–2360	06/23/97
University of Alabama Health Services Foundation, P.C., The Eye Foundation, Inc., The Eye Foundation, Inc	97–2392	06/23/97
Coca-Cola Enterprises Inc., The Coca-Cola Bottling Company, The Coca-Cola Bottling Company of New York, Inc	97–2440	06/23/97
The Dow Chemical Company, The Dow Chemical Company, DowElanco (a partnership)	97–2284	06/24/97
China National Nonferrous Metals Industry Corp, MQ Holdings, Inc., MQ Holdings, Inc	97–2421	06/24/97
Thomas H. Dittmer, Forstmann-Leff Associates, Inc., Forstmann-Leff Associates, Inc	97–2429	06/24/97
Folksamerica Holding Co., Inc., Munchener Ruckversicherungs-Gesellschaft [*continued], Great Lakes American Reinsurance Company	97–2434	06/24/97
General Electric Company, Roy G. Gullberg, Jr., Preco Turbine Services, Inc. & G&B Partnership	97–2435	06/24/97

TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 06/23/97 AND 07/04/97—Continued

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date terminated
Roy G. Gullberg, Jr., General Electric Company, General Electric Company	97–2436	06/24/97
Intermedia Communications, Inc., DIGEX, Incorporated, DIGEX, Incorporated	97–2439	06/24/97
The Registry, Inc., Renaissance Solutions, Inc., Renaissance Solutions, Inc	97–2447	06/24/97
FirstCity Financial Corporation, Harbor Financial Group, Inc., Harbor Financial Group, Inc	97–2450	06/24/97
Ed A. Smith, FirstCity Financial Corporation, FirstCity Financial Corporation	97–2451	06/24/97
Richard J. Gillen and Bernice J. Gillen, FirstCity Financial Corporation, FirstCity Financial Corporation	97–2452	06/24/97
Clear Channel Communications, Inc., American Tower Corporation, American Tower Corporation	97–2455	06/24/97
David A. Lubin, The Registry, Inc., The Registry, Inc	97–2456	06/24/97
Allegheny Health, Education and Research Foundation, Canonsburg General Hospital, Canonsburg General Hospital	97–2466	06/24/97
Travelers Group, Inc., BankAmerica Corporation, Security Pacific Finance System Inc	97–2487	06/24/97
Atlas Copco AB, Prime Service, Inc., Prime Service, Inc	97–2498	06/24/97
Catholic Health Initiatives, Sloan's Lake Management Corporation, Sloan's Lake Management Corporation	97–2502	06/24/97
Archer-Daniels-Midland Company, United Grain Growers Limited, United Grain Growers Limited	97–2503	06/24/97
U.S. Office Products Company, Bruce Rognlien, Associated Travel Services, Inc	97–2514	06/24/97
Bruce W. Rognlien, U.S. Office Products Company, U.S. Office Products Company	97–2515	06/24/97
Nuclear Electric Insurance Limited, Nuclear Mutual Limited, Nuclear Mutual Limited	97–2465	06/25/97
Family Golf Centers, Inc., Arthur J. Calace, Jr., Leisure Complexes, Inc	97–2474	06/25/97
Republic Industries, Inc., Desert GMC-East, Inc., Desert GMC-East, Inc.	97–2479	06/25/97
Republic Industries, Inc., Desert GMC, Inc., Desert GMC, Inc.	97–2480	06/25/97
Republic Industries, Inc., Desert Buick-GMC Trucks, Inc., Desert Buick-GMC Trucks, Inc.	97–2481	06/25/97
General Electric Company, Intelligent Electronics, Inc., XL Source, Inc., and RCK Computers, Inc	97–2493	06/25/97
A.G. Lowenthal, First of Michigan Capital Corporation, 1888 Limited Partnership and DST Systems, Inc	97–2516	06/25/97
Columbia/HCA Healthcare Corporation, Neponset Valley Health Systems, Inc., Norwood Hospital, Southwood Community Hospital, Inc	97–2374	06/26/97
Albert Einstein Healthcare Network, The Germantown Medical Center Foundation, The Germantown Medical Center Foundation	97–2382	06/26/97
Healthcare COMPARE Corp., First Data Corporation, First Health Strategies Inc	97–2431	06/26/97
Warburg, Pincus Investors, L.P., Robert W. Felton, the Indus Group	97–2485	06/26/97
Henkel KGaA, Paul R. Ellsworth, Resin Technology Group, Inc	97–2051	06/27/97
Nextel Communications, Inc., CellCall, Inc., CellCall, Inc	97–2314	06/27/97
Den norske stats oljeselskap a.s., Ashland, Inc., Blazer Energy Corp	97–2326	06/27/97
Bob G. Gower, Howell Corporation, Howell Hydrocarbons & Chemicals, Inc	97–2366	06/27/97
PMT Services, Inc., Leon and Susan Ladd, Ladco Financial Group	97–2422	06/27/97
Leon and Susan Ladd, PMT Services, Inc., PMT Services, Inc	97–2423	06/27/97
Imation Corp., Cemax-Icon, Inc., Cemax-Icon, Inc	97–2475	06/27/97
Republic Industries, Inc., Mitsubishi Motors Corporation, Value Rent–A–Car, Inc	97–2483	06/27/97
Steven K. Uhlmann, William A. Schmidt, American Precision Plastics Corporation	97–2490	06/27/97
Mail-Well, Inc., L.E. Rhian, Jr., Murray Envelope Corp	97–2491	06/27/97
Boral Limited, Resource Holding, Inc., Resource Holding, Inc	97–2492	06/27/97
Broderbund Software, Inc., Intuit, Inc., Parsons Technology, Inc	97–2495	06/27/97
Regal Cinemas, Inc., Cobb Theatres, L.L.C., R.C. Cobb, Inc., Cobb Threatres II, Inc., Cobb Finance Co	97–2500	06/27/97
Metals USA, Inc., Queensboro Steel Corporation, Queensboro Steel Corporation	97–2509	06/27/97
Metals USA, Inc., Texas Aluminum Industries, Inc., Texas Aluminum Industries, Inc	97–2510	06/27/97
Metals USA, Inc., Patrick A. Notestine, Affiliated Metals, Inc	97–2511	06/27/97
Metals USA, Inc., Uni-Steel, Inc., Uni-Steel, Inc	97–2512	06/27/97
East Texas Medical Center Regional Healthcare System, Nan Travis Memorial Hospital, Nan Travis Memorial Hospital	97–2523	06/27/97
Philip Services Corp., International Alliance Services, Inc., Republic Environmental Recycling, Inc.; Republic	97–2524	06/27/97
Cooper Industries, Inc., Coiltronics, Inc., Coiltronics, Inc	97–2525	06/27/97
Vishay Intertechnology, Inc., Diodes Incorporated, Diodes Incorporated	97–2532	06/27/97
Marshall I. Wais, Colorstrip, Inc., Colorstrip, Inc	97–2533	06/27/97
Burnham Corporation, Jack R. Cunningham, Thermo Products, Inc	97–2539	06/27/97
Letitia Corporation, Chase Manhattan Corporation (The), PHI Acquisition Holdings, Inc	97–2540	06/27/97
Gateway 2000, Inc., Advanced Logic Research Inc., Advanced Logic Research Inc	97–2544	06/27/97
Apple South, Inc., Jacob C. Baum, Canyon Cafes, Inc	97–2553	06/27/97
Fluor Corporation, John W. Burress, III, J.W. Burress, Incorporated	97–2554	06/27/97
Micron Technology, Inc., NetFRAME Systems Incorporated, NetFRAME Systems Incorporated	97–2559	06/27/97
Lamar Eugene Evans, Republic Industries, Inc., Republic Industries, Inc	97–2567	06/27/97
Republic Industries, Inc., Lamar Eugene Evans, Gene Evans Ford, Inc	97–2568	06/27/97
Ebara Corporation, New Elliott Corporation, New Elliott Corporation	97–2339	06/30/97
Sobel N.V., a Netherlands limited liability company, Sidmak Laboratories, Inc., Sidmak Laboratories, Inc	97–2361	06/30/97
Tenet Healthcare Corporation, Incarnate World Health System, Deaconess Incarnate World Health System	97–2371	06/30/97
Tenet Healthcare Corporation, Deaconess Foundation, Deaconess Incarnate World Health System	97–2373	06/30/97
Lutheran Medical Center, Sisters of Charity of Leavenworth Health Services Corp., Primera Healthcare, LLC	97–2453	06/30/97
Sisters of Charity of Leavenworth Health Services Corp., Lutheran Medical Center, Newco	97–2454	06/30/97
Philip Services Corp., Laurence N. Roth, Roth Bros. Smelting Corp	97–2471	06/30/97
Caribiner International, Inc., Meredith Family Limited Partnership, Bauer Audio Visual, Inc	97–2501	06/30/97
Electronic Arts Inc., Maxis, Inc., Maxis, Inc	97–2580	06/30/97
MAN Gutehoffnungshutte AG, New Elliott Corporation, New Elliott Corporation	97–0977	07/01/97
The Boeing Company, McDonnell Douglas Corporation, McDonnell Douglas Corporation	97–1121	07/01/97

TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 06/23/97 AND 07/04/97—Continued

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date terminated
Gerald W. Schwartz, Hewlett-Packard Company, Hewlett-Packard Company (Computer Systems Manufacturing)	97–2499	07/01/97
John M. Rudey, Ochoco Lumber Company, Ochoco Lumber Company	97–2543	07/01/97
MicroAge, Inc., Steven R. Becker, KNB, Inc	97–2551	07/01/97
Gordon S. Lang, SEDA Specialty Packaging Corp., Specialty Packaging Corp	97–2561	07/01/97
Lancaster Colony Corporation, Chatham Village Foods, Inc., Chatham Village Foods, Inc	97–2585	07/01/97
Brunswick Corporation, Mancuso/Equity Partnership No. 2, L.P., Life Fitness	97–2386	07/02/97
Pechiney, Financiere Techpack, Financiere Techpack	97–2414	07/02/97
David Vaccarezza, United Waste Systems, Inc., United Waste Systems, Inc	97–2448	07/02/97
United Waste Systems, Inc., David Vaccarezza, California Waste Recovery Systems, Inc	97–2449	07/02/97
Harman International Industries, Inc., Michael J. Oslac, Oxford International, Ltd	97–2537	07/02/97
PacificCorp, U.S. West, Inc., U.S. West Communications, Inc.	97–2547	07/02/97
Trico Marine Services, Inc., Otto Candies, Inc., Otto Candies, Inc	97–2548	07/02/97
U.S. Office Products Company, Mail Boxes Etc., Mail Boxes Etc	97–2552	07/02/97
Lowell L. Paxson, Landmark Communications, Inc., The Travel Channel, Inc	97–2556	07/02/97
Gannett Co., Inc., Army Times Publishing Company, Army Times Publishing Company	97–2565	07/02/97
Usinor, Macsteel Services Centers USA, Inc. (NEWCO), Macsteel Service Centers USA, Inc. (NEWCO)	97–2572	07/02/97
The Second Dave Samson Trust, Macsteel Service Centers USA, Inc. (NEWCO), Macsteel Service Centers USA, Inc. (NEWCO)	97–2575	07/02/97
Nextel Communications, Inc., Potomac Corporation, Crescent Communications	97–2591	07/02/97
Jon M. Huntsman, Rexene Corporation, Rexene Corporation	97–2489	07/03/97
KMart Corporation, Venture Stores, Inc., Venture Stores, Inc	97–2589	07/03/97

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Parcellena P. Fielding, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, D.C. 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 97–18989 Filed 7–17–97; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

Report of the Tar, Nicotine, and Carbon Monoxide Yield of 1206 Varieties of Domestic Cigarettes for the Year 1994

ACTION: Notice.

SUMMARY: The Federal Trade Commission publishes the Report of the Tar, Nicotine, and Carbon Monoxide Yield of 1206 Varieties of Domestic Cigarettes.

DATE: July 18, 1997.

ADDRESSES: Copies of the full report are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave., N.W., Washington, D.C. 20580. (202) 326–3222.

FOR FURTHER INFORMATION CONTACT: Phillip S. Priesman, Attorney, Federal Trade Commission, Bureau of Consumer Protection, 6th St. and Pennsylvania Ave., N.W., Washington, D.C. 20580. Telephone (202) 326–2484.

SUPPLEMENTARY INFORMATION: These are the most recent test results of the tar, nicotine, and carbon monoxide levels of the smoke of domestic cigarettes reported by the FTC. This Report contains data on 1206 varieties of cigarettes manufactured and sold in the United States in 1994. The Tobacco Institute Testing Laboratory (TITL), a private laboratory operated by the cigarette industry, conducted the tar, nicotine, and carbon monoxide testing for the widely-available domestic cigarette varieties. This testing was conducted under the review of a representative of the FTC through periodic unannounced inspections. TITL provided the results to the respective cigarette companies. The companies provided the data generated by TITL regarding their own brands to the FTC in response to compulsory process issued by the Commission. Cigarette smoke from generic, private label, and not-widely-available cigarettes was not tested by TITL, but was tested by the cigarette companies and provided under compulsory process to the FTC. The methodology, processes, and procedures that the companies and TITL employed are required to be the same as those the Commission has followed in the past.

In October 1996, the National Cancer Institute (NCI) published the 7th monograph in its smoking and tobacco control series: ''The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes: Report of the NCI Expert Committee.'' In light of the concerns raised by the NCI conferees about the current system, the Commission is giving careful consideration to possible changes in the test method.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 97–18990 Filed 7–17–97; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Vaccine Injury Compensation Program: Public Hearing Regarding Vaccine Administration Guidelines

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of public hearing.

SUMMARY: This document announces a public hearing to receive information and views on the section entitled, ''Guidelines'' in the Notice of Proposed Rulemaking (NPRM) entitled ''National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table–II.''

DATES: The public hearing will be held on September 11, 1997, at 1:00 p.m. Requests to testify should be submitted by August 28, 1997.

ADDRESSES: The public hearing will be held in Conference Rooms D and E in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas E. Balbier, Jr., Director, Division of Vaccine Injury Compensation, at (301) 443–6593.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act

of 1986 (Pub. L. 99–660) created a system of no-fault compensation for certain individuals who have been injured by specific childhood vaccines: namely, diphtheria, tetanus, pertussis, polio, measles, mumps or rubella vaccines. Section 313 of Public Law 99–660 called for the Secretary of Health and Human Services to arrange for a study of the risks associated with certain of these vaccines and to establish guidelines based on the results of the 313 study ''respecting the administration'' of the vaccines that were reviewed, which guidelines shall include:

(i) The circumstances under which any such vaccine should not be administered;

(ii) The circumstances under which administration of any such vaccine should be delayed beyond its usual time of administration; and

(iii) The groups, categories, or characteristics of potential recipients of such vaccine who may be at significantly higher risk of major adverse reactions to such vaccine than the general population of potential recipients.

We have examined the recommendations of the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), as set forth in the Morbidity and Mortality Weekly Reports Recommendations and Reports, dated September 6, 1996, entitled, ''Update: Vaccine Side Effects, Adverse Reactions, Contraindications and Precautions.'' Members of the public may obtain copies of the report by writing to MS Publications, C.S.P.O. Box 9120, Waltham, MA 02254, telephone 1–800–843–6356, 617–893–3800 (Massachusetts). The cost of the publication is $4.00. It may be obtained without charge through use of the World-Wide Web (WWW). The address is ''http://www.cdc.gov/epo/mmwr/mmwr—rr.html.'' As stated by the Secretary in the February 20, 1997, **Federal Register** (62 Fed. Reg. 7687), we have found that the ACIP recommendations are consistent with the findings that the Department made as part of section 313 NPRM (60 FR 56289, Nov. 8, 1995), and that they satisfy the statutory requirements for guidelines. Accordingly, we proposed that the ACIP recommendations will constitute the guidelines called for by section 313.

Section 313 calls for consultation with the Advisory Commission on Childhood Vaccines (ACCV) and notice and opportunity for public hearing with respect to these guidelines. The ACIP recommendations were submitted to the ACCV at its meeting of June 6–7, 1996.

The hearing will be held on September 11, 1997, beginning at 1:00 p.m., in Conference Rooms D and E in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. The hearing will be held following the noon adjournment of the September 10–11 meeting of the ACCV.

The presiding officer representing the Secretary of HHS, will be Mr. Thomas E. Balbier, Jr., Director, Division of Vaccine Injury Compensation, Bureau of Health Professions (BHPr), Health Resources and Services Administration.

Persons who wish to participate are requested to file a notice of participation with the Department on or before August 28, 1997. The notice should be mailed to Division of Vaccine Injury Compensation, BHPr, Room 8A–35, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. To ensure timely handling, any outer envelope should be clearly marked ''Guidelines.'' The notice of participation should contain the interested person's name, address, telephone number, any business or organizational affiliation of the person desiring to make a presentation, a brief summary of the presentation, and the approximate time requested for the presentation. Groups that have similar interests should consolidate their comments as part of one presentation. Time available for the hearing will be allocated among the persons who properly file notices of participation. If time permits, interested parties attending the hearing who did not submit a notice of participation in advance will be allowed to make an oral presentation at the conclusion of the hearing.

Persons who find that there is insufficient time to submit the required information in writing may give oral notice of participation by calling Mr. Thomas E. Balbier, Jr., Director, Division of Vaccine Injury Compensation, at (301) 443–6593 no later than August 28, 1997. Those persons who give oral notice of participation should also submit written notice containing the information described above to the Department by the close of business September 4, 1997.

After reviewing the notices of participation and accompanying information, the Department will schedule each appearance and notify each participant by mail or telephone of the time allotted to the person(s) and the approximate time the person's oral presentation is scheduled to begin.

Written comments and transcripts of the hearing will be made available for public inspection as soon as they have been prepared, on weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5:00 p.m. at the Division of Vaccine Injury Compensation, Room 8A–35, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Dated: July 14, 1997.

Claude Earl Fox,

Acting Administrator.

[FR Doc. 97–18908 Filed 7–17–97; 8:45 am]

BILLING CODE 4160–15–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 783]

Cooperative Agreements for Postdoctoral Fellowship Training Programs in Infectious Diseases

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds for cooperative agreements to provide assistance for Postdoctoral Fellowship Training Programs in Infectious Diseases.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases. (For ordering a copy of Healthy People 2000, see the section **WHERE TO OBTAIN ADDITIONAL INFORMATION.**)

Authority

This program is authorized under Sections 301 (42 U.S.C. 241) and 317(k)(2) (42 U.S.C. 247b(k)(2)) of the Public Health Service Act, as amended.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Pub. L. 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Assistance will be provided only to university affiliated schools of medicine with infectious disease programs accredited by the Accreditation Council for Graduate Medical Education (ACGME). Applicants meeting this criteria are the most appropriate

organizations to conduct the work under this cooperative agreement because: The purpose of this cooperative agreement is to respond to the documented shortage of physicians trained academically in infectious diseases. Correspondingly, the infectious disease departments of university schools of medicine are the legitimate organizations in which to base a program such as proposed in this announcement.

Availability of Funds

Approximately $130,000 is available in FY 1997 to fund two to four awards. It is expected that the average award will be $40,000. It is expected that the awards will begin on or about September 30, 1997, and be made for a 12-month budget period within a project period of up to 3 years. Funding estimates may vary and are subject to change. Continuation awards within an approved project period will be made on the basis of satisfactory progress and availability of funds. Preference will be given to competing continuation applications over applications for programs not already receiving support under the PFTP program. Current grantees have physicians/fellows enrolled in their programs with 2–3 years remaining in their fellowship. It is expected, though, that one or more new awards will be made in addition to any competing continuations.

Use of Funds

Grantee cost-sharing is required under this program. CDC will provide up to 50 percent of the total costs for items directly related to support of fellows' stipends (consistent with PHS policies), and professional travel. CDC funds will not be provided to support salaries/fringe, travel, etc., for recipient's faculty or administrative personnel. In a training grant, recipient indirect charges are limited to 8 percent of direct costs.

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of Department of Health and Human Services (HHS) funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or ''grass roots'' lobbying efforts that are designed to support or defeat legislation pending before State legislatures. Section 503 of this new law, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, Section 101(e), Pub. L. No. 104–208 (September 30, 1996), provides as follows:

> Sec. 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, * * * except in presentation to the Congress or any State legislative body itself.
>
> (b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Background

In the past decade, much has been written about emerging microbial threats to health. Recently, the Institute of Medicine's (IOM) Committee on Emerging Microbial Threats to Health published its report entitled ''Emerging Infections: Microbial Threats to Health in the United States'', (National Academy Press, 1992). This report discusses one of the key problems facing the U.S. public health system's ability to adequately respond to the problem of emerging infectious diseases—the present and projected future shortage of scientists, physicians, and others trained to conduct basic and applied research on infectious diseases. Because of this shortage of appropriately trained public health researchers, strategies to anticipate the emergence of infectious diseases and prevent them from becoming significant threats to public health are lacking.

This is corroborated by other sources such as the American Society for Microbiology, Infectious Diseases Society of America, American Society of Tropical Medicine and Hygiene, American Public Health Association, and by previously published IOM reports. All cite the need for increases in programs for the recruitment and training of professionals for careers in infectious diseases, such as epidemiology, basic laboratory research, and clinical research.

In 1994, CDC initiated the Postdoctoral Fellowship Training Program in Infectious Diseases (PFTP) and made awards to two U.S. medical schools. Under these awards, the PFTP was integrated into the school's existing postdoctoral program as a separate PFTP track and several physicians have been enrolled. Through this program announcement, CDC intends to continue the PFTP.

Purpose

The purpose of this cooperative agreement is to assist recipients in the development and implementation of a two-to three-year Postdoctoral Fellowship Training Program in Infectious Diseases (PFTP) which utilizes the combined resources of the recipient and CDC to provide a combination of clinical training and basic laboratory or epidemiologic training in infectious diseases. The goal is to improve the ability of the U.S. public health system to respond to the problem of infectious diseases by increasing the number of academic infectious disease physicians with demonstrated skills in the public health aspects of infectious diseases and to provide them with the essential, pertinent clinical and research skills.

The PFTP is designed to be implemented as a separate track or component of recipient's existing infectious disease postdoctoral training program and is aimed at physicians with training in infectious diseases who wish to pursue a career in academic infectious diseases. The objective is to offer a combination of research and clinical training which will lead to eligibility for certification in infectious diseases by the American Board of Internal Medicine, Subspecialty Board of Infectious Diseases (the cognizant member board of the American Board of Medical Specialties). Specific areas of clinical concentration at recipient's facilities may include: clinical rotations in infectious diseases, infectious diseases in transplant recipients, clinical microbiology, outpatient infectious diseases, pediatric infectious diseases, or infectious disease pharmacology. The recipient must be able to provide support for physicians of unusual ability and promise or proven achievement by giving them an opportunity to conduct clinical, laboratory, and epidemiologic research on significant public health problems caused by infectious diseases. Specific areas of research may include: viral and rickettsial infections, nosocomial

infections, antimicrobial resistance, acquired immunodeficiency syndrome, vector-borne infectious diseases, respiratory and food-borne bacterial diseases, sexually transmitted diseases, and parasitic diseases. The laboratory or epidemiologic research may be conducted at CDC facilities under the guidance of a CDC preceptor.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for the activities under A., below, and CDC shall be responsible for conducting activities under B., below:

A. Recipient Activities

1. As a track or component of recipient's existing infectious disease postdoctoral fellowship program, develop and conduct a two- to three-year PFTP that combines clinical and basic laboratory or epidemiologic research in prevention and control of infectious diseases of public health importance. The clinical training will occur at recipient facilities. Conduct the PFTP such that the clinical training and the research activities are appropriately interrelated.
2. Design and conduct the PFTP such that, upon completion of the fellowship, fellows will become eligible for certification in infectious diseases by the American Board of Internal Medicine.
3. Provide preceptors for training conducted at recipient's facilities.
4. Develop a fellowship candidate application, review, ranking, and selection process. Based on this process, select applicants to be awarded two-to three-year PFTP fellowships.
5. Provide administrative support to fellows during their tenure in the PFTP including the payment of stipends, professional travel, etc. (see Availability of Funds for cost sharing requirements).
6. Assist fellows in publishing and/or otherwise disseminating results of their research.
7. Monitor and evaluate the progress of fellows and progress toward achieving program goals. To measure the overall success of the PFTP, establish a mechanism to follow-up and report on fellows (e.g., where they work, in what field, etc.) periodically for up to 5 years after they complete the PFTP.

B. CDC Activities

1. Provide technical assistance in the development and management of the PFTP.
2. The laboratory or epidemiologic research may occur at CDC facilities.
3. Provide preceptors for research/training that occurs at CDC facilities.
4. Assist in monitoring and evaluating the progress of fellows and of the progress toward achieving program goals.

Technical Reporting Requirements

Narrative progress reports are required semiannually. The first semiannual report is required with each year's noncompeting continuation application and should cover program activities from date of the previous report (or date of award for reporting in the first year of the project). The second semiannual report is due 90 days after the end of each budget period and should cover activities from the date of previous report. Progress reports should address the status of all recipient activities above, including the status of training and research activities for individual fellows enrolled. Progress reports should also include copies of any publications resulting from the PFTP.

An original and two copies of a financial status report (FSR) are required no later than 90 days after the end of each budget period. A final performance report and financial status report are due no later than 90 days after the end of the project period.

All reports are submitted to the Grants Management Branch, Centers for Disease Control and Prevention (CDC), Attention: Sharron Orum, Grants Management Officer, Procurement and Grants Office, 255 East Paces Ferry Road, NE., Mailstop E18, Room 300, Atlanta, Georgia 30305.

Notification of Intent to Apply

In order to assist CDC in planning and executing the evaluation of applications submitted under this Program Announcement, all parties intending to submit an application should inform CDC of their intention to do so as soon as possible but not later than 10 business days prior to the application due date. Notification should include (1) name and address of institution and (2) name, address, and telephone number of contact person. Notification can be provided by facsimile, postal mail, or electronic mail (Email) to Greg Jones, M.P.A., National Center for Infectious Diseases, CDC, 1600 Clifton Road, NE., Mailstop C–19, Atlanta, Georgia 30333, facsimile (404) 639–4195, Email address gjj1@cdc.gov.

Application Content

All applicants must develop their application in accordance with the PHS Form 5161–1 (OMB Number 0937–0189), information contained in this cooperative agreement announcement, and the instructions outlined below.

Typing and Mailing

All pages must be clearly numbered and a complete index to the application and its appendices must be included. Do not bind, staple, or paperclip any pages of any copy of the application, including appendices. Do not include any bound documents (e.g., pamphlets or other publications) in the appendices. Do not include cardboard, plastic, or other page separators between sections. The entire application must be typewritten, single spaced, and in unreduced type on 8 1/2'' by 11'' white paper, with at least 1'' margins, including headers and footers, and printed on one side only.

Specific Instructions

The application narrative must not exceed 10 pages (excluding abstract, budget, and appendixes). Unless indicated otherwise, all information requested below must appear in the narrative. Materials or information that should be part of the narrative will not be accepted if placed in the appendices. The application narrative must contain the following sections in the order presented below:

1. Abstract

Provide a brief (less than 2 pages) summary of the proposed PFTP.

2. Background and Need

Discuss the background and need for the proposed project. Demonstrate a clear understanding of the purpose and objectives of the PFTP cooperative agreement program. Demonstrate a clear understanding of the requirements, responsibilities, problems, constraints, complexities, etc., that may be encountered in administration of the proposed PFTP.

3. Capacity and Personnel

a. Describe applicant's goals, objectives, and efforts to promote the field of academic infectious diseases. Describe relevant degree programs and sponsored regular national meetings, seminars, and/or workshops devoted to pertinent issues in academic infectious diseases with relevance to public health.

b. Demonstrate applicant's experience in academic infectious diseases education and training in general, including experience in maintaining programs that lead to eligibility for certification in infectious diseases by the American Board of Internal Medicine. Describe applicant's existing postdoctoral fellowship training programs for physicians in infectious diseases.

c. Describe applicant's resources, facilities, and professional personnel that will be involved in conducting the project. Include (in an appendix) curriculum vitae for all professional personnel involved with the project. Describe plans for administration of the project and identify administrative resources/personnel that will be assigned to the project. Provide (in an appendix) letters of support from all key participating non-applicant organizations, individuals, etc., which clearly indicate their commitment to participate as described in the operational plan. Do not include letters of support from CDC personnel. Letters of support from CDC will not be accepted in the application.

4. Operational Plan

Present a detailed and time-phased plan for establishing and conducting the PFTP. Describe procedures to accomplish all of the required recipient activities, within the performance period. Describe how the clinical and research activities will be coordinated within the PFTP. Present a plan for monitoring and evaluating the progress of fellows and the progress toward achieving program goals. Describe how the plan will ensure that all fellows become eligible for certification in infectious diseases by the American Board of Internal Medicine by the end of fellowship tenure.

5. Budget

Provide a line-item budget and accompanying detailed, line-by-line justification that demonstrates the request is consistent with the purpose and objectives of this program. Clearly indicate by line-item:

(1) The full cost of the PFTP
(2) The amount requested from CDC
(3) The amount of cost sharing (not less than 50 percent) to be provided by applicant (see Availability of Funds section for further information).

Evaluation Criteria (100 Points)

The applications will be reviewed and evaluated based on the following criteria:

1. The extent to which the applicant demonstrates that they have been and are devoted to promoting the field of academic infectious diseases. The extent to which the applicant has promoted the field of academic infectious diseases by conducting regular national meetings and workshops devoted to current topics. The extent to which the applicant documents experience in education and training in academic infectious diseases, including documentation of relevant degree programs offered and evidence of experience in successfully preparing students for certification in infectious diseases by the American Board of Internal Medicine. (15 points)

2. The extent to which applicant describes adequate resources and facilities (clinical, academic, and administrative) for conducting the PFTP. Extent to which applicant documents that professional personnel involved in the PFTP are qualified and have past experience and achievements related to that proposed as evidenced by curriculum vitae, publications, etc. (15 points)

3. The extent to which the applicant demonstrates significant institutional experience in managing postdoctoral fellowship training programs for physicians in the area of infectious diseases. The extent to which applicant documents they have a successful existing postdoctoral fellowship program in infectious diseases. (30 points)

4. The extent to which the proposed operational plan is clear, detailed, and meets the purpose and goals of this cooperative agreement program. The extent to which the proposed operational plan addresses all required recipient activities. The extent to which the proposed plan coordinates the clinical and research activities so that they comprise a complementary and congruent training program. (30 points)

5. The quality of the proposed plan to monitor, evaluate and track individual fellows; and overall plan to evaluate activities and objectives. (10 points)

6. The extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of cooperative agreement funds. (not scored)

Executive Order 12372 Review

Applications are not subject to review as governed by Executive Order 12372 (45 CFR part 100), Intergovernmental Review of Federal Programs.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.283.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by the cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If any research/training activities for the fellows involve research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and form provided in the application kit.

Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, dated Friday, September 15, 1995.

Application Submission and Deadline

The original and two copies of the application Form PHS–5161–1 (OMB Number 0937–0189) must be submitted to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–18, Atlanta, Georgia 30305, on or before August 19, 1997.

1. *Deadline:* Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. *Late Applications:* Applications which do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description and information on application procedures are contained in the application package. Business management technical assistance may be obtained from Bernice A. Moore, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–18, Atlanta, Georgia 30305, telephone (404) 842–6802, facsimile (404) 842–6513, or Internet or CDC WONDER electronic mail at bam0@cdc.gov.

Programmatic technical assistance may be obtained from Greg Jones, M.P.A., National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Mailstop C–19, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639-2434, facsimile (404) 639–4195, or Internet or CDC WONDER electronic mail at gjj1@cdc.gov.

To receive an application kit, please call (404) 332–4561. You will be asked to leave your name, mailing address, and telephone number. Please refer to Announcement Number 783 when requesting information regarding this program. You may obtain this announcement from one of two Internet sites on the actual publication date: CDC's homepage at http://www.cdc.gov or at the Government Printing Office homepage (including free on-line access to the **Federal Register**) at http://www.access.gpo.gov.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the **INTRODUCTION** through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512-1800.

Dated: July 14, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–18947 Filed 7–17–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement Number 781]

Cooperative Agreement To Provide Information Concerning the Diagnosis, Prevention and Treatment of Viral Hepatitis-Related Liver Disease

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of funds beginning in fiscal year (FY) 1997 for a cooperative agreement program with one or more national organizations to develop and distribute materials to educate the general public, affected patients, risk groups, physicians, and other health care providers about the prevention, diagnosis and medical management of acute and chronic liver disease due to all types of viral hepatitis, with initial emphasis on hepatitis C.

CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2000,'' a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases. (To order a copy of Healthy People 2000, see **WHERE TO OBTAIN ADDITIONAL INFORMATION.**)

Authority

This program is authorized under sections 301 (42 U.S.C. 241) and 317(k)(2) (42 U.S.C. 247b(k)(2)) of the Public Health Service Act, as amended.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and promote the nonuse of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants are limited to national nonprofit organizations which devote a major portion of their activities to educating the public, patients, and health care providers about the diagnosis, prevention, and medical management of viral hepatitis-related liver disease. Eligible applicants must also have established collaboration with diverse national organizations and groups that represent health care professionals, minority populations, volunteers, consumers, patients, community organizations, groups at risk of infection with hepatitis viruses, government entities, and others.

Organizations that meet these eligibility requirements are the most appropriate applicants because:

1. They have the expertise and experience needed to produce effective health education materials and messages and develop strategies to maximize health care professionals and public awareness and education about the risk factors, preventive measures, and treatment options for viral hepatitis, including hepatitis C.

2. They have demonstrated interest in providing accurate, pertinent information on viral hepatitis-related liver disease to the public, populations at risk of infection, patients, and health care professionals.

3. They have the ability to collaborate with health professional schools (medical, dental, public health, nursing, allied health), medical and health professional societies, blood banks, health care facilities, community organizations, at-risk populations, and local, State, and Federal government agencies to increase awareness of how viral hepatitis, in general, and hepatitis C virus (HCV) infections specifically, can be identified, treated, and prevented.

4. They can conduct formative research, pilot test potential messages and materials, and evaluate their effectiveness in increasing knowledge and motivating behavior change.

Availability of Funds

Approximately $250,000 is available in FY 1997 to fund up to two cooperative agreements. It is expected that the awards will begin on or about September 1, 1997, for a 12-month budget period within a project period of up to three years. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds. Funding estimates may vary and are subject to change.

Use of Funds

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of Department of Health and Human Services (HHS) funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or ''grass roots'' lobbying efforts that are designed to support or defeat legislation pending before State legislatures. Section 503 of this new law, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, Section 101(e), Pub. L. No. 104–208 (September 30, 1966), provides as follows:

Sec. 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, * * * except in presentation to the Congress or any State legislative body itself.

(b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Background

Hepatitis C virus (HCV) is an important cause of acute and chronic hepatitis in the United States. The CDC estimates 30,000 persons were infected with HCV in 1995, with most infections occurring among young adults with high-risk behaviors or lifestyles. The most efficient mode of transmission of HCV is through direct percutaneous exposures, such as from sharing of contaminated needles among injection drug users or from blood transfusion. Exposures associated with acquiring HCV infection include blood transfusion prior to 1990, receipt of clotting factor concentrates that were not virally inactivated, injection drug use, snorting cocaine, hemodialysis, health care work involving frequent exposure to blood (in particular, accidental needle sticks), sexual contact with a partner infected with HCV, multiple sex partners (heterosexual or homosexual), and birth to a HCV-infected woman. Currently, most HCV infections are acquired by high-risk drug use (60 percent) and sexual behaviors (20 percent). There is no evidence that transmission of HCV is associated with commercial use of equipment for tattooing, body piercing, hair cutting (razors), or manicures.

The most important feature of hepatitis C is the high rate of progression to chronic infection, even in the absence of active liver disease. About 70 percent of HCV infected persons develop chronic hepatitis that can progress to cirrhosis and hepatocellular carcinoma, with an estimated 8–10,000 HCV-related chronic liver disease deaths each year. A national survey conducted in the U.S. from 1988 to 1994 found that 1.8 percent of a representative sample of the civilian population had antibody to HCV, corresponding to 3.9 million HCV-infected Americans. Infection rates were higher in males than in females, and higher in African Americans than in Caucasians. The highest rates of HCV infection were found in adults aged 30–49 years.

Because of the large degree of confusion and lack of accurate information about hepatitis C, educational materials are necessary for both health care providers and the general public about the risks of acquiring HCV infection, indications for serological testing and other diagnostic methods, treatment issues, and means to prevent the spread of infection. Prevention strategies to identify, treat and counsel persons with chronic infection and measures to reduce transmission in high-risk groups are needed. For health care providers, these should include information on identifying patients with a history of high-risk exposures, interpretation of diagnostic test results, discussion of treatment options, guidelines for counseling patients, and the importance of appropriate disease reporting.

Hepatitis A virus (HAV) infection is a major cause of acute hepatitis in the United States (U.S.). At least 150,000 persons are newly infected each year with 75,000 developing clinical illness associated with substantial morbidity and medical and work-loss costs. Up to 20 percent of persons with hepatitis A are hospitalized with an average 27 days of work loss. Direct and indirect costs were estimated to be more than $200 million in 1991. Most cases of hepatitis A occur by person-to-person transmission in community-wide outbreaks. The highest rates of disease occur in children, adolescents and young adults, and among American Indians/Alaska Natives and Hispanics. Children may be the major reservoir for transmission of HAV; nearly 30 percent of reported cases occur among children less than 15 years of age, and many more children probably have unrecognized or asymptomatic infection that is not recognized until transmission to older household contacts occurs.

Hepatitis A vaccines are licensed for persons over two years of age, with virtually 100 percent of children, adolescents, and adults developing protective levels of antibody after the vaccine series. While the most effective means of achieving control of HAV infection would be to include routine hepatitis A vaccination in the childhood vaccination schedule, the vaccine is not licensed, as yet, for children under two years of age. Current recommendations are for pre-exposure vaccination of groups at increased risk for HAV infection (e.g., persons traveling to countries with high rates of HAV infection, men who have sex with men, drug users) and routine vaccination of children and adults in communities with high or intermediate rates of HAV infection.

Acute and chronic hepatitis B virus (HBV) infections are a major cause of morbidity and mortality in the United States, consuming a large amount of health care resources. Approximately 60,000 new infections with HBV continue to occur each year in spite of the availability of an effective vaccine. The existing pool of 1.25 million persons with chronic HBV infection are potentially infectious to others and are at risk of long-term sequelae that include chronic active hepatitis, cirrhosis and primary hepatocellular carcinoma. Approximately 6,000 deaths occur annually from HBV-related chronic liver disease. Antiviral therapy is moderately effective in eliminating chronic HBV infection. However, most chronically infected persons are not being identified, counseled, or treated. Patients with chronic HBV infection need to be counseled about treatment options and health care interventions that can be used to prevent HBV transmission to others.

The most effective means of preventing new HBV infections and HBV-related acute and chronic liver

disease is by immunizing susceptible persons with hepatitis B vaccine. A comprehensive strategy to eliminate HBV transmission in the U.S. has been developed and includes prevention of perinatal HBV infection, routine vaccination of infants, catch-up vaccination of young children at high risk of HBV infection, routine vaccination of adolescents, and vaccination of adolescents or adults at high risk of infection. Currently, routine maternal screening to prevent perinatal HBV infection and routine vaccination of infants and adolescents have been widely implemented throughout the U.S. However, high levels of vaccination coverage have not been achieved for childhood populations at high risk of infection and for adults and adolescents in groups at high risk of infection.

Purpose

The purpose of this cooperative agreement program is to assist national organizations in fulfilling their goals of developing and disseminating accurate information on viral hepatitis to target audiences that include health care providers, at-risk populations, patients, and the general public. Specifically, the objectives are to: (1) improve health care provider knowledge about the diagnosis, prevention, health consequences, and medical management of viral hepatitis (with initial emphasis on hepatitis C), and (2) improve community, risk group, and patient awareness of the importance of and the means for the prevention of viral hepatitis (with initial emphasis on hepatitis C) by collecting, developing, and disseminating information and educational materials.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities described under A. below, and CDC will be responsible for the activities described under B. below:

A. Recipient Activities

1. Review existing available educational information on the diagnosis, prevention, health consequences, and medical management of viral hepatitis. Such materials may be available from the recipient and others (e.g., nonprofit organizations, pharmaceutical and vaccine manufacturers, provider organizations, Federal and State governments, etc.). Determine gaps and in information and efforts to effectively reach groups targeted by these available materials. For example, review the materials for accuracy, completeness, and appropriateness for target audiences which include various professional groups (i.e., physician, nursing, dental), at-risk groups, and racial/ethnic groups with high rates of the various types of viral hepatitis.

2. Develop and evaluate new educational materials that will fill identified gaps through collaboration with organizations and groups that represent the target audiences. Use formative research to develop various types of health education materials (e.g., fact sheets, brochures, pamphlets, videos, public service announcements, letters to the editor, posters, articles for the lay press) that will fill the identified gaps in health education materials needed for the various disease-specific target audiences. Such materials should target both the general public and at-risk populations. Messages for at-risk groups should be appropriate for the specific diseases (HAV, HBV, HCV) and risk groups should include men who have sex with men and injection drug users where appropriate. Evaluation of the effectiveness of newly developed materials should employ methods such as:

a. Focus groups and/or intercept interviews with the public and specific at-risk populations to determine acceptance and clarity of messages.

b. Pilot testing messages with representative audiences for appeal, effectiveness in increasing knowledge, and motivating behavior change.

3. Evaluate various methods used to disseminate health education materials/messages to determine the most effective methods for the target audiences.

4. Disseminate existing and newly developed materials to target audiences which include individuals at risk for or infected with HCV, health care providers, and the general public. Recipient may network with other organizations or groups (professional, voluntary, governmental, community-based) that represent minority populations with high rates of viral hepatitis or groups/populations at high risk of specific types of viral hepatitis, e.g., National Institute for Drug Abuse (NIDA), American Social Health Association (ASHA).

B. CDC Activities

1. Provide scientific and public health consultation and assistance in the development of materials and activities related to the cooperative agreement.

2. Provide scientific collaboration for appropriate aspects of the activities, including information on disease impact, vaccination coverage levels, and prevention strategies.

3. Assist in reporting and validating relevant information concerning viral hepatitis made available to Federal, State, local health agencies, health care providers, and volunteer organizations.

Technical Reporting Requirements

Narrative progress reports are required semiannually. The first semiannual report is required with each year's noncompeting continuation application and should cover program activities from date of the previous report (or date of award for reporting in the first year of the project). The second semiannual report is due 90 days after the end of each budget period and should cover activities from the date of previous report. Progress reports should address the status of all recipient activities above, including: (1) A comparison of actual accomplishments to the objectives established for the funding period; (2) The reasons for failing to meet any established objectives; (3) Description and explanation of any modifications of program activities and protocols; and (4) Other pertinent information such as key staffing changes or reasons for unexpectedly high or low costs for performance.

An original and two copies of a financial status report are required no later than 90 days after the end of each budget period. A final performance report and financial status report are due no later than 90 days after the end of the project period.

All reports are submitted to the Grants Management Branch, Centers for Disease Control and Prevention (CDC), Attention: Sharron P. Orum, Grants Management Officer, Procurement and Grants Office, 255 East Paces Ferry Road, NE., Mailstop E–18, Room 300, Atlanta, Georgia 30305.

Application Content

All applicants must develop their applications in accordance with PHS Form 5161–1 (OMB Number 0937–0189) information contained in this Program Announcement, and the instructions regarding typing, mailing, and format outlined below.

Typing and Mailing

An original and two copies of the application must be submitted. Pages must be clearly numbered, and a complete index to the application and its appendixes must be included. Please begin each separate section on a new page. The original and each copy of the application must be submitted unstapled and unbound. All materials must be typewritten, single-spaced, with unreduced type on 8–½″ by 11″ paper,

with at least 1'' margins headers and footers, and printed on one side only. The application narrative must not exceed 10 single-spaced pages (excluding budget and appendices). Unless indicated otherwise, all information requested below must appear in the narrative. Materials or information that should be part of the narrative will not be accepted if placed in the appendices.

Format

The application narrative must contain the following sections in the order presented below:

1. Introduction

Clearly demonstrate that applicant satisfies the eligibility requirements under **ELIGIBLE APPLICANTS** section above. Briefly provide a thorough description of the need or problem(s) to be addressed and the specific and unique contributions that applicant can make in the development and dissemination of health education materials about viral hepatitis with initial emphasis on hepatitis C.

2. Capacity and Personnel

Describe applicant's ability to develop health education materials and to conduct education and awareness campaigns for specific audiences, including populations at risk for specific types of viral hepatitis. Describe applicant's resources, facilities, and professional personnel that will be involved in conducting the activities. Include in an appendix curriculum vitae for all professional personnel involved with the project. Describe plans for administration of the project and identify administrative resources/personnel that will be assigned to the project. Provide in an appendix letters of support from all key participating non-applicant organizations which clearly indicate their commitment to participate as described in the operational plan.

3. Objectives and Technical Approach

Present specific objectives for the proposed project which are measurable, time-phased, and clearly address the Purpose and Recipient Activities for this program. Present a detailed operational plan for initiating and conducting the project which clearly and adequately addresses these objectives (if proposing a multi-year project, provide a detailed description of first-year activities and a brief overview of subsequent-year activities). Clearly identify specific assigned responsibilities for all key professional personnel and their time commitment. Include a clear description of applicant's technical approach/methods which are directly relevant to the above objectives. Describe the nature and extent of collaboration with CDC and others during various phases of the project. Describe in detail a plan for evaluating the effectiveness of newly developed educational materials in increasing target audience knowledge and facilitating changes in their behavior, including assessing the impact of strategies on professional practice behaviors. Describe plans to evaluate overall progress toward achieving project objectives.

4. Budget

Provide a line-item budget and accompanying detailed, line-by-line justification that demonstrates the request is consistent with the purpose and objectives of this program. If requesting funds for any contracts, provide the following information for each proposed contract: (1) Name of proposed contractor, (2) breakdown and justification for estimated costs, (3) description and scope of activities to be performed by contractor, (4) period of performance, and (5) method of contractor selection (e.g., sole-source or competitive solicitation).

5. Human Subjects

Whether or not exempt from DHHS regulations, if the proposed project involves human subjects, describe (in an appendix) adequate procedures for the protection of human subjects. Ensure that women, racial, and ethnic minority populations are appropriately represented in applications for research involving human subjects (see the section **OTHER REQUIREMENTS** for additional information). A copy of CDC policy is included in the application kit.

Evaluation Criteria (Total 100 points)

Applications will be reviewed and evaluated according to the following criteria:

1. Understanding (25 points)

Extent to which the application responds to the objectives of this cooperative agreement program including: (a) Applicant's understanding of the objectives of the cooperative agreement, and (b) relevance of the applicant's plan to the stated objectives.

2. Capacity (25 points)

Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements related to the proposed activities. Extent to which applicant includes letters of support from appropriate non-applicant organizations, individuals, etc., needed to carry out proposed activities and the extent to which such letters clearly indicate the author's commitment to participate as described in the operational plan.

3. Objectives and Technical Approach (45 points total)

a. Extent to which applicant describes objectives of the proposed project which are consistent with the purpose of this cooperative agreement program and which are measurable and time-phased. (15 points)

b. Extent to which applicant presents a detailed operational plan for initiating and conducting the project which clearly and appropriately addresses all Recipient Activities. Extent to which applicant clearly identifies specific assigned responsibilities and time commitment of all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies and extent to which the approach/methods are appropriate and adequate to accomplish the objectives. Extent to which applicant describes collaboration with CDC and/or others during various phases of the project. (15 points)

c. Extent to which applicant provides a detailed and adequate plan for evaluating effectiveness of newly developed educational materials in increasing target audience knowledge and facilitating changes in their behavior, including assessing the impact of strategies on professional practice behaviors. Extent to which applicant describes plans to evaluate progress toward achieving project objectives. (15 points)

4. Budget (not Scored)

Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of grant/cooperative agreement funds.

5. Human Subjects (5 Points)

If the proposed project involves human subjects, whether or not exempt from the Department of Health and Human Services (DHHS) regulations, the extent to which adequate procedures are described for the protection of human subjects. Note: Objective Review Group (ORG) recommendations on the adequacy of protections include: (1) Protections appear adequate and there are no comments to make or concerns to raise, (2) protections appear adequate,

but there are comments regarding the protocol, (3) protections appear inadequate and the ORG has concerns related to human subjects, (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable, and (5) protections appear adequate that women, racial and ethnic minority populations are appropriately represented in applications involving human research.

Executive Order 12372 Review

This program is not subject to the Executive Order 12372 review.

Public Health System Reporting Requirement

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 92.283.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by the cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit. Should human subjects review be required, the proposed work plan should incorporate time lines for such development and review activities.

Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive NO. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, dated Friday, September 15, 1995.

Application Submission and Deadline

The original and two copies of the application Form PHS–5161–1 (OMB Number 0937–0189) must be submitted to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 305, Mailstop E–18, Atlanta, Georgia 30305, on or before August 19, 1997.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications. Late applications will not be considered and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description and information on application procedures are contained in the application package. Business management technical assistance may be obtained from Bernice A. Moore, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 305 Mailstop E–18, Atlanta, Georgia 30305, telephone (404) 842–6802, fax (404) 842–6513, or Internet or CDC WONDER electronic mail at bam0@cdc.gov.

Programmatic technical assistance may be obtained from Louise S. Barden, Health Educator, Hepatitis Branch, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, Mailstop G–37, Atlanta, Georgia 30333, telephone (404) 639–2709, (fax) 404–639–1538, or Internet or CDC Wonder electronic mail lyb4@cdc.gov.

To receive an application kit, please call (404) 332–4561. You will be asked to leave your name, mailing address, and telephone number. Please reference Announcement Number 781 when requesting information and submitting your application. You may also obtain this announcement and other CDC announcements from one of two Internet sites: CDC's homepage at http://www.cdc.gov or the Government Printing Office homepage (including free on-line access to the **Federal Register** at http://www.access.gpo.gov).

Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report: Stock No. 017–001–00473–1) referenced in the **INTRODUCTION** through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: July 14, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–18948 Filed 7–17–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. ACYF–PA–CC–97–03]

Native Hawaiian and Nonprofit American Indian Organization Child Care Grants

AGENCY: Administration on Children, Youth and Families, ACF, DHHS.

ACTION: Announcement of availability of competitive financial assistance for Native Hawaiian and Nonprofit American Indian Organization Child Care Grants.

SUMMARY: The purpose of this program announcement is to announce the availability of fiscal year 1998

Discretionary Funds, authorized under the Child Care and Development Block Grant (CCDBG) Act (the Act), as amended, for child care grants to:

(1) A Native Hawaiian organization; and

(2) A private nonprofit organization established for the purpose of serving youth who are Indians or Native Hawaiians.

DATES: The closing time and date for receipt of applications is 4:30 p.m. (Eastern Time Zone) on September 16, 1997. Applications postmarked after the closing will be classified as late.

FOR FURTHER INFORMATION CONTACT: Ginny Gorman, Administration for Children and Families, Child Care Bureau, Room 320F, Hubert Humphrey Building 200 Independence Avenue, SW., Washington, DC 20201, Phone: (202) 401–7260, Fax: (202) 690–5600, E-mail: ggorman@acf.dhhs.gov

NOTICE OF INTENT TO SUBMIT APPLICATION: If you intend to submit an application, please contact ACYF's Operations Center at 1–800–351–2293 with the following information: the number and title of this announcement; your organization's name and address; and your contact person's name, phone number, fax number, and e-mail address.

The information will be used to determine the number of expert reviewers needed to evaluate applications and to update the mailing list for program announcements.

SUPPLEMENTARY INFORMATION: The ACF Uniform Discretionary Grant Application Form covering all ACF announcements, contained in the Application Kit, and this **SUPPLEMENTARY INFORMATION** section contain all the forms and instructions needed to apply for a grant under this announcement. No additional application materials are needed.

The **SUPPLEMENTARY INFORMATION** section consists of six parts. Part I provides general information about funding requirements, and application procedures for child care grants under this program announcement. Part II provides background information on ACYF, the Child Care Bureau, and funding to Indian Tribes and tribal organizations under the Child Care and Development Fund (CCDF). Part III describes child care goals and priorities related to this announcement. Part IV describes the Project Narrative Statement and outlines additional requirements for applicants in designing their projects. Part V describes the evaluation criteria and selection process. Part VI provides additional instructions for the development and submission of applications and summarizes the application review process.

Part I. General Information

A. Purpose

The purpose of this program announcement is to provide funding for two child care programs: One serving Native Hawaiian youths; and one serving Indian and/or Native Hawaiian youths.

B. Citations

1. Sponsorship

Grants being awarded under this announcement are sponsored by the Child Care Bureau (the Bureau) of the Administration on Children, Youth and Families (ACYF) in the Administration for Children and Families (ACF), U.S. Department of Health and Human Services (DHHS). The projects will be managed by the Bureau.

2. Funding Authority

Funding is being provided by ACF under Section 658B of the Child Care and Development Block Grant Act, as amended (42 U.S.C. 9858).

3. Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance Number is 93.575.

C. Number of Awards

Two projects will be funded in fiscal year 1998 (beginning October 1, 1997), subject to the availability of funds and results of the evaluation process.

D. Project Duration

The total project period will be 36 months.

E. Funding Levels and Budget Periods

Initial awards will be for a one-year budget period. Individual projects will receive between $500,000 and $1,000,000 for the first budget period of 12 months, with a possibility of between $500,000 and $1,000,000 per year in continuation funding to be awarded in each of fiscal years 1999 and 2000. The estimated total Federal funding for a three-year project is between $1,500,000 and $3,000,000.

Applications for continuation of grants funded under this announcement will be entertained in subsequent years on a non-competitive basis. The award of continuation funding beyond each one-year budget period (but within the three-year project period) will be subject to the availability of funds, satisfactory progress of the grantee, and a determination that continued funding would be in the best interest of the government.

F. Non-Federal Share of Project Costs

While grantees are not required to provide a match to receive funding under this program announcement, applicants are strongly encouraged to leverage funds from other sources for this project.

G. Eligibility

The following organizations are eligible to apply for funding under this program announcement:

- A private non-profit organization that serves the interests of Native Hawaiians and is recognized by the Governor of Hawaii for the purpose of planning, conducting, or administering programs (or parts of programs) for the benefit of Native Hawaiians; and
- A private non-profit organization established for the purpose of serving youth who are Indians or Native Hawaiians.

Any non-profit organization submitting an application must submit proof of its non-profit status in its application at the time of submission. The non-profit agency can accomplish this by providing a copy of the applicant's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in Section 501(c)(3) of the IRS code *or* by providing a copy of the currently valid IRS tax exemption certificate, *or* by providing a copy of the articles of incorporation bearing the seal of the State in which the corporation or association is domiciled.

At least 90 percent of the individuals serving on a non-profit applicant's board must fall into one or more of the following categories: (1) Must be a current or past member of the community to be served; (2) be a prospective participant in or beneficiary of the project to be funded; or (3) have a cultural relationship with the community to be served.

''Community'' is defined as a group with common interests and a common identity, such as an Indian Tribe, Alaska Native Village, or a group of Native Hawaiians living in a given geographic area, and all those residing or participating in a predominantly Native Hawaiian community.

If an Indian organization is already receiving Child Care and Development Fund (CCDF) funding, it is not eligible to apply for Discretionary Funds under this program announcement. Only one application will be accepted from each eligible applicant.

Part II. Background and Context

A. The Child Care Bureau

The Child Care Bureau is that agency within the Federal Government with the most far-reaching mandate for child care. Established in 1995 to provide new leadership and consolidate Federal responsibilities for subsidized child care programs within the Department of Health and Human Services, the Bureau administers some $2.9 billion in Federal child care dollars annually.

The Bureau works closely with States, Territories, Tribes and local communities to develop cost-effective services and delivery systems, promotes joint ventures with the private sector, and provides information and other assistance to parents. In addition, the Bureau collaborates extensively with other offices throughout the Federal government to promote integrated, family-focused services and coordinated child care delivery systems.

In all of these activities, the Bureau seeks to enhance the quality, availability and affordability of child care services, to support children's healthy growth and development in safe child care environments, to enhance parental choice and involvement in their children's care, and to facilitate the linkage of child care with other community services.

The Bureau's central responsibility is administration of a new integrated child care program created by title VI of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Pub. L. 104–193) which became effective October 1, 1996. This law created new child care funding under Sec. 418 of the Social Security Act and consolidated it under the amended Child Care and Development Block Grant Act, allowing States and Tribes to design comprehensive, integrated service delivery systems to meet the needs of low-income working families. For ease of reference, the newly consolidated funding sources are known as the ''Child Care and Development Fund'' (CCDF). In fiscal year 1997, States will receive more than $2 billion and Tribes and tribal organizations will receive $59 million in CCDF funds.

The CCDF is available to States, Territories, Indian Tribes, and tribal organizations to: Provide low-income families with the financial resources to find and afford quality child care for their children; increase the affordability of child care for low-income families; enhance the quality and increase the supply of child care for all families, including those that receive no direct assistance under CCDF; provide parents with a broad range of options in addressing their child care needs; strengthen the role of the family; and coordination among child care programs and early childhood development programs.

In administering the CCDF, the Bureau develops policies, monitors service delivery systems, and provides technical assistance in close cooperation with ten DHHS Regional Offices that in turn work directly with States, Territories and Indian Tribes and tribal consortia.

B. Grants to Indian Tribes and Tribal Consortia

The CCDF is comprised of two funding sources for Tribes and tribal consortia:

- *Discretionary Funds*—funding that is provided under the Child Care and Development Block Grant Act, as amended; and
- *Tribal Mandatory Funds*—funding that is provided to eligible tribal organizations under Section 418 of the Social Security Act.

Currently, approximately 237 Indian Tribes and tribal consortia receive CCDF funds. Through consortia arrangements, these grantees serve over 500 federally recognized Indian Tribes and Alaska Native Villages.

A Tribe is eligible to receive CCDF funds if it is federally recognized and the tribal population includes at least 50 children under 13 years of age (or such similar age, as determined by the Secretary from the best available data). A Tribe with fewer than 50 children under age 13 may participate in a consortium of eligible tribes.

In order to receive CCDF funds, eligible Tribes and tribal consortia develop a plan for child care services. The plan is an agreement between the Administration for Children and Families (ACF) and the Tribal agency responsible for administering the CCDF funds. The plans provide assurances that the funds will be administered in conformance with the Act, pertinent Federal regulations, and other applicable instructions or guidelines issued by ACF.

C. Grants to ''Other Organizations''

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) amended the Child Care and Development Block Grant Act (CCDBG), to add the following definition to the term ''tribal organization'' that are potentially eligible for Discretionary Funding:

> ''Other organizations—Such term includes a Native Hawaiian Organization, as defined in section 4009(4) of the Augustus F. Hawkins-Robert T. Stafford Elementary and Secondary School Improvement Amendments of 1988 and a private nonprofit organization established for the purpose of serving youth who are Indians or Native Hawaiians.''

Section 4009(4) of the Augustus F. Hawkins-Robert T. Stafford Elementary and Secondary School Improvement Amendments of 1988 defines a Native Hawaiian Organization as:

> ''A private nonprofit organization that serves the interests of Native Hawaiians, and is recognized by the Governor of Hawaii for the purpose of planning, conducting, or administering programs (or parts of programs) for the benefit of Native Hawaiians.''

Applicants are eligible to apply only for Discretionary Funds under this announcement. Native Hawaiian organizations and private nonprofit organizations established for the purpose of serving youth, who are Indians or Native Hawaiians are not eligible to apply for Tribal Mandatory Funds.

Part III. Native Hawaiian and Nonprofit American Indian Organization Child Care Grants—Goals and Priorities

Following the passage of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Pub. L. 104–193), the Child Care Bureau held a series of conference calls with its tribal grantees, hosted a meeting of its Tribal Work Group, and held workshops on the implementation of CCDF sections of the law at an ACF-sponsored conference for Tribes on Tribal Welfare Reform in October 1996.

As a result of these discussions, it is clear that tribal grantees are interested in designing services adapted to individual tribal circumstances and coordinating resources that will assist in moving families on the path toward social and economic self-sufficiency.

For this reason, applicants are strongly encouraged to coordinate activities with agencies serving the same population of the applicant agency for: health (including the agency responsible for immunizations), education, employment services or workforce development, and the agency responsible for providing Temporary Assistance for Needy Families (TANF).

Grants are awarded under this announcement to increase the availability, affordability and quality of child care services by establishing child care programs in areas that have been previously underserved and/or have unmet needs.

A. Regulatory and Statutory Requirements

The majority of the information requested under Section IV, Program Narrative, of this program announcement is required by the current regulations at 45 CFR part 98 and the CCDBG Act, as amended. Unless otherwise indicated, the regulations at 45 CFR part 98 will apply to grants awarded under this program announcement. As discussed in Part II., B. Background and Context, this information is requested in the CCDF plan for Tribes and tribal consortia. However, since the CCDF plan is not appropriate for grants under this announcement, the regulatory and statutory information required by the CCDF is included in Part IV, Program Narrative. An applicant must also include a statement that it will comply with the applicable list of assurances found in 45 CFR 98.15 of the CCDBG final rule.

B. Eligibility for Services

In order to best meet the purposes of the Act, we believe it is appropriate for grantees under this announcement to meet most of the same requirements as grantees receiving tribal formula grants under the CCDF program.

All eligible children must be under the age of 13 and reside with a family whose income does not exceed 85% of the grantee median income for a family of the same size and whose parent(s) are working or attending a job training or educational program or who receive or need to receive protective services. Grantee median income may be defined as: (1) Tribal median income for a family of the same size residing in the area served by the applicant; or (2) State median income for a family of the same size.

An applicant must indicate which income eligibility definition it plans to use in establishing a child care program under this announcement. In addition, an applicant must define the following terms, as used in their application: Working, attending, job training or educational program, protective services and *in loco parentis*. Instructions on defining these terms are included in the Application Kit's ''Supplemental Guide.''

An applicant may elect to establish additional eligibility criteria. For example, an applicant may establish different income limits for part of the population to be served. Any additional eligibility criteria need to be clearly identified and defined by the applicant. An applicant may also elect to waive, on a case-by-case basis, the fee and income eligibility requirements for cases in which children receive or need to receive protective services.

An applicant is encouraged to provide child care for children age 13 and older who are physically and/or mentally incapable of self-care, but must define these terms in their application. An applicant may also provide child care for children age 13 and older who are under court supervision. If care is to be provided in either circumstance, the applicant must specify the age of the children to be served, up to age 19.

In designing a child care program, an applicant is encouraged to address the before- and after-school care needs of eligible children to be served under this program announcement.

C. Coordination

The applicant must describe how it will coordinate the delivery of CCDF-funded child care services with other Federal, State, and local child care, early childhood development programs, and before- and after-school care services, if applicable.

Child care should be an integral part of a community's self-sufficiency and workforce development efforts. In addition, the quality of child care benefits greatly from close coordination with the public health and education communities. Therefore, it is recommended that the applicant include a description of its coordination activities with agencies responsible for health (including the agency responsible for immunizations), education, employment services or workforce development, and the agency responsible for providing Temporary Assistance for Needy Families (TANF).

D. Public Notice

As part of the planning process, an applicant must notify those families eligible to be served under this program announcement of the provision of child care services proposed under this project. Applicants are encouraged to engage in a planning process that includes parents, providers, and other relevant stakeholders in the community to be served.

E. Parental Choice

One of the goals of the Child Care and Development Block Grant Act is ''to promote parental choice to empower working parents to make their own decisions on the child care that best suits their family's needs.'' In support of this goal, applicants are expected to design and implement a certificate program since it promotes parental choice in selecting CCDF-funded child care providers.

However, while certificates ensure parental choice, contracted slots also play an important role in meeting the child care needs of families, particularly in rural areas, for infant-care, or for children with special needs.

Therefore, it is incumbent upon an applicant to design a child care program that will adequately address the needs and unique circumstances of the population it intends to serve through a grant awarded under this program announcement. If an applicant is unable to operate a certificate program, or chooses to provide child care services through grants and contracts exclusively, it must justify this approach in its program narrative and assure how it will promote parental choice.

F. Quality Activities

In developing a child care program, applicants are encouraged to include activities to improve the availability and quality of child care. Examples of activities undertaken by CCDF-funded tribal child care programs include: (1) Resource and referral programs; (2) grants or loans to providers to assist in meeting standards; (3) monitoring of compliance with licensing and regulatory requirements; (4) training and technical assistance; (5) compensation for child care providers; and (6) comprehensive consumer education. An applicant may select activities from this list of examples, or design other quality activities that are better suited to the population to be served through a grant awarded under this program announcement.

G. Construction and/or Renovation of Child Care Facilities

Title VI of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Pub. L. 104–193) amended the Child Care and Development Block Grant Act to permit Tribal grantees to use CCDF funds for construction and renovation of child care facilities. Therefore, in its grant application, the applicant should describe any anticipated construction and renovation projects that will be funded with CCDF funds, and estimate the amount of funds that will be used for these projects.

However, grant funds cannot be spent for construction or renovation until a grantee has applied for and received approval, through a separate application process, from the Department of Health and Human Services (DHHS). A grantee may submit a request to spend part of its grant for construction or renovation through this separate application process once it has been awarded a CCDF grant under this announcement.

As part of the separate application process, a grantee must show that adequate facilities are not otherwise available to carry out child care programs, and that the lack of facilities will inhibit the operation of such programs in the future. The amount of funds that a grantee may request for construction or renovation through the separate application process is limited to the amount estimated in the grantee's original CCDF application under this announcement.

Furthermore, statutory language at section 6580(c)(6) of the revised CCDBG Act indicates that Congress does not intend for construction and renovation projects to unnecessarily divert resources from the provision of child care services. Because grants under this announcement are designed to establish child care programs in areas with unmet need, a grantee should reserve adequate funds for direct child care services. While some construction and renovation activity is allowable under this program announcement, in accordance with Part V., Section A., 5. Budget, an applicant will have to demonstrate that funds will be used for direct child care services and the funds requested are reasonable in regard to the number of eligible children to be served.

Part IV. Project Narrative Statement

The Project Narrative Statement is that section of the application which provides most of the information on which proposals will be competitively reviewed. The standard set of Program Narrative requirements in the ACF Uniform Discretionary Grant Application Form apply broadly to all ACF program announcements. Specific requirements for this announcement are detailed below. Applicants should tailor their Project Narrative to these specific requirements.

The Project Narrative should be carefully developed in accordance with the goals and priorities described in Part III, the proposal preparation requirements described in this Part, and the evaluation criteria and selection factors described in Part V.

The Project Narrative sets forth the technical proposal and describes how it will be carried out. This statement should be organized according to the evaluation criteria contained in Part V as follows: (A) Issues, Objectives and Significance; (B) Approach and Activities; (C) Organizational Capabilities and Qualifications; (D) Results and Benefits Expected; and (E) Budget.

Applicants proposing multi-year projects must fully describe each year's project activities in the Project Narrative. A separate itemized budget of the Federal costs of the project for each budget period must be included in this section.

A. Issues, Objectives and Significance

In this section, applicants demonstrate their understanding of child care issues and present their long-range child care goals. The need for assistance must be demonstrated and the principal and subordinate objectives of the project must be clearly stated.

Applicants must clearly identify the critical child care issues affecting Native Hawaiian and/or Indian low-income families and the challenges they face. Supporting documentation such as letters of support and testimonials from concerned interests other than the applicant may be included.

Applicants must provide participant and beneficiary information. Specifically, information must be included on the number of Native Hawaiian and/or Indian children who would be eligible to receive child care services under this program announcement.

Applicants must establish payment rates for child care services that ensure eligible children equal access to comparable care. A copy of the proposed payment rates must be included in the application.

Applicants must document the type of involvement and support of the community in the planning process and implementation of the proposed project. Applicants must describe when and with whom they consulted in developing this proposal. Applicants must explain how they will notify those families eligible to be served under this grant of the provision of child care services proposed under this project.

Applicants must describe how they will coordinate the delivery of CCDF-funded child care services with other Federal, State, and local child care, early childhood development programs, and before- and after-school care services.

Any coordination activities under this project with agencies responsible for health, education, employment services or workforce development and Temporary Assistance for Needy Families (TANF) should be described in this section.

Applicants are expected to demonstrate a thorough understanding of the child care programs administered by the Child Care Bureau and the policies and funding requirements that apply to these grants.

B. Approach and Activities

The Approach and Activities section details a specific project design and implementation plan. This section should address two broad areas: (1) Specific project activities related to the design and implementation of child care services under this grant; and (2) management and coordination necessary for implementation of the project.

1. Approach

The applicant must describe its proposed approach in addressing the following:

- Offering a certificate program that allows parents to choose from a variety of child care categories, including center-based care, group home care, family child care and in-home care (including a description of the certificate payment system);
- Using grants or contracts for child care slots, if applicable;
- Reasons for limiting the use of in-home care, if applicable;
- Developing a methodologically sound system for determining the facts relied upon to determine that payment rates are sufficient to ensure equal access to comparable child care services provided to children whose parents are not eligible to receive child care assistance under the CCDF and other governmental programs. (A summary of those facts must also be included);
- Eligibility criteria and requirements, including how the applicant will give priority for child care services to children with special needs;
- The sliding fee scale to be used to determine each family's contribution to the cost of care (including whether families below the poverty level would be exempted from the fee);
- Processes with parents including: informing parents about child care services and options, making applications, and eligibility determinations; information on parental complaints; and affording parents unlimited access to their children receiving CCDF-funded child care services;
- Providing activities to improve the availability and quality of child care (examples of these activities are listed under Section III.F);
- Required health and safety standards by type of provider;
- Licensing requirements which apply to a provider of child care services under a grant; and
- Collecting data on children and families receiving CCDF-funded child care services (the Supplemental Guide

provides specific data collection requirements).

2. Implementation Plan

This section must include a sound and workable plan of action that describes how the proposed project would be carried out, including: How the project would be structured and managed; how roles and functions would be coordinated; how the timeliness of activities would be ensured; how quality control would be maintained; and how costs would be controlled. Applicants should describe their management of the project as a whole, and the management and coordinating roles of subgrantees under grants and contracts, if applicable.

- Provide a diagram showing the organizational structure of the applicant organization and the functional relationships among subgrantees, if applicable;
- Lay out the major tasks to illustrate the sequence and timing of tasks, time commitments of staff, important milestones, reports, and completion dates;
- Describe potential problems or difficulties with the proposed management approach, including factors that might affect the implementation of the child care program in the community to be served;
- Describe how subgrantees would coordinate their management of project tasks and other functions, if applicable; and
- Describe how the delivery of CCDF-funded child care services will be coordinated with other Federal, State, and local child care, early childhood development programs, and before- and after-school care services, if applicable.

C. Results or Benefits Expected

In this section applicants must identify results and benefits expected under the proposed project. These should be specific and measurable.

- At a minimum, explain how expected results under this project will benefit the population to be served in meeting its child care needs.
- Describe how the quality activities chosen will benefit the project.

D. Organizational Capabilities and Staff Qualifications

In this section, applicants must provide evidence that they, and their subgrantees, if applicable, have the experience, expertise and resources to carry out the proposed project on time, within budget, and with a high degree of quality.

1. Organizational Capability

- Provide evidence of sufficient organizational resources to ensure the applicant's successful project management, compliance with terms and conditions of the grant award and oversight of the proper use of Federal funds. Provide evidence of the applicant's capacity to coordinate the activities of subgrantees, if applicable; and
- Describe any subcontracting relationships, and the expected duration of these relationships.

2. Staff Qualifications

- Identify all key staff positions for this project, the professional requirements for each, the proportion of time to be committed to the project, and the period of time for which staff holding these positions would be employed;
- Provide evidence that individuals proposed for key positions have the necessary technical skill and experience to successfully carry out their assigned roles. Where key positions are currently vacant, include a position description outlining the qualifications necessary to carry out the duties and responsibilities of each;
- Identify the authors of the proposal and describe their continuing role in the project if funded; and
- Identify all proposed consultants, document their expertise, and describe how their services will be utilized. Include letters of commitment or intent if possible.

E. Budget

Present a detailed budget to demonstrate that the applicant will have adequate resources to carry out the proposed activities on time and with a high degree of quality.

- Include a detailed budget narrative that describes and justifies line item expenses within the budget categories listed on the Standard Form 424. If project funds will be subcontracted, a detailed budget for the use of those funds must be included; and
- Describe the extent of financial participation from other sources, if applicable. Describe the extent to which funds, staff time, in-kind services, and other resources have been committed to the proposed child care project during the total project period. Describe any other resources that are expected to help support the proposed activities, including existing commitments and negotiations in progress. Describe anticipated efforts to obtain other funding partners throughout the project, if applicable.

Part V. Evaluation and Selection

A. Evaluation Criteria

The criteria listed below will be used in conjunction with other expectations, priorities and requirements set forth in Parts III and IV above to evaluate how well each proposal addresses the goals of this announcement.

1. Significance, Issues and Objectives (Maximum of 20 Points)

- The extent to which the application reflects a solid understanding of critical child care issues, needs, and goals of the population to be served under this program announcement; and
- The extent to which the application addresses the unmet need for child care services in the population to be served under this program announcement.

2. Approach and Activities (Maximum of 40 Points)

- The extent to which proposed activities clearly relate to the applicant's child care needs and goals; and
- The extent to which the Implementation Plan: (1) Presents a sound, workable and cohesive plan of action demonstrating how the work will be carried out on time, within budget and with a high degree of quality; (2) includes a reasonable schedule of target dates and accomplishments; and (3) and presents a sound administrative framework for maintaining quality control over the implementation and ongoing operations of the child care program.

3. Results or Benefits Expected (Maximum of 10 Points)

- The extent to which the proposed activities will result in specific, measurable results.

4. Organizational Capabilities and Staff Qualifications (Maximum of 20 Points)

- The extent to which the application demonstrates that (1) facilities and organizational experience of the applicant organization are adequate to carry out the proposed project; (2) the applicant can effectively and efficiently administer a project of the proposed size, complexity and scope; and (3) the applicant has the capacity to coordinate activities with subgrantees for the successful accomplishment of project objectives, if applicable; and
- The extent to which the applicant proposes key staff with demonstrated experience in child care services, including relevant background, experience, training and work in related projects.

5. Budget (10 Points)

• The extent to which proposed project costs are reasonable, the funds are appropriately allocated across activities, and the budget is sufficient to accomplish the project objectives; and

• The extent to which the funds requested will be used for direct child care services to families through certificates and/or contracted programs for child care slots and that funds requested are reasonable in regard to the number of eligible children that will receive CCDF-funded child care services under announcement.

B. The Selection Process

The Associate Commissioner, Child Care Bureau, will make the final selection of the applicants to be funded. Applications may be funded in whole or in part depending on: (1) The ranked order of applicants resulting from the competitive review; (2) staff review and consultations; (3) the combination of projects that best meets the Bureau's objectives; (4) the funds available; and (5) other relevant considerations.

Selected applicants will be notified through the issuance of a Financial Assistance Award that sets forth the amount of funds granted, the terms and conditions of the grant award, the effective date of the award, the budget period for which support is given, and the total project period for which support is provided.

C. Funding Date

It is anticipated that successful applications will be funded by October 1, 1997.

Part VI. Instructions for the Development and Submission of Applications

This Part contains additional information and instructions for submitting applications in response to this announcement. Applicants should read this Part carefully in conjunction with other information and proposal requirements contained within this announcement.

A. Definitions

This program announcement is based on the following definitions:

• Categories of Care—center-based child care, group home child care, family child care and in-home care.

• Center-Based Child Care Provider—a provider licensed or otherwise authorized to provide child care services for fewer than 24 hours per day per child in a non-residential setting, unless care in excess of 24 hours is due to the nature of the parent(s)' work.

• Child Care Certificate—a certificate (that may be a check, or other disbursement) that is issued by a grantee directly to a parent who may use such certificate only as payment for child care services or as a deposit for child care services if such a deposit is required of other children being cared for by the provider, pursuant to § 98.30. Nothing in this part shall preclude the use of such certificate for sectarian child care services if freely chosen by the parent. For the purposes of this part, a child care certificate is assistance to the parent, not assistance to the provider;

• Construction—the building of a facility that does not currently exist;

• Discretionary Funds—the funds authorized under section 658B of the Child Care and Development Block Grant Act, as amended by PRWORA. (The Discretionary funds were formerly referred to as the Child Care and Development Block Grant);

• Eligible Child Care Provider—(1) A center-based child care provider, a group home child care provider, a family child care provider, an in-home child care provider, or other provider of child care services for compensation that is licensed, regulated, or registered under applicable State or local law as described in § 98.40; and satisfies State and local requirements, including those referred to in § 98.41 applicable to the child care services it provides; or (2) A child care provider who is 18 years of age or older who provides child care services only to eligible children who are, by marriage, blood relationship, or court decree, the grandchild, great grandchild, sibling (if such provider lives in separate residence), niece, or nephew of such provider, and complies with any applicable requirements that govern child care provided by the relative involved;

• Family Child Care Provider—one individual who provides child care services for fewer than 24 hours per day per child, as the sole caregiver, in a private residence other than the child's residence, unless care in excess of 24 hours is due to the nature of the parent(s)' work;

• Group Home Child Care Provider—two or more individuals who provide child care services for fewer than 24 hours per day per child, in a private residence other than the child's residence, unless care in excess of 24 hours is due to the nature of the parent(s)' work;

• Indian Tribe—any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. § 1601 et seq) that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians;

• In-home Child Care Provider—an individual who provides child care services in the child's own home;

• Licensing or Regulatory Requirements—requirements necessary for a provider to legally provide child care services in a State or locality, including registration requirements established under State, local or Tribal law;

• Other Tribal Organizations—such term includes a Native Hawaiian Organization, as defined in section 4009(4) of the Augustus F. Hawkins-Robert T. Stafford Elementary and Secondary School Improvement Amendments of 1988 and a private nonprofit organization established for the purpose of serving youth who are Indians or Native Hawaiians.

• Parent—a parent by blood, marriage or adoption and also means a legal guardian, or other person standing *in loco parentis;*

• Provider—the entity providing child care services;

• Sliding Fee Scale—a system of cost sharing by a family based on income and size of the family, in accordance with § 98.42;

• Tribal Mandatory Funds—the child care funds set aside at section 418(a)(4) of the Social Security Act. The funds consist of between one and two percent of the aggregate Mandatory and Matching child care funds reserved by the Secretary in each fiscal year for payments to Indian Tribes and Tribal organizations; and

• Types of Providers—the different classes of providers under each category of care. For the purposes of the CCDF, types of providers include non-profit providers, for-profit providers, sectarian providers and relatives who provide care.

B. Intergovernmental Review of Federal Programs

This program announcement is not covered under Executive Order 12372, Intergovernmental Review of Federal Programs,'' and 45 CFR Part 100, ''Intergovernmental Review of Department of Health and Human Services Program and Activities''.

C. The Application Process

1. Availability of Application Forms

In order to be considered for a grant under this program announcement, an application must be submitted on the forms supplied and in the manner

prescribed by ACYF. The application kits containing the necessary forms and instructions may be obtained from: Department of Health and Human Services, Administration for Children and Families, Child Care Bureau, Room 320F, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201–0001, Attention: ACYF–PA–CC–97–03, Telephone: (202) 401–7260.

2. Application Submission

One signed original, and two copies, of the grant application, including all attachments, must be mailed by the specific closing date to: Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., Mail Stop 6C–462, Washington, DC 20447, Attention: William J. McCarron, ACYF No. ACYF–PA–CC–97–03.

The application must be signed by an individual authorized (1) to act for the applicant organization, and (2) to assume the applicant's obligations under the terms and conditions of the grant award, including Child Care and Development Fund statutory and regulatory requirements.

ACF will accept only one application per applicant. If an eligible applicant sends in two applications, the one with the earlier postmark will be accepted for review unless the applicant withdraws the earlier application.

3. Application Consideration

The ACYF Commissioner determines the final action to be taken on each grant application received under this program announcement. Each application will be screened to determine whether the applicant organization is eligible as specified in Part I, section G, above. Applications from ineligible organizations will be excluded from the review. In addition, inadequate preparation, omission of essential components, or failure to comply with format specifications as described in Part VI will result in the application being withdrawn from further consideration. Applicants will be notified in writing of any such determination by ACYF.

Eligible applications will be scored competitively against the published evaluation criteria described above. An independent panel will review the applications in Washington, DC. The panel of expert reviewers will include tribal child care administrators and/or other individuals experienced in child care delivery systems, Native Hawaiian and/or Indian early child development and education, and other relevant areas.

Applications from Native Hawaiian organizations will be evaluated with similar applications. Likewise, applications from private nonprofit organizations serving Indians or Native Hawaiian youths will be evaluated separately.

A panel of at least three reviewers will evaluate each application to determine the strengths and weaknesses of the proposal in terms of the Bureau's goals, the expectations as discussed in Part III, requirements for the Project Narrative Statement described in Part IV, and the evaluation criteria listed in Part V., Section A. Panelists will provide written comments and assign numerical scores for each application. The indicated point value for each criterion is the maximum numerical score for that criterion. The assigned scores for each criterion will be summed to yield a total evaluation score for the proposal.

In addition to the panel review, the Bureau may solicit comments from other Federal offices and agencies, from the States, from relevant Native Hawaiian and tribal organizations, and from individuals whose particular expertise is identified as necessary for the consideration of technical issues arising during the review. Their comments, along with those of the panelists, will be considered by the Bureau in making funding decisions.

The Commissioner makes grant awards consistent with the purpose of the Act, all relevant statutory and regulatory requirements, this program announcement, and the availability of funds.

After the Commissioner has made decisions on all applications, unsuccessful applicants are notified in writing within approximately 30 days of the decision.

Successful applicants are notified through an official Financial Assistance Award (FAA) document. ACYF staff cannot respond to requests for information regarding funding decisions prior to the official notification to the applicants. The FAA will state the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the grant award, the effective date of the award, the project period, and the budget period.

D. Receipt of Applications

Applications must either be hand delivered or mailed to the address in Part VI., Section C., 2. Application Submission.

1. Deadline

Mailed applications shall be considered as meeting an announced deadline if they are either postmarked on or before the deadline date and received by ACF in time for the independent review to: U.S. Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., Mail Stop 6C–462, Washington, DC 20447, Attention: Application for Native Hawaiian and Nonprofit American Indian Organization Child Care Grants, ACYF No: ACYF–PA–CC–97–03.

Applicants are cautioned to request a legibly dated U.S. Postal Service postmark or to obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private Metered postmarks shall not be acceptable as proof of timely mailing.

Applications handcarried by applicants and applicant couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8:00 a.m. and 4:30 p.m., at the U.S. Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, ACF Mailroom, 2nd Floor Loading Dock, Aerospace Center, 901 D Street, SW., Washington, DC 20024, between Monday and Friday (excluding weekends and Federal holidays). Any application postmarked after 4:30 p.m. on the deadline date will not be considered for competition.

ACF cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ACF electronically will not be accepted regardless of date or time of submission and time of receipt.

2. Late Applications

Applications which do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

3. Extension of Deadlines

ACF may extend the deadline for all applicants because of acts of God such as floods, hurricanes, etc., or when there is a widespread disruption of the mails. However, if ACF does not extend the deadline for all applicants, it may not waive or extend the deadline for any applicants.

4. Notification

All applicants will be notified automatically about the receipt of their application and of the four digit identification number assigned to the application. This number and the priority area must be referred to in all

subsequent communication with the Child Care Bureau, ACYF, or ACF concerning the application. If you do not receive acknowledgment of your application within eight weeks after the deadline date, please contact the ACYF Operations Center at 1–800–351–2293.

E. The Review Process

1. Initial Application Review

Applications submitted by the closing date and verified by the postmark under this program announcement will undergo a pre-review to determine that (1) the applicant is eligible in accordance with the Eligible Applicants Section of this announcement; and (2) the application narrative, forms and materials submitted are adequate to allow the review panel to undertake an in depth evaluation. (All required materials and forms are listed in the Grant Application Checklist in the Application Kit).

2. Competitive Review of Accepted Applications

Applications that pass the pre-review will be evaluated and rated by an independent review panel on the basis of the specific evaluation criteria listed in Part V. These criteria are used to evaluate the quality of a proposed project, and to determine the likelihood of its success.

F. General Guidance to Applicants

The following information is provided to assist applicants in developing a competitive application.

1. Program Guidance

The Administration on Children, Youth and Families funds projects that demonstrate the strongest prospects for addressing the stated purposes of this program announcement.

In describing the goals, strategy, and problems being addressed in the application, include sufficient background and/or history of the community concerning these issues and/or progress to date, as well as the size of the population to be served. This material will assist the reviewers in determining the appropriateness and potential benefits of the proposed project.

The project application must clearly identify in measurable terms the expected results, benefits or outcomes of the proposed project, and the positive or continuing impact that the project will have on the population to be served.

In its data collection approach or design, an applicant should review the data collection/reporting requirements section contained in the Supplemental Guide (included in the Application Kit). This section provides specific information on data that must be collected and reported for children and families receiving CCDF-funded child care.

2. Technical Guidance

Applicants should prepare their application packages according to the application checklist and suggested ordering of materials located at the end of the ACF Uniform Discretionary Grant Application Form. This form is included in the Application Kit.

Applicants should closely tailor their applications to the specific requirements of this announcement. Previous experience has shown that an application that is broader and more general in concept than outlined in the agency's request for proposals is less likely to score as well as one that is more clearly focused on and directly responsive to the concerns and objectives outlined in the announcement.

Applications must have a cover letter followed by the Table of Contents and Project Abstract (Executive Summary). The Project Abstract should be a short, concise, and accurate description of the proposed project. This summary, together with the information on the SF 424 is the major source of information about the proposed project and is usually the first part of the application that the reviewers read in evaluating the application. It should provide a snapshot of the project objectives, the approaches to be used, and the outcomes expected. The summary should also describe the population to be served.

The summary should be clearly marked with the applicant's name as shown in item 5 of the SF 424, the announcement number and title, and the title of the project as shown in item 11 of the SF 424. At the bottom of the page, following the summary description, type up to 10 key words that best describe the proposed project, the service(s) involved and the target population(s) to be covered. These key words will be used for computerized information retrieval. Key words should be selected from commonly used research and policy terminology.

In preparing the application, applicants should fill out SFs 424, 424A, and 424B, all of which are included in the Application Kit. Forms should be prepared in accordance with the detailed instructions contained in the ACF Uniform Discretionary Grant Application Form.

The application's Form 424 must be signed by the applicant's representative authorized to act with full authority on behalf of the applicant.

The Project Narrative Statement should be clear, concise, and address the specific expectations and requirements described in Parts III and IV. The narrative should also provide information concerning how the application meets the evaluation criteria described in Part V. Inclusion and description of the evaluation criteria is important since the reviewers will rate the application against the evaluation criteria. Applicants should use the following section headings:

(A) Significance, Issues and Objectives;

(B) Approach, and Activities;

(C) Results and Benefits Expected;

(D) Organizational Capacity and Staff Qualifications; and

(E) Budget.

The specific information to be included under each of these headings is described in Part IV, Project Narrative, and Part V., Section A., Evaluation Criteria.

The narrative should be double-spaced and single-sided on 8½″ x 11″ plain white paper, with 1″ margins on all sides. Use 10 or 12 pitch throughout the proposal. All pages of the narrative (including appendices, resumes, charts, references/footnotes, tables, maps and exhibits) must be sequentially numbered, beginning with ''Significance, Issues, and Objectives'' as page number one. Applicants should not submit reproductions of larger sized paper reduced to meet the size requirement. Applicants should not send pamphlets, brochures, or other printed material along with their applications, as these items pose copying difficulties. These materials, if submitted, will not be included in the review process, although they will be kept on file.

An applicant must provide all applicable certifications, disclosures and assurances included in the ACF Uniform Discretionary Grant Application Form. In addition, an applicant must include a statement that it will comply with the applicable list of assurances found in § 98.15 of the CCDBG final rule.

The entire Project Narrative Statement and supporting materials (including text, resumes, and appendices) may not exceed 100 pages single-spaced (200 pages double spaced). All supporting materials, such as resumes, letters of support, and other documents should be organized into appropriate appendices and securely bound into the application package.

Applicants are encouraged to have someone other than the author apply the

evaluation criteria in the program announcement and score the application prior to its submission, in order to gain a better sense of the application's quality and potential competitiveness in the ACYF review process.

For purposes of developing an application, applicants should plan for a project start date approximately 120 days after the closing date under which the application is submitted.

Two copies of the application plus the original are required. The Cover Page (included in the Application Kit) should be the first page of an application, followed by the one-page abstract.

Dated: July 9, 1997.

James A. Harrell,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 97–19009 Filed 7–17–97; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

Title: National Directory of New Hires.

OMB No.: New.

Description: Public Law 104–193, the ''Personal Responsibility and Work Opportunity Reconciliation Act of 1996,'' requires the Office of Child Support Enforcement (OCSE) to develop a National Directory of New Hires (NDNH) to improve the ability of State Child support agencies to locate noncustodial parents and collect child support across State lines.

The NDNH will contain employment, wage and unemployment compensation data on all employees within the United States. Public Law 104–193 requires States and territories to periodically transmit new hire data received from employers to the NDNH, and to transit wage and unemployment compensation claims data to the NDNH on a quarterly basis.

Employers must report specified information (based on the IRS W–4 Form) on all new hires to State agencies for transmittal to the NDNH. States will transmit all data to the NDNH electronically. The purpose of the NDNH is to develop a repository of information on newly-hired employees, and on the earnings and unemployment compensation claims data on all employees, to provide the necessary information to locate child support obligors, and to establish and enforce child support orders.

As planned, the approximately 6.3 million United States' employers will submit approximately 60 million new hire records to the State Directory of New Hires (SDNH). If reports are submitted manually, employers must submit new hire reports not later than 20 days after the date the employer hires the employee. If employers submit new hire reports electronically, reports must be submitted to the SDNH twice a month and not less than 12 days nor more than 16 days apart. The State shall have the option to set a civil money penalty for noncomplying employers.

The information will be entered into the data base maintained by the SDNH within five business days of receipt from an employer. Within three business days after the date information regarding a newly hired employee is entered into the SDNH, the information shall be furnished to the NDNH.

State agencies charged with the administration of the unemployment compensation program must submit to the NDNH approximately 140 million records quarterly. These State records contain the wages and unemployment compensation paid to individuals within the fifty States, Guam, Virgin Islands, Puerto Rico and the District of Columbia.

Provided below are the proposed Record Layouts and Field Descriptions along with the Supplemental Specifications. The supplemental specifications contain additional explanation regarding format and content of items in the record specifications. The Record Layouts and Field Descriptions apply to the W–4, Quarterly Wage and Unemployment Compensation records respectively. Descriptions are also provided for header, data and trailer subrecords.

Respondents: States and Employers.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
New Hire: Employers Not Currently Required to Report (manual reporting) *	* 3,372,250	** 3,484	.0417 hours (2.5 minutes).	489,930
New Hire: Employers Not Currently Required to Report (electronically) *	* 740,250	** 37,037	***.00028 hours (1 second).	7,677
New Hire: Multistate Employers' Registration Form	375,000	1	.050	18,750
New Hire: States Not Currently Requiring New Hire Reporting	29	**** 83,333	***** 266,668	644,445
New Hire: States Currently Requiring New Hire Reporting	25	**** 83.333	****** 70.741	147,376
Quarterly Wage & Unemployment Compensation	54	******* 4	.033	7.13

Estimated Total Annual Burden Hours: 1,308,185.

Footnotes:

The above burden estimates are based on the following assumptions and factors:

Twenty-five States already had a new hire reporting system in place before PRWORA was passed. Within those 25 States, on average, it is estimated that 75% of employers already report new hire data (based on the fact that some States require all employers to report, some require only targeted industries to report, and some are voluntary reporting programs). It is estimated that these employers represent the same proportional number of new hire reports (75% of 25/54).

These estimates include the 25% remaining employers who do not report within those 25 States, in addition to all of the employers within the remaining 29 States.

* Eighteen percent of all employers will report manually and 82% will report electronically (based on SSA's experience). The number of employers is based on the following calculation: the total number of employers (6,300,000) multiplied by 29/54 (the proportion of States that do not have new hire programs) plus the total number of employers multiplied by the number of employers not already reporting in the States that do have new hire programs (25% of 25/54). The result (4,122,500) is then broken down into two categories: those who report manually and those who report electronically.

** For the ''Employers'' tiers, ''response'' is defined as the number of new hire reports. Thirty percent of all new hire reports will be reported manually and 70% will be reported electronically (based on SSA's experience).

*** Based on the assumption that employers reporting new hires electronically will most likely transmit their reports in a batch file, thus significantly reducing the per-response burden.

**** For the ''States'' tiers, ''response'' is defined as the number of transmissions to the NDNH. All States are required by law to transmit new hire data to the NDNH electronically, within three business days after entering the data into the SDNH. There are 250 business days per year. States will send a transmission once every three business days, which is equal to 83.333 transmissions per year.

***** Based on the average number of reports per transmission and the average burden per new hire report. The average number of reports per transmission is calculated by dividing 32,222,220 (total number of new hire reports in those 29 States) by 29 (number of States). The result (1,111,111) is then divided by 83.333 (estimated number of transmissions per State, see above explanation). Based on this calculation, the average number of reports per transmission is 13,333.39 reports. The average burden per new hire report is estimated to be .02 hours (1.2 minutes), which is based on a range of two seconds to four minutes. The burden is estimated to be two seconds per report for the 70% of new hire reports submitted to the State electronically. This two second burden estimate is based on the same batch-file assumption as above, and includes data receipt and data transmission. If the State has to manually enter the new hire data before transmitting to the NDNH (which is the case for 30% of all new hire reports), the burden is estimated to be four minutes (based on the number of characters in a record). The average burden hours per report (.02) multiplied by the average number of reports per transmission (13,333.39) is equal to the average burden hours per transmission (266.668).

****** Within the 25 States that already have a new hire reporting program in place, the burden is broken down into three categories. The total number of new hire reports for those 25 States is 27.8 million (46% of 60 million, or 25/54 times 60 million). Seventy-five percent of employers already submit to those States, so the incremental burden for that group is only the transmission to the NDNH (1 second per report). Twenty-five percent of employers do not already submit to those States, so the burden for that group is based on the same calculation as above: 30% of all new hire reports are reported manually (@ 4 minutes each) and 70% are reported electronically (@ 2 seconds each). The following table represents the exact formula for the calculation:

Types of reports	Number of new hire reports	Time per new hire report	Total time (hours)
Already Received From Employers (75%)	20,833,333	.000278 hours (1 second)	5787.0370
Reports Not Currently Received (25%)—Manual (30%)	2,083,333	.066667 hours (4 minutes)	138888.8889
Reports Not Currently Received (25%)—Electronic (70%)	4,861,111	.000556 hours (2 seconds)	2700.6173

Total time for all three types of reports: 147,376.543 hours.

Total time per transmission (83.333) per State (25): 70.741 hours.

******* ''Response'' is defined here as the number of transmissions to the NDNH. States are required to transmit quarterly wage and unemployment compensation data four times a year.

Detailed Input Information

Record Layouts and Field Descriptions for Input to the National Directory of New Hire (NDNH)

Field name	Location position	Length	Alpha/ numeric	Description/remarks	Mandatory/optional
W4 Transmitter Record					
Record Identifier	1–2	2	A/N	'H4'	M.
Transmitter State Code	3–4	2	N	State FIPS Code (for states only)	M for states.
Transmitter Agency Code	5–13	9	A/N	Federal Agency Code (for federal agencies only)	M for agencies.
Transmission Type	14–15	2	A/N	'W4' for W4 data	M.
Department of Defense Code.	16	1	A	'A' for active duty 'C' for civilian 'R' for reserves States may leave this field blank.	M for DOD.
Version Control Number	17–18	2	A/N	Must be '01', controlled by OCSE	M.
Data Stamp	19–26	8	N	Format=YYYYMMDD. Must be current system date of file generation	M.
Batch Number	27–32	6	N	Sequential number to identify a submission as unique.	M.
Filler	33–801	769	A/N	Spaces. To be used for future versions.	
W4 Total Record					
Record Identifier	1–2	2	A/N	'T4'	M.
Data Record Count	3–13	11	N	Total record count for transmission, including header and trailer records.	M.
Filler	14–801	787	A/N	Spaces. To be used for future versions	
W4 Data Record					
Record Identifier	1–2	2	A/N	'W4'	M.
Employee SSN	3–11	9	N	As reported by employee	M.
Employee Name:					
First Name	12–27	16	A	At least one character No special characters	M.
Middle Name	28–43	16	A	If non-blank, must be at least one character No Special characters	O.
Last Name	44–73	30	A	At least one character No special characters, except for hyphen.	M.

RECORD LAYOUTS AND FIELD DESCRIPTIONS FOR INPUT TO THE NATIONAL DIRECTORY OF NEW HIRE (NDNH)—Continued

Field name	Location position	Length	Alpha/ numeric	Description/remarks	Mandatory/optional
Employee Address					
Street Address (line 1).	74–113	40	A/N	Non-blank	M.
Street Address (line 2).	114–153	40	A/N	If your address line is less than 40 characters, do not concentrate into one line.	O.
Street Address (line 3).	154–193	40	A/N		O.
City	194–218	25	A	At least two characters No special characters, except for hyphen	M.
State	219–220	2	A	Valid state or territory abbreviation	M.
Zip Code (1)	221–225	5	N	Must be numeric	M.
Zip Code (2)	226–229	4	A/N	If present, must be numeric	O.
Employee Foreign Address Foreign Country Code.	230–231	2	A/N	Refer to U.S. Department of Commerce FIPS code manual, National Institute of Standards and Technology, FIPS PUB 10–4 (April 1995).	M for foreign address.
Foreign Country Name.	232–256	25	A/N	If present, at least two characters	O.
Foreign Zip Code	257–271	15	A/N		O.
Employee Date of Birth	272–279	8	A/N	If present, numeric Format—YYYYMMDD	O.
Employee Date of Hire	280–287	8	A/N	If present, numeric Format—YYYYMMDD	O.
Employee State of Hire	288–289	2	A	Alphabetic state or territory abbreviation	O.
Federal EIN	290–298	9	N	Federal Employer Identification Number	M.
State EIN	299–310	12	A/N	If no FEIN is available, send the State EIN If present and less than 12 characters, left justify	O.
Employer Name	311–355	45	A/N	At least two characters FEIN address from W4	
Employer Address:					
Street Address (line 1).	356–395	40	A/N	At least two characters	M.
Street Address (line 2).	396–435	40	A/N	If your address line is less than 40 characters, do not concentrate into one line.	O.
Street Address (line 3).	436–475	40	A/N	.	
City	476–500	25	A	At least two characters	M.
State	501–502	2	A	Valid state or territory abbreviation	M.
Zip Code (1)	503–507	5	N	Must be numeric	M.
Zip Code (2)	508–511	4	A/N	If present, must be numeric	O.
Employer Foreign Address:					
Foreign Country Code.	512–513	2	A/N	Refer to U.S. Department of Commerce FIPS code manual, National Institute of Standards and Technology, FIPS PUB 10–4 (April 1995).	M for foreign address.
Foreign Country Name.	514–538	25	A/N	If present, at least two characters	O.
Foreign Zip Code	539–553	15	A/N		O.
Employer Optional				This address will be blank if only collecting one address. If there is a second address, it should be the address where child support orders should be sent.	O.
Street Address (line 1).	554–593	40	A/N	If your address line is less than 40 characters, do not concentrate into one line.	O.
Street Address (line 2).	594–633	40	A/N		O.
Street Address (line 3).	634–673	40	A/N		O.
City	674–698	25	A	If present, at least two characters	O.
State	699–700	2	A	If present, valid state or territory abbreviation	O.
Zip Code (1)	701–705	5	A/N	If present, must be numeric	O.
Zip Code (2)	706–709	4	A/N	If present, must be numeric	O.
Employer Optional Foreign Address:					
Foreign Country Code.	710–711	2	A/N	Refer to U.S. Department of Commerce FIPS code manual, National Institute of Standards and Technology FIPS PUB 10–4 (April 1995).	O.
Foreign Country Name.	712–736	25	A/N	If present, at least two characters	.
Foreign Zip Code	737–751	15	A/N		O.
Filler	752–801	50	A/N	Spaces. To be used for future versions..	

RECORD LAYOUTS AND FIELD DESCRIPTIONS FOR INPUT TO THE NATIONAL DIRECTORY OF NEW HIRE (NDNH)—Continued

Field name	Location position	Length	Alpha/ numeric	Description/remarks	Mandatory/optional
Quarterly Wage Transmitter Record					
Record Identifier	1–2	2	A	'HQ'	M.
Transmitter State Code	3–4	2	N	State FIPS Code (for states only)	M for states.
Transmitter Agency Code	5–13	9	A/N	Federal Agency Code (for federal agencies only)	M for agencies.
Transmission Type	14–15	2	A/N	'QW' for quarterly wage data	M.
Department of Defense Code	16	1	A	'A' for active duty	M for DOD.
				'C' for civilian	
				'R' for reserves	
				States may leave this field blank.	
Version Control Number	17–18	2	A/N	Must be '01', controlled by OCSE	M.
Date Stamp	19–26	8	N	Format=YYYYMMDD	M.
				Must be current system date of file generation	
Batch Number	27–32	6	N	Sequential number to identify a submission as unique..	M.
Filler	33–601	569	A/N	Spaces. To be used for future versions..	
Quarterly Wage Total Record					
Record Identifier	1–2	2	A	'TQ'	M.
Data Record Count	3–13	11	N	Total record count for transmission, including header and trailer record.	M.
Filler	14–601	588	A/N	Spaces. To be used for future versions..	
Quarterly Wage Data Record					
Record Identifier	1–2	2	A	'QW'	M.
Employer SSN	3–11	9	N	As reported by employee	M.
Employee Name:					
First Name	12–27	16	A	At least one character	M.
				No special characters	
Middle Name	28–43	16	A	If non-blank, must be at least one character	O.
				No special characters	
Last Name	44–73	30	A	At least one character	M.
				No special characters, except for hyphen	
Employee Wage Amount	74–84	11	N	Last two positions are decimal places	M.
				No negative values, zeroes are allowed	
				Gross amount paid with the quarter	
Reporting Period	85–89	5	N	Format—QYYYY for Calendar year	M.
				Q=1 for Jan–Mar	
				Q=2 for Apr–Jun	
				Q=3 for Jul–Sep	
				Q=4 for Oct–Dec	
Federal EIN	90–98	9	N	Federal Employer Identification Number	M.
State EIN	99–110	12	A/N	If present and less than 12 characters, left justify	O.
Employer Name	111–155	45	A/N	At least two characters FEIN address	M.
Employer Address:					
Street Address (line 1).	156–195	40	A/N	At least two characters	M.
Street Address (line 2).	196–235	40	A/N	If your address line is less than 40 characters, do not concentrate into one line.	O.
Street Address (line 3).	236–275	40	A/N		O.
City	276–300	25	A	At least two characters	M.
State	301–302	2	A	Valid state or territory abbreviation	M.
Zip Code (1)	303–307	5	N		M.
Zip Code (2)	308–311	4	A/N	If present, must be numeric	O.
Employer Foreign Address:					
Foreign Country Code.	312–313	2	A/N	Refer to US Department of Commerce FIPS code manual, National Institute of Standards and Technology, FIPS PUB 10–4 (April 1995).	M for foreign address.
Foreign Country Name.	314–338	25	A/N	If present, at least two characters	O
Foreign Zip Code	339–353	15	A/N		O
Employer Optional Address.				This address will be blank if only collecting one address. If there is a second address, it should be the address where child support orders should be sent.	

RECORD LAYOUTS AND FIELD DESCRIPTIONS FOR INPUT TO THE NATIONAL DIRECTORY OF NEW HIRE (NDNH)—Continued

Field name	Location position	Length	Alpha/ numeric	Description/remarks	Mandatory/optional
Street Address (line 1).	354–393	40	A/N	At least two characters if your address is less than 40 characters, do not concentrate into one line.	O
Street Address (line 2).	394–433	40	A/N		O
Street Address (line 3).	434–473	40	A/N		O
City	474–498	25	A	If present, at least two characters	O
State	499–500	2	A	If present, valid state or territory abbreviation	O
Zip Code (1)	501–505	5	A/N	If present, must be numeric	O
Zip Code (2)	506–509	4	A/N	If present, must be numeric	O
Employer Optional Foreign Address:					
Foreign Country Code.	510–511	2	A/N	Refer to U.S. Department of Commerce FIPS code manual, National Institute of Standards and Technology, FIPS PUB 10–4 (April 1995).	O
Foreign Country Name.	512–536	25	A/N	If present, at least two characters	O
Foreign Zip code	537–551	15	A/N		O
Filler	552–601	50	A/N	Spaces. To be used for future versions..	
UI Transmitter Record					
Record Identifier	1–2	2	A	'HU'	M
Transmitter State Code..	3–4	2	N	State FIPS (for states only)	M for states.
Transmitter Agency Code.	5–13	9	A/N	Federal Agency Code (for federal agencies only)	M for agencies.
Transmission Type	14–15	2	A/N	'UI' for unemployment insurance data	M
Filler	16	1	A/N		M for DOD.
Version Control Number.	17–18	2	A/N	Must be '01', controlled by OCSE	M
Date Stamp	19–26	8	N	Format=YYYYMMDD Must be current system date of file generation.	
Batch Number	27–32	6	N	Sequential number to identify a submission as unique.	M
Filler	32–295	263	A/N	Spaces. To be used for future versions.	
UI Total Record					
Record Identifier	1–2	2	A	'TU'	M
Data Record Count	3–13	11	N	Total record count for transmission, including header and trailer record.	M
Filler	14–295	282	A/N	Spaces. To be used for future versions.	
UI Data Record					
Record Identifier	1–2	2	A	'UI'	M.
Claimant SSN	3–11	9	N	As reported by claimant	M.
Claimant Name:					
First Name	12–27	16	A	At least one character No special characters	M.
Middle Name	28–43	16	A	If non-blank, must be at least one character No special characters	0.
Last Name	44–73	30	A	At least one character No special characters except for hyphen	M.
Claimant Address:					
Street Address (line 1).	74–113	40	A/N	Non-blank	M.
Street Address (line 2).	114–153	40	A/N	If your address line is less than 40 characters, do not concentrate into one line.	O.
Street Address (line 3)	154–193	40	A/N		O.
City	194–218	25	A	At least two characters No special characters, except for hyphen	M.
State	219–220	2	A	Valid state or territory abbreviation	M.
Zip Code (1)	221–225	5	N	Must be numeric	M.
Zip Code (2)	226–229	4	A/N	If present, must be numeric	O.

RECORD LAYOUTS AND FIELD DESCRIPTIONS FOR INPUT TO THE NATIONAL DIRECTORY OF NEW HIRE (NDNH)—Continued

Field name	Location position	Length	Alpha/ numeric	Description/remarks	Mandatory/optional
Benefit Amount	230–240	11	N	Last two positions are decimal places No negative values, zeroes are allowed Gross amount paid within the quarter before withholding offsets. This amount is a total of all benefits that are tracked electronically.	M
Reporting Period	241–245	5	N	Format—QYYYY for Calendar year Q=1 for Jan—Mar Q=2 for Apr—Jun Q=3 for Jul—Sep Q=4 for Oct—Dec	M.
Filler	246–295	50	A/N	Spaces. To be used for future versions..	

Supplement to New Hire Record Specifications

At the suggestion of the workgroup that assisted in developing the record specifications for the National Directory of New Hires (NDNH), this is an accompanying document that contains some additional clarification or explanation of items in the record specifications.

Mandatory Fields: The legislation mandates the collection of only the following six data elements from the W–4 form:

Employee SSN
Employee Name
Employee Address
Employer Name
Employer Address
Employer ID number

On the W–4 record specifications these fields are marked with (M) to designate mandatory. There are three additional optional fields that are highly desirable for the New Hire data base. These are:

Employee Date of Birth
Employee Date of Hire
Employee State of Hire

While the legislation precludes the federal government from mandating the collection and retention of additional data elements, the states are not bound by those rules. The New Hire record specifications were developed in collaboration with State child support enforcement staff, State Employment Security Agency (SESA) staff, and federal and Department of Defense staff. Consequently, the specifications include additional data elements that will be collected by the states and passed to the NDNH. There data elements will be used by the states and other authorized users of NDNH data.

Following are some clarifying statements that apply to all of the NDNH data elements and record formats.

1. All data is to be in EBCDIC format.
2. All alphanumeric data are to be in upper case.
3. All alphanumeric data are to be left justified.
4. All numeric data are to be right justified and zero filled.
5. All dates are to be in the Year 2000-compliant format of YYYYMMDD.
6. Name and city data are to be stripped of special characters except for the hyphen.
7. State and territory abbreviations in addresses should be the US Postal Service abbreviations
8. Name fields should not include suffixes such as ''Jr.'', ''Sr.'', and ''III''.
9. The NDNH will contain two addresses for the employer. The first address is that noted on the W–4 form. The second address is where child support orders should be sent. If only one address is available or known, use the first set of address data elements and leave the second set of data elements blank.
10. National standard codes are to be used for foreign country code abbreviations as assigned by the Department of Commerce FIPS codes (FIPS PUB 10–4).
11. For Quarterly Wage data, the employee wage amount is to be the gross amount paid during the quarter, regardless of when the amount was earned.
12. For Unemployment Insurance data, the benefit amount is to be the gross amount paid within the quarter before any deductions or offsets are applied, regardless of when the benefit was earned or accrued.
13. WHEN IN DOUBT, SEND THE DATA. While the NDNH wants to receive clean, edited data, we want to receive all data in a timely manner. Consequently, if some data is missing or incomplete at the time of transmission, include the record(s) in the transmission. Hopefully, this will also make processing easier at the State level.
14. Output records returned from the NDNH will contain all of the input data sent to the NDNH and indications of errors or changes that took place at the federal level.
15. States have the option of receiving error records. The NDNH will maintain a matrix of which states want to be notified of errors and which do not.

Input Records

When sending data to the federal level, there will be three record types in each transmission of data. These will include a header record, a series of data records, and concluded by a trailer record.

Header Record

The header record will be the first record in the data set and will contain the following fields.

Field name	Comments
Record Identifier	Enter 'H4' for W4 data. Enter 'HQ' for Quarterly Wage data. Enter 'HU' for Unemployment Insurance data.
Transmitter State Code	Refer to US Department of Commerce FIPS code manual, National Institute of Standards and Technology, FIPS PUB 10–4 (April 1995).

Field name	Comments
Transmitter Agency Code	Some federal agencies act as service bureaus for other federal agencies. Enter the Federal Employer Identification Number (FEIN) of the agency transmitting the data to the National Directory of New Hires.
Transmission Type	Identifies the type of data in this data set. Enter 'W4' for W4 data. Enter 'QW' for Quarterly Wage data. Enter 'UI' for Unemployment Insurance data.
Department of Defense Code	This field is mandatory only for DOD data transmissions. All others can ignore this field. DOD data is separated into several categories. This field indicates which category of data is being transmitted. Enter 'A' for active duty personnel. Enter 'C' for civilian personnel. Enter 'R' for reservist personnel.
Version Control Number	It is assumed that the system will be modified over time to accommodate future requirements. The version Control Number indicates which version of the system is in operation and will provide a means of communicating with data suppliers about record formats. Enter '01' until notified by OCSE to change this value.
Date Stamp	Enter the system generated date on the date the data set is transmitted to the federal level. Enter the date in the format YYYYMMDD.
Batch Number	A sequential number generated by the transmitting agency. This field is to uniquely identify a transmission. Do not repeat batch numbers.
Filler	Each record contains filler to be used for future versions of the record formats.

Total Record

Each data set is to be terminated with a Total Record which will contain the count of the total number of records transmitted in this data set.

Field name	Comments
Record Identifier	Enter 'T4' for W4 data. Enter 'TQ' for Quarterly Wage data. Enter 'TU' for Unemployment Insurance data.
Data Record Count	Enter the total number of records transmitted in this data set, including the header and trailer records. This will be used to verify that all records are received and processed.
Filler	Spaces. To be used for future versions of the system.

Data Record

Each of the data records for W4, Quarterly Wage, and UI is different in several ways. Following is further explanation of some of the data elements in those record layouts. See the Record Layout specifications for detailed information on all data elements.

Field name	Comments
Record Identifier	Enter 'W4' for W4 record. Enter 'QW' for Quarterly Wage record. Enter 'UI' for Unemployment Insurance record.
Foreign Address Data Elements	If an address supplied for the employee or employer is outside the United States, include the Foreign County Code for the address, the Foreign Country Name, and the Foreign Zip Code.
Employee Wage Amount (QW)	For Quarterly Wage data, provide the gross amount paid to the employee during the quarter, regardless of when the amount was earned.
Reporting Period	Use the quarters that correspond to the calendar year rather than quarters that correspond to fiscal accounting periods. Use the format QYYYY where Q=1 for January–March Q=2 for April–June Q=3 for July–September Q=4 for October–December
Benefit Amount (UI)	The UI Benefit Amount is the gross amount paid within the reporting quarter before any withholding offsets are applied. This amount should be the sum of benefits received from all programs tracked electronically by the State. However, only include those benefits that are housed in the same hardware environment. Do not include benefits from sources that must be translated or imported to the mainframe environment.

Output Records

FPLS will return records to the data transmitters when errors were detected. The states can elect to have these records returned for error resolution or not as they choose. Federal agencies, however, will receive all error records from each transmittal.

The record formats for the error records are identical to the input record provided by the submitter except that error codes will be appended that explain the nature of the error. Errors can occur at the transmission level and at the individual record level.

Transmission Control Records

This is the output equivalent of the input TRANSMITTER RECORD and includes counts of records received, records rejected, error records returned, records posted to the National Directory of New Hires, records posted to the Suspense File and up to five Error Codes pertaining to the transmission level error conditions encountered.

Data Records

Each output version of the input DATA RECORD had appended to it up to five record level error codes that indicate the nature of the error encountered during editing. It also contains a Social Security Number Verification Indicator that indicates whether multiple valid SSNs were encountered during the SSN verification process. In addition, a corrected SSN is returned if during the SSN verification process the supplied SSN was determined to be incorrect and the verification procedure was able to provide the correct SSN.

Total Records

No transmission total records will be returned to the submitting State or federal agency

Additional Information

ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by August 15, 1997. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Driscoll at (202) 410–9313 or (202) 401–6465. Internet address: rdriscoll@acf.dhhs.gov

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street N.W., Washington, D.C. 20503, (202) 395–7316.

Dated: July 10, 1997.

Robert Driscoll,

Reports Clearance Officer.

[FR Doc. 97–18675 Filed 7–17–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0077]

Determination of Regulatory Review Period for Purposes of Patent Extension; GLYSET™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for GLYSET™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product GLYSET™ (miglitol). GLYSET™ is indicated as an adjunct to diet to improve glycemic control in patients with non-insulin-dependent diabetes mellitus whose hyperglycemia cannot be managed with diet alone. GLYSET™ may also be used in combination with a sulfonylurea when diet plus either GLYSET™ or a sulfonylurea alone do not result in adequate glycemic control. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GLYSET™ (U.S. Patent No. 4,639,436) from Bayer Aktiengesellschaft, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 21, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of GLYSET™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for GLYSET™ is 4,900 days. Of this time, 4,544 days occurred during the testing phase of the regulatory review period, while 356 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* July 22, 1983. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on July 22, 1983.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* December 29, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for GLYSET™ (NDA 20–682) was initially submitted on December 29, 1995.

3. *The date the application was approved:* December 18, 1996. FDA has verified the applicant's claim that NDA

20–682 was approved on December 18, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,827 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 16, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 14, 1998, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–18909 Filed 7–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0067]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZYFLO™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZYFLO™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ZYFLO™ (zileuton). ZYFLO™ is indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZYFLO™ (U.S. Patent No. 4,873,259) from Abbott Laboratories, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 12, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZYFLO™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ZYFLO™ is 3,329 days. Of this time, 2,454 days occurred during the testing phase of the regulatory review period, while 875 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: October 31, 1987. The applicant claims October 30, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 31, 1987, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: July 19, 1994. The applicant claims July 18, 1994, as the date the new drug application (NDA) for ZYFLO™ (NDA 20–471) was initially submitted. However, FDA records indicate that NDA 20–471 was submitted on July 19, 1994.

3. *The date the application was approved*: December 9, 1996. FDA has verified the applicant's claim that NDA 20–471 was approved on December 9, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,398 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 16, 1997 submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 14, 1998 for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review

period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–18910 Filed 7–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96E–0439]

Determination of Regulatory Review Period for Purposes of Patent Extension; ANTISEDAN®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ANTISEDAN® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product ANTISEDAN® (atipamezole hydrochloride). ANTISEDAN® is indicated to reverse the clinical effects of the sedative and analgesic agent medetomidine hydrochloride in dogs. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ANTISEDAN® (U.S. Patent No. 4,689,339) from ANTISEDAN®, and the Patent and Trademark Office requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated February 21, 1997, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of ANTISEDAN® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ANTISEDAN® is 2,663 days. Of this time, 1,429 days occurred during the testing phase of the regulatory review period, while 1,234 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act became effective*: April 24, 1989. FDA has verified the applicant's claim that April 24, 1989, was the date that the investigational new animal drug application became effective.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the Federal Food, Drug, and Cosmetic Act*: March 22, 1993. The applicant claims March 17, 1993, as the date the new animal drug application (NADA) for ANTISEDAN® (NADA 141–033) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to the NADA was March 22, 1993, which is considered to be the initially submitted date for the NADA.

3. *The date the application was approved*: August 6, 1996. FDA has verified the applicant's claim that NADA 141–033 was approved on August 6, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,718 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 16, 1997 submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 14, 1998 for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–18911 Filed 7–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0075]

Determination of Regulatory Review Period for Purposes of Patent Extension; Lipitor™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Lipitor™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Lipitor™ (atorvastatin calcium). Lipitor™ is indicated as an adjunct to diet to reduce elevated total-C, LDL–C, apo B, and TG levels in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (*Frederickson* Types IIa and IIb). Lipitor™ is also indicated to reduce total-C and LDL–C in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Lipitor™ (U.S. Patent No. 4,681,893) from Warner-Lambert Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 12, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Lipitor™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Lipitor™ is 2,241 days. Of this time, 2,057 days occurred during the testing phase of the regulatory review period, while 184 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: October 31, 1990. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on October 31, 1990.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: June 17, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Lipitor™ (NDA 20–702) was initially submitted on June 17, 1996.

3. *The date the application was approved*: December 17, 1996. FDA has verified the applicant's claim that NDA 20–702 was approved on December 17, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,213 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 16, 1997 submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 14, 1998, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–18915 Filed 7-17-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0066]

Determination of Regulatory Review Period for Purposes of Patent Extension; ARICEPT™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ARICEPT™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ARICEPT™ (donepezil hydrochloride). ARICEPT™ is indicated for the treatment of mild to moderate dementia of the Alzheimer's type. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ARICEPT™ (U.S. Patent No. 4,895,841) from Eisai Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 10, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and the approval of ARICEPT™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ARICEPT™ is 2,135 days. Of this time, 1,900 days occurred during the testing phase of the regulatory review period, while 235 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: January 23, 1991. The applicant claims January 19, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 23, 1991, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: April 5, 1996. The applicant claims March 29, 1996, as the date the new drug application (NDA) for ARICEPT™ (NDA 20–690) was initially submitted. However, FDA records indicate that NDA 20–690 was submitted on April 5, 1996, the date the NDA and user fee payment was received.

3. *The date the application was approved*: November 25, 1996. FDA has verified the applicant's claim that NDA 20–690 was approved on November 25, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 888 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 16, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 14, 1998, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–18916 Filed 7-17-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96E–0508]

Determination of Regulatory Review Period for Purposes of Patent Extension; NAROPIN™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for NAROPIN™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product NAROPIN™ (ropivacaine hydrochloride monohydrate). NAROPIN™ is indicated for the production of local or regional anesthesia for surgery, for postoperative pain management and for obstetrical procedures. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NAROPIN™ (U.S. Patent No. 4,870,086) from Astra Lakemedel Aktiebolag, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 21, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of NAROPIN™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for NAROPIN™ is 3,147 days. Of this time, 2,603 days occurred during the testing phase of the regulatory review period, while 544 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: February 14, 1988. The applicant claims February 15, 1988, as the date the investigational new drug application (IND) for NAROPIN™ (IND 31,121) became effective. However, FDA records indicate that the effective date for IND 31,121 was February 14, 1988, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: March 31, 1995. The applicant claims March 29, 1995, as the date the new drug application (NDA) for NAROPIN™ (NDA 20–533) was initially submitted. However, FDA records indicate that NDA 20–533 was submitted on March 31, 1995.

3. *The date the application was approved*: September 24, 1996. FDA has verified the applicant's claim that NDA 20–533 was approved on September 24, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,400 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 16, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 14, 1998, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–18917 Filed 7–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0110]

Determination of Regulatory Review Period for Purposes of Patent Extension; MONUROL™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MONUROL™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was

marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product MONUROL™ (fosfomycin tromethamine). MONUROL™ is indicated only for the treatment of uncomplicated urinary tract infections (acute cystitis) in women due to susceptible strains of *Escherichia coli* and *Enterococcus faecalis*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MONUROL™ (U.S. Patent No. 4,863,908) from ZAMBON GROUP, S.p.A., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 1, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MONUROL™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for MONUROL™ is 2,241 days. Of this time, 1,428 days occurred during the testing phase of the regulatory review period, while 813 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: November 2, 1990. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on November 2, 1990.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357)*: September 29, 1994. The applicant claims September 28, 1994, as the date the new drug application (NDA) for MONUROL™ (NDA 50–717) was initially submitted. However, FDA records indicate that NDA 50–717 was submitted on September 29, 1994.

3. *The date the application was approved*: December 19, 1996. FDA has verified the applicant's claim that NDA 50–717 was approved on December 19, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,525 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 16, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 14, 1998, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–18919 Filed 7–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96D–0137]

Medical Device Reporting, Guidance Document for Manufacturers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Medical Device Reporting (MDR) for Manufacturers.'' The guidance describes the new medical device reporting requirements for manufacturers, and it is intended for both domestic and foreign medical device manufacturers. The MDR regulations provide a mechanism for FDA to identify and monitor significant adverse events involving medical devices so that problems may be detected and corrected in a timely manner.

ADDRESSES: Submit written requests for single copies of the ''Medical Device Reporting (MDR) for Manufacturers'' guidance document to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. Requestors will be sent a floppy diskette with a Microsoft Word document file containing the guidance document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Bryan H. Benesch, Center for Devices and Radiological Health, HFZ–220, 1350 Piccard Dr., Rockville, MD 20850, 301–443–7491, ext. 131.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 31, 1996 (61 FR 27361), FDA announced the availability of a draft guidance entitled ''Medical Device Reporting for Manufacturers.'' The guidance document contained information to help manufacturers comply with the new MDR regulations. The purpose of the guidance document was to: (1) Provide domestic and foreign manufacturers with a thorough description of the current MDR regulations; (2) give a clear

understanding of their reporting responsibilities and guidance to aid in the completion of the MDR forms; (3) give an overview of required written MDR procedures, records and files; and (4) supply information on sources for forms, instructions, and other MDR information.

Comments were requested and the guidance has been revised. FDA addressed the changes mandated by the Safe Medical Devices Act and the Medical Device Amendments of 1992.

''Medical Device Reporting (MDR) for Manufacturers'' represents the agency's current thinking on medical device reporting for manufacturers. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. Electronic Access

In order to receive the ''Medical Device Reporting (MDR) for Manufacturers'' guidance document via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt, press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 987 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may do so by using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. The CDRH home page is updated on a regular basis and includes the ''Medical Device Reporting (MDR) for Manufacturers'' guidance document, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Medical Device Reporting for Manufacturers'' is available on the medical device reporting page at: http://www.fda.gov/cdrh/mdr.html.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

Dated: June 13, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–18918 Filed 7–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Submission for OMB Review; 30-Day Comment Period Proposed Information Collection: Evaluation of the IHS–Supported Alcohol and Substance Abuse Treatment Programs for American Indian/Alaska Native Women

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed information collection projects, the Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection project was previously published in the **Federal Register** (62 FR 15191) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow 30 days for public comment to be submitted to OMB.

Proposed Collection.

Title: Evaluation of the IHS–Supported Alcohol and Substance Abuse Treatment Program for American Indian/Alaska Native (AI/AN) women. *Type of Information Collection Request:* New. *Need and Use of the Information Collection:* Section 703, ''Indian Women Treatment Programs'' of Public Law 102–573, the Indian Health Care Amendments of 1992, (the act) authorizes the IHS to develop and implement a comprehensive alcohol and alcohol and substance abuse (A/SA) program that specifically addresses the cultural, historical, social, and child care needs of AI/AN women. Section 801 of these Amendments requires a report on the progress made in meeting the objectives of the Act, a review of programs established or assisted pursuant to the Act, and an assessment of such programs. Support Services International, Inc, (SSI) an Indian-owned consulting firm, will develop the data collection instruments and conduct the study. The information collected will be used to assess and improve the effectiveness of the IHS-supported A/SA treatment program.

Data will be collected from a sample of AI/AN women who use the services provided by the IHS-supported A/SA treatment programs, and from a sample of treatment program staff. Findings from the study will be used to determine (1) What works, what does not work, and why; (2) what resources are required for successful A/SA treatment for AI/AN women; (3) what factors help or hinder women from maintaining sobriety; (4) how many women achieve success (3–, 6–, and 12-months after admission into A/SA treatment; (5) what are the characteristics, life conditions, and service needs of the women who use the treatment programs; (6) what are the common strengths and problems of the treatment programs, and what are recommendations for improvement. The study is expected to be completed in FY 1998. *Affected Public:* Individuals.

See Table 1 below for Types of Data Collection Instruments, Estimated Number of Respondents, Number of Responses per Respondent, Average Burden Hour per Response, and Total Annual Burden Hour.

TABLE 1

Data collection Instrument	Estimated no. of respondents	Responses per respondent	Average burden hour per response*	Total annual burden hrs
Project Director	24	1	0.75 hr (45 minutes)	18.0
Project Staff	216	1	0.50 hr (30 minutes)	108.0

TABLE 1—Continued

Data collection Instrument	Estimated no. of respondents	Responses per respondent	Average burden hour per response*	Total annual burden hrs
Client Intake	550	1	0.50 hr (30 minutes)	275.0
Client History	550	1	1.00 hr (60 minutes)	550.0
Client Discharge	523	1	0.50 hr (30 minutes)	261.5
Client 3-month follow-up	467	1	0.4175 hr (25 minutes)	194.9
Client 6-month follow-up	440	1	0.50 hr (30 minutes)	220.0
Client 12-month follow-up	412	1	0.41752 hr (25 minutes)	172.0
Total	790			1,799.4

*For ease of understanding, burden hours are alos provided in actual minutes.

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report for this information collection.

Request for Comments

Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function and whether the IHS processes the information collected in a useful and timely fashion; (b) the accuracy of the public burden estimate (this is the amount of time needed for individual respondents to provide the requested information) and the methodology and assumptions used to determine the estimate; (c) way to enhance the quality, utility, and clarity of the information being collected; and (d) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology

Direct Comments To OMB

Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time, to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS. To request more information on the proposed collection or to obtain a copy of the data collection plan(s) and/or instruction(s), contact: Mr. Lance Hodahkwen, Sr., M.P.H., IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852. 1601, or call non-toll free (301) 443–0461, or send via facsimile to (301) 443–1522, or send your E-mail requests, comments, and return address to: Ihodahkw@smtp.ihs.gov.

Comment Due Date

Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: July 8, 1997.

Michael H. Trujillo,

Assistant Surgeon General Director.

[FR Doc. 97–18907 Filed 7–17–97; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Health

Meeting of the Advisory Committee on Blood Safety and Availability

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Advisory Committee on Blood Safety and Availability, Department of Health and Human Services, August 11–12, 1997. This meeting will be held at the National Library of Medicine in the Lister Hill National Center for Biomedical Communications, Building 38A, 1st Floor–Auditorium 8600 Rockville Pike, Bethesda, Maryland 20892.

The entire meeting will be opened to the public from 9:30 a.m. to 5:30 p.m. on August 11 and from 8:00 a.m. to 3:00 p.m. on August 12. The Committee will continue its discussion of hepatitis C lookback issues and will be expected to provide recommendations for a course(s) of action for the Department of Health and Human Services. Limited time has been set aside for additional public comment. Prospective speakers should notify the Acting Executive Secretary for this meeting of their intent to make a presentation and should plan for no more than five minutes of comments.

Contact: Paul R. McCurdy, M.D., Acting Executive Secretary, Advisory Committee on Blood Safety and Availability, Director, Blood Resources Program, DBDR, Two Rockledge Center, 6701 Rockledge Drive, Room 10138, MSC–7950, NHLBI, NIH, Bethesda, Maryland 20892–7950. Phone: 301–435–0065; Fax: 301–480–1060; E-Mail: paul__mccurdy@nih.gov.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Acting Executive Secretary in advance of the meeting.

Dated: July 14, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–18981 Filed 7–17–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences, Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Environmental Health Sciences Special Emphasis Panel (SEP) meetings:

Name of SEP: Modulation by Growth Factors and Signal Transduction Pathways of Environmentally Induced Disease/Dysfunction (Telephone Conference Call).

Date: July 21, 1997.

Time: 1:00 p.m.

Place: National Institute of Environmental Health Sciences, 79 T.W. Alexander Drive, Building 4401, Room 3453, Research Triangle Park, NC 27709.

Contact Person: Dr. Linda K. Bass, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541–1307.

Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: Pregnancy, Heredity, and Environment; a Case-Control Study of Facial Clefts (Telephone Conference Call).

Date: July 30, 1997.

Time: 1:00 p.m.

Place: National Institute of Environmental Health Sciences, 79 T. W. Alexander Drive, Building 4401, Room 3453, Research Triangle Park, NC 27709.

Contact Person: Dr. Linda K. Bass, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541–1307.

Purpose/Agenda: To review and evaluate contract proposals.

Name of SEP: Mutagenicity Testing in Salmonella.

Date: August 14, 1997.

Time: 9:00 a.m.

Place: National Institute of Environmental Health Sciences, 101 T.W. Alexander Drive, South Campus, Research Triangle Park, NC 27709.

Contact Person: Dr. Linda K. Bass, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541–1307.

Purpose/Agenda: To review and evaluate contract proposals.

These meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Grant applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to these meetings due to the urgent need to meet timing limitations imposed by the grant/contract review and funding cycle.

(Catalog of Federal Domestic Assistance Programs Nos. 93.113, Biological Response to Environmental Agents; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation; 93.894, Resource and Manpower Development, National Institutes of Health)

Dated: July 14, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–18974 Filed 7–17–97; 8:45 am]

BILLING CODE 4110–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health:

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Institute of Mental Health:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: July 29,1997.

Time: 10:30 a.m.

Place: Parklawn, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Gloria B. Levin, Parklawn, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–1367.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: July 14, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–18976 Filed 7–17–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meeting:

Name of SEP: Innovation Grant Program for Approaches in HIV Vaccine Research.

Date: August 4–5, 1997.

Time: 8:00 a.m. to Adjournment.

Place: Washington National Airport, Dewey I, 2399 Jefferson Davis Highway, Arlington, VA 22202, (703) 418–6800.

Contact Person: Dianne Tingley, Scientific Review Adm., 6003 Executive Boulevard, Solar Bldg., Room 4C07, Bethesda, MD 20892, (301) 496–2550.

Purpose/Agenda: To evaluate grant applications.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: July 14, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–18978 Filed 7–17–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Child Health and Human Development Special Emphasis Panel (SEP) meeting:

Name of SEP: Perinatal Studies.

Date: July 30, 1997.

Time: 9:30 a.m.–adjournment.

Place: 6100 Executive Boulevard, 6100 Building, Room 5E01, Rockville, Maryland 20852.

Contact Person: Gopal Bhatnagar, Ph.D., Scientific Review Administrator, NICHD, 6100 Executive Boulevard, 6100 Building, Room 5E01, Rockville, Maryland 20852, Telephone: 301–496–1485.

Purpose: To evaluate and review grant applications.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. The discussions of these applications could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Nos. [93.864, Population Research and No. 93.865, Research for Mothers and Children], National Institutes of Health)

Dated: July 14, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–18980 Filed 7–17–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health (NIH)

National Institute on Aging; Notice of Meeting of the National Advisory Council on Aging

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the

National Advisory Council on Aging, National Institute on Aging, Thursday, September 25, and Friday, September 26, 1997, to be held at the National Institutes of Health, Building 31, Conference Room 6, Bethesda, Maryland. This meeting will be open to the public on Thursday, September 25, from 9:00 a.m. to 3:00 p.m. for the Director's Status Report, a presentation from the Food and Drug Administration, a presentation on NIA implementation of NIH policy on Data Sharing and an Extramural Report.

The meeting will be open again on Friday, September 26, from 8:00 a.m. until adjournment for a report on the Working Group on Program, a report on the Minority Task Force, and the NIA Overall Program Review: Translational Research at NIA. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92–463, the meeting of the Council will be closed to the public on Thursday, September 25, from 3:00 p.m. to recess for the review, discussion and evaluation of grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. June McCann, Committee Management Officer for the National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Suite 2C218, Bethesda, Maryland 20892 (301/496–9322), will provide a summary of the meeting and a roster of committee members upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. McCann at (301) 496–9322, in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.866, Aging Research, National Institutes of Health)

Dated: July 14, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–18982 Filed 7–17–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.
Name of SEP: Biological and Physiological Sciences.
Date: July 17, 1997.
Time: 12:00 p.m.
Place: NIH, Rockledge 2, Room 4202, Telephone Conference.
Contact Person: Dr. Eugene Zimmerman, Scientific Review Administrator, 6701 Rockledge Drive, Room 4202, Bethesda, Maryland 20892, (301) 435–1220.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the grant review and funding cycle.

Name of SEP: Biological and Physiological Sciences.
Date: August 7, 1997.
Time: 3:00 p.m.
Place: NIH, Rockledge 2, Room 5196, Telephone Conference.
Contact Person: Ms. Carol Campbell, Scientific Review Administrator, 6701 Rockledge Drive, Room 5196, Bethesda, Maryland 20892, (301) 435–1257.

Name of SEP: Behavioral and Neurosciences.
Date: August 8, 1997.
Time: 10:00 a.m.
Place: Ramada Inn, Rockville, MD.
Contact Person: Dr. Luigi Giacometti, Scientific Review Administrator, 6701 Rockledge Drive, Room 5170, Bethesda, Maryland 20892, (301) 435–1246.

Name of SEP: Biological and Physiological Sciences.
Date: August 13, 1997.
Time: 2:00 p.m.
Place: NIH, Rockledge 2, Room 4152, Telephone Conference.
Contact Person: Dr. Marcelina Powers, Scientific Review Administrator, 6701 Rockledge Drive, Room 4152, Bethesda, Maryland 20892, (301) 435–1720.

Name of SEP: Clinical Sciences.
Date: August 15, 1997.
Time: 10:00 a.m.
Place: NIH, Rockledge 2, Room 4106, Telephone Conference.
Contact Person: Ms. Josephine Pelham, Scientific Review Administrator, 6701 Rockledge Drive, Room 4106, Bethesda, Maryland 20892, (301) 435–1786.

Name of SEP: Biological and Physiological Sciences.
Date: August 19, 1997.
Time: 2:00 p.m.
Place: NIH, Rockledge 2, Room 4152, Telephone Conference.
Contact Person: Dr. Marcelina Powers, Scientific Review Administrator, 6701 Rockledge Drive, Room 4152, Bethesda, Maryland 20892, (301) 435–1720.

Name of SEP: Clinical Sciences.
Date: August 19, 1997.
Time: 12:00 p.m.
Place: NIH, Rockledge 2, Room 4106, Telephone Conference.
Contact Person: Ms. Josephine Pelham, Scientific Review Administrator, 6701 Rockledge Drive, Room 4106, Bethesda, Maryland 20892, (301) 435–1786.

Name of SEP: Biological and Physiological Sciences.
Date: August 26, 1997.
Time: 2:00 p.m.
Place: NIH, Rockledge 2, Room 4152, Telephone Conference.
Contact Person: Dr. Marcelina Powers, Scientific Review Administrator, 6701 Rockledge Drive, Room 4152, Bethesda, Maryland 20892, (301) 435–1720.
Purpose/Agenda: To review Small Business Innovation Research.

Name of SEP: Chemistry and Related Sciences.
Date: August 7, 1997.
Time: 8:30 a.m.
Place: Holiday Inn, Chevy Chase, MD.
Contact Person: Dr. Nancy Lamontagne, Scientific Review Administrator, 6701 Rockledge Drive, Room 4170, Bethesda, Maryland 20892, (301) 435-1726.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the application and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 14, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–18975 Filed 7–17–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Division of Research Grants; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meeting:

Purpose/Agenda: To Review Individual Gramt Applications.

Name of SEP: Biological and Physiological Sciences.

Date: July 16, 1997.

Time: 11:00 a.m.

Place: NIH, Rockledge 2, Room 4204, Telephone Conference.

Contact Person: Dr. Calbert Laing, Scientific Review Administrator, 6701 Rockledge Drive, Room 4204, Bethesda, Maryland 20892, (301) 435–1221.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the grant review and funding cycle.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 14, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–18997 Filed 7–17–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Division of Research Grants; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meeting.

Purpose/Agenda: To Review Individual Grant Applications.

Name of SEP: Behavioral and Neurosciences Sciences.

Date: August 6, 1997.

Time: 2:00 p.m.

Place: NIH, Rockledge 2, Room, Telephone Conference.

Contact Person: Dr. Leonard Jakubczak, Scientific Review Administrator, 6701 Rockledge Drive, Room 5172, Bethesda, Maryland 20892, (301) 435–1247.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 14, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–18979 Filed 7–17–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4235–N–12]

Federal Property Suitable as Facilities to Assist the Homeless

AGENCY: Office of the Assistance Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, room 7256, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708–1226; TDD number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Brian Rooney, Division of Property Management, Program Support Center, HHS, room 5B–41, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available, or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing

sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: ARMY: Mr. Jeff Holste, CECPW–FP, U.S. Army Center for Public Works, 7701 Telegraph Road, Alexandria, VA 22310–3862; (703) 428–6316; COE: Mr. Bob Swieconek, Army Corps of Engineers, Management and Disposal Division, Pulaski Building, Room 4224, 20 Massachusetts Avenue, NW., Washington, DC 20314–1000; (202) 761–1749; GSA: Mr. Brian K. Polly, Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th and F Streets, NW., Washington, DC 20405; (202) 501–2059; INTERIOR: Ms. Lola D. Knight, Department of the Interior, 1849 C Street, NW., Mail Stop 5512–MIB, Washington, DC 20240; (202) 208–4080; NAVY: Mr. Charles C. Cocks, Department of the Navy, Director, Real Estate Policy Division, Naval Facilities Engineering Command, Code 241A, 200 Stovall Street, Alexandria, VA 22332–2300; (703) 325–7342; DOT: Mr. Philip Rockmaker, Acting Principal, Space Management, SVC–140, Transportation Administrative Service Center, Department of Transportation, 400 7th Street, SW., Room 2310, Washington, DC 20590; (202) 366–4246; (These are not toll-free numbers).

Dated: July 11, 1997.

Fred Karnas, Jr.,

Acting Deputy Assistant Secretary for Economic Development.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM, FEDERAL REGISTER REPORT FOR 07/18/97

Suitable/Available Properties

Buildings (by State)

Colorado

Residence
Cherry Creek Lake Project
3311 Parker Road
Aurora Co: Arapahoe CO 80112–
Landholding Agency: COE
Property Number: 319720001
Status: Excess
Comment: 1000 sq. ft. house and 900 sq. ft. garage, needs rehab, off-site use only.

Storage Shed
Cherry Creek Lake Project
3311 Parker Road
Aurora Co: Arapahoe CO 80112–
Landholding Agency: COE
Property Number: 319720002
Status: Excess
Comment: 600 sq. ft. w/dirt floor, off-site use only.

Hawaii

Bldg. 148, Hale Moku Housing
Navy Public Works Center, Pearl Harbor
Pearl Harbor Co: Honolulu HI 96818–
Landholding Agency: Navy
Property Number: 779720122
Status: Excess
Comment: 2148 sq. ft., concrete/masonry/wood, needs major rehab, off-site use only.

New Jersey

Former Tyberg Residence
National Park Service
Wallpack Co: Sussex NJ 07881–
Landholding Agency: Interior
Property Number: 619720053
Status: Unutilized
Comment: most recent use—housing, off-site use only.

North Dakota

House #1 (OJ1)
OMEGA Station
213 2nd St. NE
LaMoure Co: LaMoure ND 58458–
Landholding Agency: GSA
Property Number: 549720010
Status: Excess
Comment: 1500 sq. ft., most recent use—residential, federally endangered and threatened species may be present in area.
GSA Number: 7–U–ND–0494 A & B

House #2 (OJ2)
OMEGA Station
216 2nd St. NE
LaMoure Co: LaMoure ND 58458–
Landholding Agency: GSA
Property Number: 549720011
Status: Excess
Comment: 1500 sq. ft., most recent use—residential, federally endangered and threatened species may be present in area.
GSA Number: 7–U–ND–0494 A & B

House #3 (OJ3)
OMEGA Station
310 2nd St. NE
LaMoure Co: LaMoure ND 58458–
Landholding Agency: GSA
Property Number: 549720012
Status: Excess
Comment: 1500 sq. ft., most recent use—residential, federally endangered and threatened species may be present in area.
GSA Number: 7–U–ND–0494 A & B

House #4 (OJ4)
OMEGA Station
316 2nd St. NE
LaMoure Co: LaMoure ND 58458–
Landholding Agency: GSA
Property Number: 549720013
Status: Excess
Comment: 1500 sq. ft., most recent use—residential, federally endangered and threatened species may be present in area
GSA Number: 7–U–ND–0494 A & B

House #5 (OJ5)
OMEGA Station
122 4th Ave. NW
LaMoure Co: LaMoure ND 58458–
Landholding Agency: GSA
Property Number: 549720014
Status: Excess
Comment: 1500 sq. ft., most recent use—residential, federally endangered and threatened species may be present in area.
GSA Number: 7–U–ND–0494 A & B

House #6 (OJ6)
OMEGA Station
417 2nd St. NW
LaMoure Co: LaMoure ND 58458–
Landholding Agency: GSA
Property Number: 549720015
Status: Excess
Comment: 1500 sq. ft., most recent use—residential, federally endangered and threatened species may be present in area.
GSA Number: 7–U–ND–0494 A & B

House #7 (OJ7)
OMEGA Station
421 2nd St. NW
LaMoure Co: LaMoure ND 58458–
Landholding Agency: GSA
Property Number: 549720016
Status: Excess
Comment: 1500 sq. ft., most recent use—residential, federally endangered and threatened species may be present in area.
GSA Number: 7–U–ND–0494 A & B

House #8 (OJ8)
OMEGA Station
123 5th Ave. NW
LaMoure Co: LaMoure ND 58458–
Landholding Agency: GSA
Property Number: 549720017
Status: Excess
Comment: 1500 sq. ft., most recent use—residential, federally endangered and threatened species may be present in area.
GSA Number: 7–U–ND–0494 A & B

House #9 (OJ9)
OMEGA Station
517 2nd St. NW
LaMoure Co: LaMoure ND 58458–
Landholding Agency: GSA
Property Number: 549720018
Status: Excess
Comment: 1700 sq. ft., most recent use—residential, federally endangered and threatened species may be present in area.
GSA Number: 7–U–ND–0494 A & B.

House #10 (OJ10)
OMEGA Station
521 2nd St. NW
LaMoure Co: LaMoure ND 58458–
Landholding Agency: GSA
Property Number: 549720019
Status: Excess
Comment: 1700 sq. ft., most recent use—residential, federally endangered and threatened species may be present in area.
GSA Number: 7–U–ND–0494 A & B

Pennsylvania

Former Florio House
National Park Service
Bushkill Co: Monroe PA 18324–
Landholding Agency: Interior
Property Number: 619720050
Status: Unutilized
Comment: 936 sq. ft. frame, most recent use—housing, off-site use only.

Former Hardtla House
Raymondskill
Milford Co: Pike PA
Landholding Agency: Interior
Property Number: 619720051
Status: Unutilized
Comment: 1527 sq. ft. frame, 2-story, needs repair, most recent use—housing, off-site use only.

Former Hickman House
National Park Service
Bushkill Co: Monroe PA 18324–
Landholding Agency: Interior
Property Number: 619720052
Status: Unutilized
Comment: approx. 1604 sq. ft. frame, 2-story, most recent use—housing, off-site use only.

Suitable/Unavailable Properties

Buildings (by State)

Iowa

Naval Family Housing
23-Units
Waverly Co: Bremer IA 50677–
Landholding Agency: GSA
Property Number: 549720009
Status: Excess
Comment: 23-housing units, sq. ft. varies from 864–1760, capehart, wood frame, 1-story.
GSA Number: 7–D–LA–0463B

Land (by State)

New York

Galeville Army Training Site
Shawangunk Co: Ulster NY 12589–
Landholding Agency: GSA
Property Number: 219510128
Status: Excess
Comment: 621 acres, improved w/inactive runways, 234 acres is wetlands and habitat for threatened species.
GSA Number 2–D–NY–807

North Dakota

Lot 3/0.16 acre
Snake Creek Cabin Site/Tract C272A Co: Mclean ND
Landholding Agency: COE
Property Number: 319720003
Status: Unutilized
Comment: 0.16 of an acre, most recent use—private recreation (cottage site), floodplain.

Unsuitable Properties

Buildings (by State)

Alaska

Bldg. R13, USCG ISC Kodiak
Holiday Beach
Kodiak Co: Kodiak Is Bor AK 99619–
Landholding Agency: DOT
Property Number: 879720003
Status: Excess
Reason: Secured Area

Bldg. 172, USCG ISC Kodiak
Nyman's Peninsula
Kodiak Co: Kodiak Is Bor AK 99619–
Landholding Agency: DOT
Property Number: 879720004
Status: Excess
Reason: Secured Area

Bldg. 160, USCG ISC Kodiak
Comsta/Buskin Lake
Kodiak Co: Kodiak Is Bor AK 99619–
Landholding Agency: DOT
Property Number: 879720005
Status: Excess
Reason: Secured Area; Extensive deterioration

California

Bldg. 331
Pinnacles National Monument
Paicines Co: San Benito CA 95043–
Landholding Agency: Interior
Property Number: 619720046
Status: Unutilized
Reason: Extensive deterioration

15 Buildings, Davison Ranch
Orick Co: Humboldt CA 95555–
Landholding Agency: Interior
Property Number: 619720047
Status: Unutilized
Reason: Extensive deterioration

Bldg. 5500
Wolf Creek Outdoor School Lodge
Orick Co: Humboldt CA 95555–
Landholding Agency: Interior
Property Number: 619720048
Status: Unutilized
Reason: Extensive deterioration

Bldg. 766
Naval Air Weapons Station, Point Mugu
Oxnard Co: Ventura CA 93042–5001
Landholding Agency: Navy
Property Number: 779720107
Status: Excess
Reason: Secured Area

Bldg. 81
Naval Air Weapons Station, Point Mugu
Oxnard Co: Ventura CA 93042–5001
Landholding Agency: Navy
Property Number: 779720108
Status: Excess
Reason: Secured Area

Bldg. 712
Naval Air Weapons Station, Point Mugu
Oxnard Co: Ventura CA 93042–5001
Landholding Agency: Navy
Property Number: 779720109
Status: Excess
Reason: Secured Area

Bldg. 736
Naval Air Weapons Station, Point Mugu
Oxnard Co: Ventura CA 93042–5001
Landholding Agency: Navy
Property Number: 779720110
Status: Excess
Reason: Secured Area

Bldg. 7005
Naval Air Weapons Station, Point Mugu
Oxnard Co: Ventura CA 93042–5001
Landholding Agency: Navy
Property Number: 779720111
Status: Excess
Reason: Secured Area

Guam

Bldg. 259
U.S. Naval Forces, Marianas
NAVACTS Co: Waterfront Anne GU 96540–1000
Landholding Agency: Navy
Property Number: 779720112
Status: Unutilized
Reason: Secured Area; Extensive deterioration

Bldg. 522
U.S. Naval Forces, Marianas
NAVACTS Co: Waterfront Anne GU 96540–1000
Landholding Agency: Navy
Property Number: 779720113
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Extensive deterioration

Bldg. 548
U.S. Naval Forces, Marianas
NAVACTS Co: Waterfront Anne GU 96540–1000
Landholding Agency: Navy
Property Number: 779720114
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Extensive deterioration

Bldg. 722
U.S. Naval Forces, Marianas
NAVACTS Co: Waterfront Anne GU 96540–1000
Landholding Agency: Navy
Property Number: 779720115
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration

Bldgs. 794, 795
U.S. Naval Forces, Marianas
NAVACTS Co: Waterfront Anne GU 96540–1000
Landholding Agency: Navy
Property Number: 779720116
Status: Unutilized
Reason: Secured Area

Bldg. 835
U.S. Naval Forces, Marianas
NAVACTS Co: Waterfront Anne GU 96540–1000
Landholding Agency: Navy
Property Number: 779720117
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area

Bldg. K24
U.S. Naval Forces, Marianas
NAVACTS Co: Waterfront Anne GU 96540–1000
Landholding Agency: Navy
Property Number: 779720118
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration

Bldg. K25
U.S. Naval Forces, Marianas
NAVACTS Co: Waterfront Anne GU 96540–1000
Landholding Agency: Navy
Property Number: 779720119
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration

Bldg. K26
U.S. Naval Forces, Marianas
NAVACTS Co: Waterfront Anne GU 96540–1000
Landholding Agency: Navy
Property Number: 779720120
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration

Bldg. Orote K-Span
U.S. Naval Forces, Marianas
NAVACTS Co: Waterfront Anne GU 96540–1000
Landholding Agency: Navy
Property Number: 779720121
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration

Louisiana

Bldg. A102–3.507 acres
Portion/Louisianna Army Ammunition Plant
Shreveport Co: Webster Parish LA 71055–
Landholding Agency: GSA
Property Number: 549720023
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material

GSA Number: 7–D–LA–420–J

North Carolina

Bldg. 478
Marine Corps Air Station, Cherry Point
Havelock Co: Craven NC 28533–
Landholding Agency: Navy
Property Number: 779720123
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration

North Dakota

Monitor Site (OW3)
OMEGA Station
Dickey Co: LaMoure ND 58431–
Landholding Agency: GSA
Property Number: 549720020
Status: Excess
Reason: Secured Area
GSA Number: 7–U–ND–0494 A & B

Pennsylvania

Former Ebert House
Johnny Bee Rd.
Dingmans Co: Pike PA 18328–
Landholding Agency: Interior
Property Number: 619720049
Status: Unutilized
Reason: Extensive deterioration

Puerto Rico

NIH Primate Research Facility
Sabena Seca PR
Landholding Agency: GSA
Property Number: 549720021
Status: Excess
Reason: Other
Comment: Landlocked
GSA Number: 1–H–PR–503

Land (by State)

California

69 acres
Santa Rosa High Frequency Radio Station
Santa Rosa CA
Landholding Agency: Army
Property Number: 219720219
Status: Underutilized
Reason: Secured Area

Michigan

Port/EPA Large Lakes Rsch Lab
Grosse Idle Twp Co: Wayne MI
Landholding Agency: GSA
Property Number: 549720022
Status: Excess
Reason: Within airport runway clear zone
GSA Number: 1–Z–MI–554–A

[FR Doc. 97–18708 Filed 7–17–97; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Application(s) for Permit

The public is invited to comment on the following application(s) for permits to conduct certain activities with marine mammals. The application(s) was/were submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*) and the regulations governing marine mammals (50 CFR 18 and 50 CFR 216).

Applicant: Natural History Museum, Los Angeles, CA, PRT–71705.

Type of Permit: Import/Export/Reimport/Reexport for Scientific Research.

Name and Number of Animals: All marine mammal species, unlimited.

Summary of Activity to be Authorized: The applicant has requested a renewal of this permit to import, export, reimport, and reexport salvaged material from dead specimens of Cetacea, Pinnipedia, Sirenia, sea otters and marine otter for the purpose scientific research.

Source of Marine Mammals for Research: worldwide, as available.

Period of Activity: five years from issuance date of the permit, if issued.

Concurrent with the publication of this notice in the **Federal Register**, the Office of Management Authority is forwarding copies of this application to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Written data or comments, requests for copies of the complete application, or requests for a public hearing on this application should be sent to the U.S. Fish and Wildlife Service, Office of Management Authority, 4401 N. Fairfax Drive, Room 430, Arlington, Virginia 22203, telephone 703/358–2104 or fax 703/358–2281 and must be received within 30 days of the date of publication of this notice. Anyone requesting a hearing should give specific reasons why a hearing would be appropriate. The holding of such hearing is at the discretion of the Director.

Documents and other information submitted with these applications are available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act,* by any party who submits a written request for a copy of such documents within 30 days of the date of publication of this notice at the above address.

Dated: July 14, 1997.

Karen Anderson,

Acting Chief, Branch of Permits, Office of Management Authority, U.S. Fish and Wildlife Service.

Dated: July 11, 1997.

Anne Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 97–19008 Filed 7–17–97; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–320–1330–01–24A]

Extension of Currently Approved Information Collection OMB Approval Number: 1004–0073

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The Bureau of Land Management (BLM) has submitted the collection of information listed below to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). On April 14, 1997, BLM published a notice in the **Federal Register** (62 FR 11842) requesting comments on the collection. The comment period ended June 13, 1997. No comments were received. Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the BLM clearance officer at the telephone number listed below.

OMB is required to respond to this request within 60 days but may respond after 30 days. For maximum consideration your comments and suggestions on the requirement should be made within 30 days directly to the Office of Management and Budget, Interior Desk Officer (1004–0073), Office of Information and Regulatory Affairs, Washington, DC 20503, telephone (202) 395–7340. Please provide a copy of your comments to the Bureau Clearance Officer (WO–630), 1849 C St., NW., Mail Stop 401 LS, Washington, DC 20240.

Nature of Comments: We specifically request your comments on the following:

1. Whether the collection of information necessary for the proper functioning of the BLM, including whether the information will have practical utility;
2. The accuracy of BLM's estimate of the burden of collecting the information, including the validity of the methodology and assumptions used;
3. The quality, utility and clarity of the information to be collected; and
4. How to minimize the burden of collecting the information on those who are to respond, including the use of appropriate automated electronic, mechanical and other forms of information technology.

Title: Coal Management (43 CFR Group 3400).

OMB Approval Number: 1004–0073.

Abstract: Respondents supply information which will be used to

determine procedures for the leasing and management of Federal coal resources. The information supplied allows the BLM to determine that operations are conducted in a manner consistent with the regulations and environmental requirements in accordance with the National Environmental Policy Act of 1969, as amended.

Form Numbers: 3400–12, 3440–1.

Frequency: On occasion.

Description of Respondents: Those seeking to lease coal and Federal coal lessees.

Estimated Completion Times:

Type of application	Number of responses	Hours/response	Total response
Exploration License	10	30	300
Coal & Other Resource Information	5	3	15
Surface Owner Consultation	50	1	50
Expressions of Leasing Interest	5	6.6	32
Notice of Sale	20	3	60
Leasing on Application	2	150	300
Surface Owner Consent	10	10	100
PRLA's	2	750	1,500
Lease Modification	10	35	350
License to Mine	2	5	10
Lease Transfer (incl. assignments)	10	30	300
Sp. Leasing Qualifications	10	4	40
Bonding Requirements	10	40	400
Lease Form	5	1	5
Exploration Plans	50	59	2,950
Res. Rec. & Protection Plans	30	174.8	5,245
Mining Plans	10	457.5	4,575
Mining Operations Maps	650	11.3	7,350
Performance Standards for Exploration	90	1.75	158
Unexpected Wells	10	1	10
Exploration Reports	50	7.5	375
Royalty & Rental Reductions	10	150	1,500
Suspensions	10	14.4	144
Corr. Rpts. For Noncompliance	90	3.75	338
LMU Applications/Requirements	10	32	320
Totals	1,281		29,377

BLM estimates that it will take an average of 19 hours to complete the applications, petitions, offers and statements required. The range is from 1 hour to 458 hours. The applicants will have access to records, plats and maps necessary for providing legal land descriptions. The type of information necessary is outlined in the regulations and is already maintained by the respondents for their own record keeping purposes and need only be compiled in a reasonable format. The estimate also includes the time required for assembling the information, as well as the time of clerical personnel, if needed. BLM estimates that 1,281 filings will be made annually for a total of 29,377 reporting hours.

Annual Filings: 1,281.

Annual Burden Hours: 29,377.

Bureau Clearance Officer: Carole Smith, (202) 452–0367.

Dated: June 30, 1997.

Carole Smith,

Bureau of Land Management, Clearance Officer.

[FR Doc. 97–18946 Filed 7–17–97; 8:45 am]

BILLING CODE 4310–84–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–030–1990–01]

Notice of Availability for the Spanish Springs Mineral Material Sale Finding of No Significant Impact and Record of Decision

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Notice of Availability for the Finding of No Significant Impact and Record of Decision for the Spanish Springs mineral material sale, Spanish Springs, Valley, Washoe County, Nevada.

SUMMARY: Pursuant to section 102 of the National Environmental Policy Act, 40 CFR 1500–1508 and 43 CFR 3600, notice is given that the Bureau of Land Management has prepared the final Finding of No Significant Impact and Record of Decision on the proposed Spanish Springs Mineral Material Sale and has made copies of the document available for public review.

DATES: The Finding of No Significant Impact and Record of Decision was distributed and made available to the public on July 11, 1997. Anyone wishing to appeal the Finding of No Significant Impact and Record of Decision has 30 days following the date of publication of this notice in the **Federal Register**.

ADDRESSES: A copy of the Finding of No Significant Impact and Record of Decision can be obtained from: Bureau of Land Management, Carson City District Office, Attn: Ron Moore, 1535 Hot Springs Road, Suite 300, Carson City, Nevada 89706.

FOR FURTHER INFORMATION CONTACT: For additional information, write to the above address or call Ron Moore at (702) 885–6155.

SUPPLEMENTARY INFORMATION: The Finding of No Significant Impact and Record of Decision consists of the approval of the proposed action analyzed in the environmental assessment together with mitigation and monitoring requirements. The Proposed Action consists of the sale of ten million tons of rock material over a ten year period on public lands in Spanish Spring Valley, north of Sparks, Nevada.

Dated: July 14, 1997.

Daniel L. Jacquet,

Acting Assistant District Manager, Nonrenewable Resources, Carson City, Nevada.

[FR Doc. 97–19006 Filed 7–17–97; 8:45 am]

BILLING CODE 4410–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ–910–0777–61–241A]

State of Arizona Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Arizona Resource Advisory Council Meeting, notice of meeting.

SUMMARY: This notice announces a meeting of the Arizona Resource Advisory Council. The meeting will be held August 19, 1997, beginning at 8:30 a.m. in the Nevada Room at the Bureau of Land Management National Training Center, 9828 N. 31st Avenue, Phoenix, Arizona. The agenda items to be covered at the one-day meeting include review of previous meetings minutes; BLM State Director's Update on legislation, regulations and statewide planning efforts; Update on 1997–99 RAC Nominations; Update on BLM Proposed Saguaro National Park Exchange, Update on Standards and Guidelines Implementation; Reports by the Recreation and Public Relations Working Groups; Reports from RAC Members; RAC Discussion on future meeting dates and locations. A public comment period will take place at 11:30 a.m. for any interested publics who wish to address the Council.

FOR FURTHER INFORMATION CONTACT: Deborah Stevens, Bureau of Land Management, Arizona State Office, 222 North Central Avenue, Phoenix, Arizona 85004–2203, (602) 417–9215.

Michael Ferguson,

Deputy State Director, Resources Division.

[FR Doc. 97–19007 Filed 7–17–97; 8:45 am]

BILLING CODE 4310–32–M

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Alaska Outer Continental Shelf (OCS) Region Offshore Advisory Committee; Notice and Agenda for Meeting

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of meeting.

SUMMARY: The Alaska OCS Region Offshore Advisory Committee for the Minerals Management Service will meet on August 5–6, 1997.

The agenda will cover the following principal subjects:

- The Proposal, alternatives and mitigating measures for Proposed OCS oil and gas lease Sale 170, Beaufort Sea.

The meeting is open to the public. Upon request, interested parties may make oral presentations or submit written materials to the Alaska OCS Region Offshore Advisory Committee. Such requests should be made no later than July 29, 1997. Requests to make oral statements should be accompanied by a summary of the statement to be made. All oral presentations and written statements submitted before the conclusion of the meeting will be made part of the meeting record and will be made available to the Committee for its discussions. For more information, call Michele Hope at (907) 271–6424.

Minutes of the Alaska OCS Region Offshore Advisory Committee meeting will be available for public inspection and copying at the Minerals Management Service in Anchorage, Alaska.

DATES: Tuesday, August 5, 1997, 9 a.m. to 5 p.m. and Wednesday, August 6, 1997, 9 a.m. to 12 noon.

ADDRESSES: The meeting will be held at the University Plaza Building, 949 East 36th Ave., Minerals Management Service, 3rd Floor Conference Room, Anchorage, Alaska 99508. Requests for oral presentations can be made to the same address or by phone, Attention: Michele Hope at (907) 271–6424.

FOR FURTHER INFORMATION CONTACT: Michele Hope at the address and phone number listed above.

Authority: Federal Advisory Committee Act, Pub. L. 92–463, 5 U.S.C. Appendix 1, and the Office of Management and Budget's Circular No. A–63, Revised.

Rance R. Wall,

Acting Regional Director, Alaska OCS Region, Minerals Management Service.

[FR Doc. 97–18818 Filed 7–17–97; 8:45 am]

BILLING CODE 4310–MR–M

DEPARTMENT OF THE INTERIOR

National Park Service

Dayton Aviation Heritage Commission

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting.

SUMMARY: This notice sets the schedule for the forthcoming meeting of the Dayton Aviation Heritage Commission. Notice of this meeting is required under the Federal Advisory Committee Act (Pub. L. 92–463).

DATE, TIME, AND ADDRESS: Tuesday, September 2, 1997, 5:15 p.m. to 6:30 p.m., Innerwest Priority Board conference room, 1024 West Third Street, Dayton, Ohio 45407.

This business meeting will be open to the public. Space and facilities to accommodate members of the public are limited and persons accommodated on a first-come, first-served basis. The Chairman will permit attendees to address the Commission, but may restrict the length of presentations. An agenda will be available from the Superintendent, Dayton Aviation, 1 week prior to the meeting.

FOR FURTHER INFORMATION CONTACT: William Gibson, Superintendent, Dayton Aviation, National Park Service, P.O. Box 9280, Wright Brothers Station, Dayton, Ohio 45409, or telephone 513–225–7705.

SUPPLEMENTARY INFORMATION: The Dayton Aviation Heritage Commission was established by Pub. L. 102–419, October 16, 1992.

Dated: July 11, 1997.

William W. Schenk,

Regional Director, Midwest Region.

[FR Doc. 97–18954 Filed 7–17–97; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

Keweenaw National Historical Park Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Notice of Meeting.

SUMMARY: This notice announces an upcoming meeting of the Keweenaw National Historical Park Advisory Commission. Notice of this meeting is required under the Federal Advisory Committee Act (Pub. L. 92–463).

DATE: Tuesday, August 19, 1997; 8:30 a.m. until 4:30 p.m.

ADDRESS: Keweenaw National Historical Park Headquarters, 100 Red Jacket Road (2nd floor), Calumet, Michigan 49913–0471.

This meeting is open to the public. We will begin with the Chairman's welcome; minutes of the previous meeting; update on the general management plan; update on park activities; old business; new business; next meeting date; adjournment.

FOR FURTHER INFORMATION CONTACT: Superintendent, Keweenaw National Historical Park, P.O. Box 471, Calumet, Michigan 49913–0471, or telephone 906–337–3168.

SUPPLEMENTARY INFORMATION: The Keweenaw National Historical Park was established by Pub. L. 102–543 on October 27, 1992.

Dated: July 1, 1997.

William W. Schenk,

Regional Director, Midwest Region.

[FR Doc. 97–18955 Filed 7–17–97; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (BJA)–1129]

RIN 1121–ZA75

Grant Program for Metropolitan Firefighters and Emergency Services National Training Program for First Responders to Terrorist Incidents; Extension

AGENCY: Office of Justice Programs, Bureau of Justice Assistance, Justice.

ACTION: Extension of grant application due date.

SUMMARY: This document extends the application due date for the Metropolitan Firefighters and Emergency Services National Training Program for First Responders to Terrorist Incidents from August 7, 1997 to August 20, 1997.

FOR FURTHER INFORMATION CONTACT: Andy Mitchell or Frank Le Page at 202–616–2356.

Dated: July 13, 1997.

Nancy E. Gist,

Director, Bureau of Justice Assistance.

[FR Doc. 97–18889 Filed 7–17–97; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,413]

J.R. Simplot Co., Heyburn, Idaho; Notice of Revised Determination on Reconsideration

On June 30, 1997, the Department, on its own motion, reviewed the negative determination regarding the petition for workers of the subject firm. The workers produce frozen potato products.

The initial investigation resulted in a negative determination issued on May 22, 1997, because criterion (3) of the Trade Act of 1974, as amended was not met. A survey of major declining customers revealed that none of the respondents increased their purchases frozen potato products while decreasing their purchases from the subject firm. The denial notice was published in the **Federal Register** on June 13, 1997 (62 FR 32376).

A late response to the survey conducted by the Department revealed that a customer of the subject firm increased import purchases of frozen processed potato products during the relevant time period.

Conclusion

After careful review of the additional facts obtained on reconsideration, I conclude that increased imports of articles like or directly competitive with frozen processed potato products, contributed importantly to the declines in sales or production and to the total or partial separation of workers of J.R. Simplot Company, Heyburn, Idaho. In accordance with the provisions of the Act, I make the following certification:

All workers of J.R. Simplot Company, Heyburn, Idaho, who became totally or partially separated from employment on or after April 6, 1996, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed in Washington, DC, this 10th day of July 1997.

Curtis K. Kooser,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–18898 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–01609]

J.R. Simplot Co., Heyburn, Idaho; Revised Determination on Reconsideration

On June 30, 1997, the Department, on its own motion, reviewed the negative determination regarding the petition for workers of the subject firm. The workers produce frozen potato products.

The initial investigation resulted in a negative determination issued on May 22, 1997, because criteria (3) and (4) of paragraph (a)(1) of section 250 of the Trade Act of 1974, as amended, were not met. There was no shift of production from the Heyburn, Idaho plant to Canada or Mexico, nor did J.R. Simplot import frozen potato products. A survey of major declining customers of the subject firm revealed that customers did not purchase frozen potato products from Canada or Mexico during the relevant period. The denial notice was published in the **Federal Register** on June 13, 1997 (62 FR 32377).

A late response to the survey conducted by the Department revealed that a customer of the subject firm increased import purchases of frozen processed potato products from Mexico and/or Canada during the relevant time period.

Conclusion

After careful review of the additional facts obtained on reconsideration, I conclude that increased imports of articles from Canada and Mexico like or directly competitive with frozen processed potato products, contributed importantly to the declines in sales or production and to the total or partial separation of workers of J.R. Simplot Company, Heyburn, Idaho. In accordance with the provisions of the Act, I make the following certification:

All workers of J.R. Simplot Company, Heyburn, Idaho, who became totally or partially separated from employment on or after April 6, 1996, are eligible to apply for NAFTA–TAA under Section 250 of the Trade Act of 1974.

Signed in Washington, DC, this 10th day of July 1997.

Curtis K. Kooser,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–18903 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

TA–W–30, 836; TA–W–30, 837; and TA–W–30, 837A

American Oil and Gas a/k/a K N Energy a/k/a Westar Transmission Company a/k/a H R Options, Inc.; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued a Notice of Certification Regarding Eligibility to Apply for Worker Adjustment Assistance on April 26, 1997, applicable to workers of American Oil and Gas in Amarillo, Texas, and the subject firms' Gathering and Processing Divisions in Pampa, Texas. The notice was published in the **Federal Register** on May 9, 1995 (60 FR 24653).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The

workers produced crude oil and natural gas products. Findings on review show that some of the workers have had their wages reported to Unemployment Insurance tax accounts under the new parent company name, K N Energy, and under Westar Transmission Company and HR Options, Inc. The intent of the Department's certification is to include all workers of American Oil and Gas who were affected by increased imports. Accordingly, the Department is amending the worker certification to reflect this matter.

The amended notice applicable to TA–W–30,836 is hereby issued as follows:

All workers of American Oil and Gas, also known as K N Energy, also known as Westar Transmission Company and also known as HR Options, Inc., Amarillo, Texas (TA–W–30,836), the Processing Division, Pampa, Texas (TA–W–30,837A), and the Gathering Division, Pampa, Texas (TA–W–30,837B), who became totally or partially separated from employment on or after March 7, 1994 through April 26, 1997, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, D.C. this 27th day of June 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–18894 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,477, TA–W–33,477A]

Cone Mills Corp., Haynes Plant, Henrietta, North Carolina and Cone Mills Corp., Florence Plant, Forest City, North Carolina; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on June 17, 1997, applicable to all workers of Cone Mills Corporation, Haynes Florence Plant, Henrietta, North Carolina. The notice will soon be published in the **Federal Register**.

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. New findings show that the Department incorrectly identified the subject firm plants and locations. The investigation conducted for the subject firm was conducted on behalf of the workers at the Haynes Florence Plant located in Henrietta, North Carolina. Workers of the Florence Plant, Forest City, North Carolina facility were inadvertently omitted from the certification. Accordingly, the Department is amending the certification to correctly identify the plants and cities to read Haynes Plant, Henrietta, North Carolina and Florence Plant, Forest City, North Carolina.

The intent of the Department's certification is to include all workers of Cone Mills Corporation adversely affected by imports.

The amended notice applicable to TA–W–33,477 is hereby issued as follows:

All workers of Cone Mills Corporation, Haynes Plant, Henrietta, North Carolina (TA–W–33,477) and Florence Plant, Forest City, North Carolina (TA–W–33,477A) who became totally or partially separated from employment on or after April 8, 1996 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, DC, this 27th day of June 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–18901 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33, 113 and NAFTA–01458]

Frigidaire Home Products Division of White Consolidated Industries Greenville, Michigan; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Program Manager of the Office of Trade Adjustment Assistance for workers at Frigidaire Home Products Division of White Consolidated Industries, Greenville, Michigan. The review indicated that the application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA–W–33, 113 and NAFTA–01458; Frigidaire Home Products Division of White Consolidated Industries Greenville, Michigan (July 1, 1997)

Signed at Washington, D.C. this 1st day of July, 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–18893 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility to Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Program Manager of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Program Manager, Office of Trade Adjustment Assistance, at the address shown below, not later than July 28, 1997.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Program Manager, Office of Trade Adjustment Assistance, at the address shown below, not later than July 28, 1997.

The petitions filed in this case are available for inspection at the Office of the Program Manager, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S.

Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, D.C., this 30th day of June, 1997.

Curtis K. Kooser,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

APPENDIX—PETITIONS INSTITUTED ON 06/30/97

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
33,594	Hyatt Manufacturing (Comp)	Union, NJ	06/10/97	Traction Motor Bearing and Journal Boxes.
33,595	Continental Sprayers (Wkrs)	El Paso, TX	06/10/97	Injection Molding for Trigger Sprayers.
33,596	C & H Apparel (Comp)	Milan, TN	06/10/97	Men's and Boys' Shorts, Underwear Sets.
33,597	Zimmer, Inc (Wkrs)	Warsaw, IN	06/13/97	Internal Fracture Fixation Systems.
33,598	Littlestown Manufacturing (Wkrs)	Littlestown, PA	06/16/97	Pants, Knit Shirts for Toddlers.
33,599	H.H. Cutler Co (Comp)	Statesboro, GA	06/19/97	Cutting and Screen Printing on Apparel.
33,600	Best Power (Wkrs)	Necedah, WI	06/13/97	Uninterruptible Power Systems.
33,601	A.J. Apparel, Inc (Comp)	Rocky Mount, NC	06/10/97	T-Shirts, Tank Tops.
33,602	Sweatts' Prefade, Inc (Wkrs)	Opp, AL	05/05/97	Wrangler Jeans.
33,603	Eagle Engineering & Mfg (Wkrs)	Welcome, MN	06/11/97	Air Conditioning and Heating Units.
33,604	APV Crepaco (USWA)	Lake Mills, WI	06/12/97	Food Processing and Refrigeration Equip.
33,605	Goss Graphics Systems (USWA)	Wyomissing, PA	06/06/97	Printing Presses.
33,606	SpecPrint, Inc (Wkrs)	Olney, IL	06/12/97	Screen Printed Decals.
33,607	L.C. Holdings, Inc (UAW)	Smiths Creek, MI	06/17/97	Sheetmetal Enclosures.
33,608	Occidental Oil & Gas Corp (Comp)	Bakersfield, CA	06/16/97	Oil and Gas.
33,609	Occidental Oil & Gas Corp (Comp)	Tulsa, OK	06/16/97	Oil and Gas.
33,610	Occidental Oil & Gas Corp (Comp)	Liberal, KS	06/16/97	Oil and Gas.
33,611	Occidental Oil & Gas Corp (Comp)	Midland, TX	06/16/97	Oil and Gas.
33,612	Baker School Specialties (Comp)	Orange, MA	06/17/97	Chalk and Marker Boards.
33,613	Fair Haven Industries (IBT)	Fair Haven, MI	06/19/97	Automotive Sewing Seats, Door Panels.
33,614	Huntsman Packaging (Wkrs)	Bowling Green, KY	06/16/97	Packaging Materials.
33,615	Heat-N-Glo (Comp)	Savage, MN	06/10/97	Gas and Wood Fireplaces Products.

[FR Doc. 97–18904 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–29,743E]

IBM Corporation Enterprise Systems Large Scale Computing Systems Division and Its Successors (Including Corporation Litigation Analysis and Support Department), White Plains, New York; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued an Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance on June 16, 1995, applicable to workers of IBM Corporation, Enterprise Systems, Large Scale Computing Systems Division and its successors located in White Plains, New York. The notice was published in the **Federal Register** on June 29, 1995 (60 FR 64454).

At the request of petitioners, the Department has reviewed the certification for workers at the subject firm. Information provided by the company shows that the Corporate Litigation Analysis and Support Department of IBM Corporation provided significant litigation activities relating to the IBM Enterprise Systems Division, and specifically to LSCD mainframes.

The intent of the Department's certification is to include all workers of the subject firm who were affected by increased imports. Accordingly, the Department is amending the worker certification to include the workers of the Corporate Litigation Analysis and Support Department located in White Plains, New York.

The amended notice applicable to TA–W–29,743E is hereby issued as follows:

All workers of IBM Corporation, Enterprise Systems, Large Scale Computing Systems Division and its successors, including the Corporate Litigation Analysis and Support Department, located in White Plains, New York, who became totally or partially separated from employment on or after March 31, 1993 through March 23, 1997, are eligible to apply for adjustment assistance under Section 224 of the Trade Act of 1974.

Signed at Washington, D.C. this 27th day of June 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–18895 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–32,178; TA–W–32,178F]

Kentucky Apparel LLP; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on April 29, 1996, applicable to all workers of Kentucky Apparel LLP, located in Burkesville, Kentucky. The notice was published in the **Federal Register** on May 17, 1996 (61 FR 24960).

At the request of the petitioners, the Department reviewed the certification for workers of the subject firm. New information received by the company shows that worker separations did occur

during January, 1997 at the Gamaliel, Kentucky facility of Kentucky Apparel LLP. The workers produce denim jeans.

The intent of the Department's certification is to include all workers of Kentucky Apparel LLP who were adversely affected by increased imports of jeans. Accordingly, the Department is amending the certification to cover the workers of Kentucky Apparel LLP, Gamaliel, Kentucky.

The amended notice applicable to TA–W–32,178 is hereby issued as follows:

All workers of Kentucky Apparel LLP, Burkesville, Kentucky (TA–W–32,178) and Gamaliel, Kentucky (TA–W–32,178F) who became totally or partially separated from employment on or after March 11, 1995 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington D.C. this 27th day of June, 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment.

[FR Doc. 97–18892 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33, 562]

Plaid Clothing Company, Incorporated, Cincinnati, OH; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on June 9, 1997 in response to a worker petition which was filed on May 22, 1997 on behalf of workers at the Plaid Clothing Company, Incorporated, Cincinnati, Ohio.

An active certification covering the petitioning group of workers is already in effect (TA–W–32, 944 A). Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed in Washington, D.C. this 2nd day of July, 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–18899 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–32,944; TA–W–32,944A]

Plaid Clothing Group, Incorporated, J. Schoeneman Division, Chambersburg, Pennsylvania; Plaid Clothing Company, Incorporated, Cincinnati, Ohio; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 8, 1997, applicable to all workers of Plaid Clothing Group, Incorporated, J. Schoeneman Division, Chambersburg, Pennsylvania. The notice was published in the **Federal Register** on February 3, 1997 (62 FR 5050).

At the request of the petitioners, the Department reviewed the certification for workers of the subject firm. New findings show that worker separations are expected to occur at the subject firm's Cincinnati, Ohio location in August 1997 and continue through December 1997 when it closes. The workers provide administrative and support function services for Plaid Clothing Group, Incorporated. Accordingly, the Department is amending the certification to cover workers at the subject firms' Cincinnati, Ohio location.

The intent of the Department's certification is to include all workers of Plaid Clothing Group, Incorporated adversely affected by increased imports.

The amended notice applicable to TA–W–32,944 is hereby issued as follows:

All workers of Plaid Clothing Group, Incorporated, J. Schoeneman Division, Chambersburg, Pennsylvania (TA–W–32,944), Plaid Clothing Company, Incorporated, Cincinnati, Ohio (TA–W–944A) who became totally or partially separated from employment on or after November 8, 1995 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington D.C. on this 2nd day of July, 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment.

[FR Doc. 97–18900 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Program Manager of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Program Manager, Office of Trade Adjustment Assistance, at the address shown below, not later than July 28, 1997.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Program Manager, Office of Trade Adjustment Assistance, at the address shown below, not later than July 28, 1997.

The petitions filed in this case are available for inspection at the Office of the Program Manager, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, DC, this 23rd day of June 1997.

Curtis K. Kooser,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

APPENDIX—PETITIONS INSTITUTED ON 06/23/97

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
33,581	Pro-Line Cap Co (Wkrs)	Bowie, TX	05/09/97	Licensed Baseball Caps.
33,582	Pawnee pants (UNITE)	Olyphant, PA	06/10/97	Pants.
33,583	Spotlight Co., Inc (Wkrs)	Ashdown, AR	06/06/97	Ladies' Lingerie.
33,584	Lovable Company (Wkrs)	Braselton, GA	06/09/97	Ladies' Bras and Panties.
33,585	Utica Corp. (IAMAW)	Whitesboro, NY	06/09/97	Turbine Blades and Airfolds for jet engine.
33,586	Ford Electronics and Refrig (UAW)	Lansdale, PA	05/23/97	Anti-Lock Brake Sys. Electronic Control.
33,587	Missouri Service Center (Wkrs)	Mt. View, MO	06/04/97	Uniforms.
33,588	Miller Group (The) (Co.)	Sch'll Haven, PA	06/10/97	T-Shirts.
33,589	KAO Infor Systems (Wkrs)	Plymouth, MA	06/03/97	3½ Inch Computer Disks.
33,590	Maine Shoe, Inc (Wkrs)	Lewiston, ME	06/06/97	Men's and Ladies' shoes.
33,591	Bel Tronics Limited (Co.)	Covington, GA	06/10/97	Circuit Board Assembly.
33,592	Texas Boot Co. (Co.)	Lebanon, TN	06/11/97	Western and Fashion Boots.
33,593	Lithonia Lighting (Wkrs)	Conyers, GA	06/10/97	Industrial and fluorescent light fixtures.

[FR Doc. 97–18906 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,210; TA–W–33,210B]

Singer Furniture Company, Lenoir, North Carolina; Singer Furniture Company, Roanoke, Virginia; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on April 17, 1997, applicable to all workers of Singer Furniture Company, Lenoir, North Carolina. The notice was published in the **Federal Register** on May 9, 1997 (62 FR 25659).

At the request of the petitioners, the Department reviewed the certification for workers of the subject firm. New findings show that worker separations occurred during the past year at Singer Furniture Company, Roanoke, Virginia. The workers are engaged in employment related to the production of household furniture.

The intent of the Department's certification is to include all workers of Singer Furniture Company adversely affected by increased imports of household furniture. Accordingly, the Department is amending the certification to cover the workers of Singer Furniture Company, Roanoke, Virginia.

The amended notice applicable to TA–W–33,210 is hereby issued as follows:

All workers of Singer Furniture Company, Lenoir, North Carolina (TA–W–33,210), and Roanoke Virginia (TA–W–32,210B) who became totally or partially separated from employment on or after February 4, 1996 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington D.C. on this 27th day of July, 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment.

[FR Doc. 97–18890 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–01707]

Sugar Cane Services Pahokee, FL; Notice of Termination of Investigation

Pursuant to Title V of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182) concerning transitional adjustment assistance, hereinafter called (NAFTA–TAA), and in accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended (19 U.S.C. 2273), an investigation was initiated on May 27, 1997 in response to a petition filed on behalf of workers at Sugar Cane Services, Pahokee, Florida.

This case is being terminated because the workers were separated from the subject firm more than one year prior to the date of the petition. The NAFTA Implementation Act specifies that no certification may not apply to any worker whose last separation occurred more than one year before the date of the petition. Consequently further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, D.C., this 7th day of July 1997.

Curtis K. Kooser,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–18905 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,488]

Unocoal Corporation; 76 Products Company; Headquartered in Costa Mesa, California and Operating at Various Locations in the State of California; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on May 19, 1997 in response to a worker petition which was filed on behalf of workers at Unocol Corporation, 76 Products Company, Headquarters in Costa Mesa, California and operating at various locations in the State of California.

All workers of the subject firm are covered under an existing denial (TA–W–33,335) and there is no new information to reopening the case. Consequently, further investigation in this case would serve no purpose; and the investigation has been terminated.

Signed at Washington, DC this 2nd day of July, 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–18891 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–33,643]

Wyeth-Ayerst Laboratories, Inc., Mason, Michigan; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on July 7, 1997 in response to a worker petition which was filed on behalf of workers at Wyeth-Ayerst Laboratories, Inc., Mason, Michigan.

A negative determination applicable to the petitioning group of workers was issued on August 26, 1996 (TA–W–32,484). No new information is evident which would result in a reversal of the Department's previous determination. Consequently further investigation in this case would serve no purpose; and the investigation has been terminated.

Signed at Washington, DC this 7th day of July, 1997.

Curtis K. Kooser,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–18896 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–01631, NAFTA–01631A]

Cone Mills Corp., Haynes Plant, Henrietta, North Carolina and Cone Mills Corp., Florence Plant, Forest City, North Carolina; Amended Certification Regarding Eligibility To Apply for NAFTA Transitional Adjustment Assistance

In accordance with Section 250(a), Subchapter 2, Title II, of the Trade Act of 1974, as amended (19 U.S.C. 2273), the Department of Labor issued a Certification for NAFTA Transitional Adjustment Assistance on June 17, 1997, applicable to all workers of Cone Mills Corporation, Haynes Florence Plant, Henrietta, North Carolina. The notice will soon be published in the **Federal Register**.

At the request of the State Agency, the Department reviewed the certification for workers of the subject firm. New findings show that the Department incorrectly identified the subject firm plants and locations. The investigation conducted for the subject firm was conducted on behalf of the workers and the Haynes Florence Plant located in Henrietta, North Carolina. Workers of the Florence Plant, Forest City, North Carolina facility were inadvertently omitted from the certification. Accordingly, the Department is amending the certification to correctly identify the plants and cites to read Haynes Plant, Henrietta, North Carolina and Florence Plant, Forest City, North Carolina.

The intent of the Department's certification is to include all workers of Cone Mills Corporation adversely affected by imports from Mexico.

The amended notice applicable to NAFTA–01631 is hereby issued as follows:

All workers of Cone Mills Corporation, Haynes Plant, Henrietta, North Carolina (NAFTA–01631) and Florence Plant, Forest City, North Carolina (NAFTA–01631A) who became totally or partially separated from employment on or after April 8, 1996 are eligible to apply for NAFTA–TAA under Section 250 of the Trade Act of 1974.

Signed at Washington, DC, this 27th day of June 1997.

Russell T. Kile,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–18902 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determination Regarding Eligibility to Apply for Worker Adjustment Assistance and NAFTA Transitional Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) issued during the period of June and July, 1997.

In order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or in appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separation at the firm.

TA–W–33,421; Exide Corp., Frankfort, IN

TA–W–33,570; Butterick Co., Altoona, PA

TA–W–33,497; Big River Luggage Co., Inc., Corpus Christi, TX

TA–W–33,516; Brown & Bigelow, Inc., Hoyle Products, East Saint Paul, MN

TA–E–33,423; Mid-Coast Marine, Coos Bay, OR

TA–W–33,515; ICI Explosives, Aerospace and Automotive Products, Tamaqua, PA

TA–W–33,535; General Pneumatics Corp, Orange, NJ

TA–W–33,117; Halliburton Energy Service, Logging & Perforating Product Service Line, Homer, PA

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

TA–W–33,563; Corona USA Corp., Fort Lee, NJ

TA–W–33,180; N.L.C., Inc., Trout Creek, MT

The workers firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–33,456; DMC Apparel, Knoxville, TN

TA–W–33,444; The Genlyte Group, Inc., E-Lite Div., Cameron, WV

Separations at the subject firm were due to a corporate decision to consolidate operations and move production to another domestic facility.

TA–W–33,416; Shape, Inc., Kennebunk, ME

TA–W–33,289; CDR Ridgway, Ridgway, PA

The investigation revealed that criteria (2) has not been met. Sales or production did not decline during the relevant period as required for certification.

TA–W–33,422; Rema Bakeware, Salena, KA

TA–W–33,384; LFI North America, A/K/A Language for Industry, Inc., Beachwood, OH

TA–W–33,585; Utica Corp. Whitesboro, NY

TA–W–33,529; Norton McNaughton, Inc., New York, NY

TA–W–33,538; American Magnetics Corp., Carson, CA

Increased imports did not contribute importantly to worker separations at the firm.

TA–W–33,553; Thomas & Betts, LRC Electronics, Horseheads, NY

The investigation revealed that criteria (1) has not been met. A significant number or proportion of the workers did not become totally or partially separated as required for certification.

TA–W–33,430; Bijur Lubricating Corp., A subsidiary of Visper Corp., Bennington, VT

The investigation revealed that criteria (2) and criteria (3) have not been met. Sales or production did not decline during the relevant period as required for certification. Increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have not contributed importantly to the separations or threat thereof, and the absolute decline in sales or production.

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name & location for each determination references the impact date for all workers for such determination.

TA–W–33,467; International Wire Group, Rolling Prairie, IN: April 15, 1996.

TA–W–33,502; Power Guard, A Division of Antec, Opelika, AL: April 27, 1996.

TA–W–33,540; Medarville Garment Factory, Div. of Universall Overall Co., Medarville, IN: May 8, 1996.

TA–W–33,509; Church Dwight Co., Inc., Syracuse, NY: May 15, 1996.

TA–W–33,560; Zenith Goldline Pharmaceuticals, Ft. Lauderdale, FL: May 27, 1996.

TA–W–33,544; Trinity Industries, Inc., Plant #102—Railcar Div., Greenville, PA: May 20, 1996.

TA–W–33,466; C-Cor Electronics, Inc., Reedsville, PA: April 15, 1996.

TA–W–33,489; Frigidaire Co., Athens, TN: May 6, 1996. 1996.

TA–W–33,507; Guardian Industries Corp., Falconer, NY: May 6, 1996.

TA–W–33,486; Item Limited A.K.A. Melanzona & Impasse Limited, New York, NY: May 7, 1996.

TA–W–33,543; Greater Texas Finishing Corp., El Paso, TX: May 20, 1996.

TA–W–33,334; LAN Technologies, Inc., Pueblo CO: March 5, 1996.

TA–W–33,559; Dunbrooke, Div. of American Marketing Industries, Inc., Mt. Vernon, MO: May 22, 1996.

TA–W–33,521; Boise Cascade Corp., Timber and Wood Products Div., Yakima, WA: May 14, 1996.

TA–W–33,557 & A; Knapp Shoes, Brockton, MA and Holbrook, MA: May 14, 1996.

TA–W–33,524; Standard Industries, Inc., San Antonio, TX: May 12, 1996.

TA–W–33,411; J.R. Simplot Co., Food Group, Caldwell, ID: March 24, 1996.

TA–W–33,425; Anchor Bay Corp., Denver, CO: April 17, 1996.

TA–W–33,477; Cone Mills Corp., Haynes Florence Plant, Henrietta, NC: April 8, 1996.

TA–W–33,534; Milaca Mills, Inc., Milaca, MN: May 17, 1996. 1996.

TA–W–33,396; Alofs Manufacturing Co., Grand Rapids, MI: March 25, 1996.

TA–W–33,399; Tri-Con Industries, Ltd., Columbia, MO: March 27, 1996.

TA–W–33,492; K–D Industries, Inc., Div. of Lees Manufacturing Co., Inc., Blountsville, AL: May 2, 1996.

TA–W–33,366; Lacy Diversified Industries, Jessup Door Co. Div., Dowagiac, MI: February 22, 1996.

TA–W–33,579; AMP, Inc., Advanced Cable Systems Div., Middletown, PA: June 6, 1996.

TA–W–33,545; CNI, Inc., Port Huron, MI: May 21, 1996.

TA–W–33,564; Hudson Valley Tree A/K/A Noma International of Canada, Newburg, NY: May 5, 1996.

Also, pursuant to Title V of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182) concerning transitional adjustment assistance hereinafter called (NAFTA–TAA) and in accordance with Section 250(a) Subchapter D, Chapter 2, Title II, of the Trade Act as amended, the Department of Labor presents summaries of determinations regarding eligibility to apply for NAFTA–TAA issued during the month of June and July, 1997.

In order for an affirmative determination to be made and a certification of eligibility to apply for NAFTA–TAA the following group eligibility requirements of Section 250 of the Trade Act must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, (including workers in any agricultural firm or appropriate subdivision thereof) have become totally or partially separated from employment and either—

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely,

(3) That imports from Mexico or Canada of articles like or directly competitive with articles produced by such firm or subdivision have increased, and that the increases in imports contributed importantly to such workers' separations or threat of separation and to the decline in sales or production of such firm or subdivision; or

(4) That there has been a shift in production by such workers' firm or subdivision to Mexico or Canada of articles like or directly competitive with articles which are produced by the firm or subdivision.

Negative Determinations NAFTA–TAA

In each of the following cases the investigation revealed that criteria (3) and (4) were not met. Imports from Canada or Mexico did not contribute importantly to workers' separations. There was no shift in production from the subject firm to Canada or Mexico during the relevant period.

NAFTA–TAA–01670; Anvil Knitwear, Inc ., Aynor, SC

NAFTA–TAA–01545; Owens-Illinois Closure, Inc., Erie, PA

NAFTA–TAA–01619; Alofs Manufacturing Co., Grand Rapids, MI

NAFTA–TAA–01642; The Genlyte Group, Inc., E–Lite Div., Cameron, WV

NAFTA–TAA–01647; Big River Luggage Co., Inc., Corpus Christi, TX

NAFTA–TAA–01728; Flowers Industries, Inc., Aunt Fannys Bakery of PA., Inc., North East, PA

NAFTA–TAA–01694; ICI Explosives, Aerospace and Automotive Products, Tamaqua, PA

NAFTA–TAA–01682; Butterick Co., Altooma, PA

NAFTA–TAA–01657; Johnstown America Corp., Johnstown, PA

NAFTA–TAA–01677; Suckle Corp., Scranton, PA

NAFTA–TAA–01636; Unocal Corp., 76 Products Co. Headquartered in Costa Mesa, CA and Operating at Various Locations in the State of CA

NAFTA–TAA–01430; Halliburton Energy Services, Logging and Perforating Product Service Line, Homer City, PA

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

NAFTA–TAA–01613; Rip Curl, d/b/a Lowers, Inc., Oceanside, CA

Worker separations at the subject firm occurred prior to March 25, 1996, the date of earliest certification under legislation.

NAFTA–TAA–01672; Thomas & Betts, LRC Electronics, Horseheads, NY

A significant number or proportion of the workers in such workers' firm or an appropriate subdivision have not become totally or partially separated from employment.

Affirmative Determinations NAFTA–TAA

The following certifications have been issued; the date following the company name and location for each determination references the impact date for all workers for such determination.

NAFTA–TAA–01603; J.R. Simplot Co., Food Group, Caldwell, ID: March 24, 1996.

NAFTA–TAA–01662; Springlift Corp., Div. of Attwood Corp., Monticello, AR: May 12, 1996.

NAFTA–TAA–01680; Holland Atlantic Hitch Co., Denmark, SC: May 28, 1996.

NAFTA–TAA–01652; Guardian Industries Corp., Falconer, NY: May 2, 1996.

NAFTA–TAA–01598; Tri-Con Industries, Ltd, Columbia, MO: March 27, 1996.

NAFTA–TAA–01631; Cone Mills Corp., Haynes Florence Plant, Henrietta, NC: April 8, 1996.

NAFTA–TAA–01665; American Magnetics Corp., Carson, CA: May 16, 1996.

NAFTA–TAA–01666; Frigidaire Co., Athens, TN: May 6, 1996.

NAFTA–TAA–01650; C-Cor Electronics, Inc., Reedsville, PA: April 30, 1996.

NAFTA–TAA–01691; AMP, Inc., Advanced Cable Systems Div., Middletown, PA: June 6, 1996.

NAFTA–TAA–01654; Standard Industries, Inc., San Antonio, TX: May 12, 1996.

NAFTA–TAA–01658; Sandvik Rock Tools, Inc., Houston, TX: May 15, 1996.

NAFTA–TAA–01668; Greater Texas Finishing Corp., El Paso, TX: May 20, 1996.

NAFTA–TAA–01608; United Technologies Automotive, Inc., Zanesville, OH: March 25, 1996.

NAFTA–TAA–01681; Medarville Garment Factory, Div. of Universal Overall Co., Medarville, IN: May 8, 1996.

NAFTA–TAA–01700; International Wire Group, Rolling Prairie, IN: June 4, 1996.

NAFTA–TAA–01671; Trinity Industries, Inc., Plant #102—Railcar Div., Greenville, PA: May 20, 1996.

NAFTA–TAA–01739; ABL Engineering, Inc., Mentor, OH: May 9, 1996.

NAFTA–TAA–01776; Littlestown Mfg Co., Strouse-Baer Div., Littlestown, PA: June 16, 1996.

NAFTA–TAA–01701; C and H Apparel, Milan, TN: June 10, 1996.

I hereby certify that the aforementioned determinations were issued during the month of June and July, 1997. Copies of these determinations are available for inspection in Room C–4318, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: July 10, 1997.

Curtis K. Kooser,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 97–18897 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment Standards Administration

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR Part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR Part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon And Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, N.W., Room S–3014, Washington, D.C. 20210.

Modifications to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts'' being modified are listed

by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Massachusetts
MA970016 (Feb. 14, 1997)
Maine
ME970025 (Feb. 14, 1997)
New Hampshire
NH970017 (Feb. 14, 1997)
New Jersey
NJ970009 (Feb. 14, 1997)
Rhode Island
RI970006 (Feb. 14, 1997)

Volume II

Delaware
DE970008 (Feb. 14, 1997)
Maryland
MD970045 (Feb. 14, 1997)
Pennsylvania
PA970024 (Feb. 14, 1997)
PA970050 (Feb. 14, 1997)

Volume III

None

Volume IV

Illinois
IL970001 (Feb. 14, 1997)
Indiana
IN970001 (Feb. 14, 1997)
IN970002 (Feb. 14, 1997)
IN970003 (Feb. 14, 1997)
IN970004 (Feb. 14, 1997)
IN970006 (Feb. 14, 1997)
IN970016 (Feb. 14, 1997)
IN970017 (Feb. 14, 1997)
IN970018 (Feb. 14, 1997)
IN970020 (Feb. 14, 1997)
IN970059 (Feb. 14, 1997)
IN970060 (Feb. 14, 1997)
IN970061 (Feb. 14, 1997)
Wisconsin
WI970049 (Feb. 14, 1997)

Volume V

Texas
TX970018 (Feb. 14, 1997)
TX970100 (Feb. 14, 1997)
TX970114 (Feb. 14, 1997)

Volume VI

Washington
WA970023 (Feb. 14, 1997)
WA970026 (Feb. 14, 1997)

Volume VII

California
CA970001 (Feb. 14, 1997)
CA970033 (Feb. 14, 1997)
CA970037 (Feb. 14, 1997)
CA970049 (Feb. 14, 1997)
CA970050 (Feb. 14, 1997)
CA970051 (Feb. 14, 1997)
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CA970065 (Feb. 14, 1997)
CA970066 (Feb. 14, 1997)
CA970067 (Feb. 14, 1997)
CA970068 (Feb. 14, 1997)
CA970069 (Feb. 14, 1997)
CA970070 (Feb. 14, 1997)
CA970071 (Feb. 14, 1997)
CA970072 (Feb. 14, 1997)
CA970073 (Feb. 14, 1997)
CA970074 (Feb. 14, 1997)
CA970075 (Feb. 14, 1997)
CA970076 (Feb. 14, 1997)
CA970077 (Feb. 14, 1997)
CA970078 (Feb. 14, 1997)
CA970079 (Feb. 14, 1997)
CA970080 (Feb. 14, 1997)
CA970081 (Feb. 14, 1997)
CA970082 (Feb. 14, 1997)
CA970083 (Feb. 14, 1997)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon and Related Acts''. This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

The general wage determinations issued under the Davis-Bacon and related Acts are available electronically by subscription to the FedWorld Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at (703) 487–4630.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the seven separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates are distributed to subscribers.

Signed at Washington, DC, this 11th day of July 1997.

Carl J. Poleskey,

Chief, Branch of Construction Wage Determinations.

[FR Doc. 97–18673 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. ICR–97–41]

Agency Information Collection Activities; Proposed Collection; Comment Request; Safety Testing and Certification (29 CFR 1910.7(e)(1)(i))

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and impact of collection requirements on respondents can be properly assessed. Currently, the Occupational Safety and Health Administration (OSHA) is soliciting comments concerning the proposed extension of the information collection requirements contained in 29 CFR 1910.7. The Agency is particularly interested in comments which:

- evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;
- evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- enhance the quality, utility, and clarity of the information to be collected; and
- minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

DATES: Written comments must be submitted on or before September 16, 1997.

ADDRESSES: Comments are to be submitted to the Docket Office, Docket No. ICR–97–41, Occupational Safety and Health Administration, U.S.

Department of Labor, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone: (202) 219–7894. Written comments limited to 10 pages or less in length may also be transmitted by facsimile to (202) 219–5046.

FOR FURTHER INFORMATION CONTACT: Joseph E. Pipkin, Directorate of Safety Standards Programs, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3605, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone 219–8161, ext. 125. Copies of the referenced information collection request are available for inspection and copying in the Docket Office and will be mailed to persons who request copies by telephoning Theda Kenney at (202) 219–8061, ext. 100, or Barbara Bielaski at (202) 219–8067, ext. 142. For electronic copies of the Information Collection Request for Safety Testing and Certification OSHA's WebPage on the Internet at http://www.osha.gov/ and clock on ''standards.''

SUPPLEMENTARY INFORMATION:

I. Background

The Occupational Safety and Health Act of 1970 (the Act) authorizes the promulgation of such health and safety standards as are necessary or appropriate to provide safe or healthful employment and places of employment. The statute specifically authorizes information collection by employers as necessary or appropriate for the enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents.

A number of OSHA's standards require certain equipment to be ''tested'' (or ''approved'') by a ''nationally recognized testing laboratory'' (NRTL). In order for an organization to meet the definition of a NRTL, it must be ''recognized'' by OSHA and laboratories must apply to OSHA for recognition. Recognition is granted after OSHA determines that the organization meets certain criteria. OSHA can only make this determination after reviewing and evaluating ''information'' provided by the organizations seeking such recognition. The applicant would have to provide OSHA with sufficient information and detail to demonstrate that the applicant meets the definition of a NRTL and that it has the capability to test and examine equipment and materials for fire or electrical safety. More specifically, the applicant must demonstrate that it has the facilities, equipment, trained staff, test procedures and calibration, and quality control programs.

II. Current Actions

This notice requests an extension of the current Office of Management and Budget (OMB) approval of the paperwork collection requirements contained in 29 CFR 1910.7 (currently approved under OMB Control No. 1218–0147).

Type of Review: Extension.

Agency: U.S. Department of Labor, Occupational Safety and Health Administration.

Title: Safety Testing and Certification (29 CFR 1910.7).

OMB Number: 1218–0147.

Agency Number: Docket Number ICR–97–41.

Affected Public: State of local governments; Business or other for-profit.

Number of Respondents: 12.

Frequency: Varies.

Average Time per Response: 65 hours.

Estimated Total Burden Hours: 600.

Total Annualized Capital/Startup Costs: $0.

Signed at Washington, D.C., this 14th day of July 1997.

John F. Martonik,

Acting Director, Directorate of Safety Standards Programs.

[FR Doc. 97–18984 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–26–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. ICR–97–40]

Agench Information Collection Activities; Proposed Collection; Comment Request; Shipyard Certification Records (29 CFR 1915.113(b)(1) and 29 CFR 1915.172(d)—Test Certifications

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and impact of collection requirements on respondents can be properly assessed. Currently, the Occupational Safety and Health Administration (OSHA) is soliciting comments concerning the proposed approval of the paperwork requirements of 29 CFR 1915.113(b)(1) and 1915.172(d), when all shackles and hooks for which no applicable manufacturer's recommendations are available and when portable, unfired pressure vessels are not built to the code requirements of 29 CFR 1915.172(a).

- evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;
- evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- enhance the quality, utility, and clarity of the information to be collected; and
- minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

DATES: Written comments must be submitted on or before September 16, 1997.

ADDRESSES: Comments are to be submitted to the Docket Office, Docket No. ICR–97–40, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone: (202) 219–7894. Written comments limited to 10 pages or less in length may also be transmitted by facsimile to (202) 219–5046.

FOR FURTHER INFORMATION CONTACT: Odet Shaw, Directorate of Safety Standards Programs, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3605, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone: (202) 219–7234, ext. 121. Copies of the referenced information collection request are available for inspection and copying in the Docket Office and will be mailed to persons who request copies by telephoning Theda Kennedy at (202) 219–8061 ext. 100, or Barbara Bielaski at (202) 219–8076, ext. 142. For electronic copies of the Information Collection Request on the certification provisions

in 29 CFR 1915.113(b)(1) (Shackles and Hooks) and 29 CFR 1915.172(d) (Portable Air Receivers and Other Unfired Pressure Vessels, contact OSHA's WebPage on the Internet at http://www.osha.gov/ and click on ''standards.''

SUPPLEMENTARY INFORMATION:

I. Background

The Occupational Safety and Health Act of 1970 (the Act) authorizes the promulgation of such health and safety standards as are necessary or appropriate to provide safe or healthful employment and places of employment. The statute specifically authorizes information collection by employers as necessary or appropriate for the enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents.

The test certification records required in 29 CFR 1915.113(b)(1) and 29 CFR 1915.172(d) are necessary to assure compliance with the requirement for shackles and hooks and portable air receivers and other unfired pressure vessels in shipyards. They are intended to assure that the certification records required for these examinations and tests are maintained.

II. Current Actions

This notice requests an extension of the current Office of Management and Budget (OMB) approval of the test certification requirements contained in 29 CFR 1915.113(b)(1) and 1915.172(d) (currently approved under OMB Control No. 1218–0210).

Type of Review: Extension.

Agency: U.S. Department of Labor, Occupational Safety and Health Administration.

Title: Shipyard Certification Records (29 CFR 1915.113(b)(1) and 29 CFR 1915.172(d)—Test Certifications.

OMB Number: 1218–.

Agency Number: ICR–97–40.

Affected Public: State of local governments; Business or other for-profit.

Number of Respondents: 900.

Ferequency: Quarterly, Yearly.

Average Time per Response: 10 minutes (.17 hr.).

Estimated Total Burden Hours: 1,846.

Total Annualized Capital/Startup Costs: $0.

Signed at Washington, D.C., this 14th day of July 1997.

John F. Martonik,

Acting Director, Directorate of Safety Standards Programs.

[FR Doc. 97–18985 Filed 7–17–97; 8:45 am]

BILLING CODE 4510–26–M

NATIONAL BANKRUPTCY REVIEW COMMISSION

Meeting

AGENCY: National Bankruptcy Review Commission.

ACTION: Notice of public meeting.

TIME AND DATE: Monday, August 11, 1997; 8:30 a.m. to 5:30 p.m. and Tuesday, August 12, 1997; 8:30 a.m. to 5:00 p.m.

PLACE: Federal Judicial Center/ Education Center Auditorium, Thurgood Marshall Federal Judiciary Building, One Columbus Circle, N.E., Washington, D.C. It is recommended that the public use the South Lobby entrance to the meeting site.

STATUS: The meeting will be open to the public.

NOTICE: At its public meeting, the Commission will consider general administrative matters and substantive agenda items including tax issues, data collection and dissemination, transnational insolvencies, consumer debtor education, small business and single asset bankruptcies, and dischargeability issues. Other substantive matters include: Chapter 11, consumer bankruptcy, government, the use of mediators and examiners, and service to the estate and ethics. Two open forum sessions for public participation are tentatively scheduled for August 11, 1997 from 4:30 p.m. to 5:30 p.m. and August 12, 1997 from 3:45 p.m. to 5:00 p.m. The dates and times for the open forum sessions are subject to change.

SUPPLEMENTARY INFORMATION: Any individual or organization who wants to make an oral presentation to the National Bankruptcy Review Commission concerning the Commission's statutory responsibilities may do so at the open forum sessions. Persons who would like to make an oral presentation to the Commission at the open forum sessions should register in advance by contacting the National Bankruptcy Review Commission at (202) 273–1813 no later than 5:00 p.m. EST on August 10, 1997 or register in person at the National Bankruptcy Review Commission registration desk at the meeting site. Open forum registrants are asked to provide their name, organization (if applicable), address and phone number. If the volume of requests to speak at the open forum sessions exceeds the time available to accommodate all such requests, the speakers will be chosen on the basis of order of registration.

Oral presentations will be limited to five minutes per speaker. Persons speaking at the open forum sessions are requested, but not required, to supply twenty (20) copies of their written statements prior to their presentations to the National Bankruptcy Review Commission, Thurgood Marshall Federal Judiciary Building, One Columbus Circle, N.E., Suite 5–130, Washington, DC 20544. Written submissions are not subject to any limitations.

CONTACT PERSONS FOR FURTHER INFORMATION: Contact Susan Jensen-Conklin or Carmelita Pratt at the National Bankruptcy Review Commission, Thurgood Marshall Federal Judiciary Building, One Columbus Circle, N.E., Suite 5–130, Washington, D.C. 20544; Telephone Number: (202) 273–1813.

Susan Jensen-Conklin,

General Counsel.

[FR Doc. 97–18952 Filed 7–17–97; 8:45 am]

BILLING CODE 6820–36–P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act Meeting

TIME AND DATE: 8:15 a.m., Wednesday, July 23, 1997.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314-3428.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Requests from Federal Credit Unions to Convert to a Community Charter.

2. Requests from Federal Credit Unions to Expand their Community Field of Membership.

3. Appeal from a Federal Credit Union of the Regional Director's Approval of a Federal Credit Union's Name Change.

4. Proposed National Small Credit Union Development Program (NSCUDP).

5. Midsession Budget Review.

6. Proposed Amendments to Interpretive Ruling and Policy Statement (IRPS) 94–1, Chartering Manual.

7. Proposed Rule: Amendments to Section 701.21(h), Member Business Loans.

8. Final Rule: Amendment to Section 701.21(c)(7)(ii)(C), Interest Rate Ceiling.

9. Request for Approval of an Investment Pilot Program.

FOR FURTHER INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone 703–518–6304.

Becky Baker,

Secretary of the Board.

[FR Doc. 97–19042 Filed 7–15–97; 4:31 pm]

BILLING CODE 7535–01–M

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act Meeting

TIME AND DATE: 10:30 a.m., Tuesday, July 22, 1997.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Administrative Actions under Section 205 of the Federal Credit Union Act and Section 708b of NCUA's Rules and Regulations. Closed pursuant to exemption (8).
2. Administrative Action under Sections 125 and 206 of the Federal Credit Union Act and Section 708b of NCUA's Rules and Regulations. Closed pursuant to exemption (8).
3. Proposed National Small Credit Union Development Program (NSCUDP). Closed pursuant to exemptions (2), (6) and (8).
4. Personal Actions. Closed pursuant to exemptions (2) and (6).

FOR FURTHER INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone 703–518–6304.

Becky Baker,

Secretary of the Board.

[FR Doc. 97–19043 Filed 7–15–97; 4:31 pm]

BILLING CODE 7535–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 30–30691-CivP; ASLBP No. 97–730–02-CivP]

Barnett Industrial X-Ray, Inc.; Establishment of Atomic Safety and Licensing Board

Pursuant to delegation by the Commission dated December 29, 1972, published in the **Federal Register**, 37 FR 28710 (1972), and Sections 2.105, 2.700, 2.702, 2.714, 2.714a, 2.717, 2.721, and 2.772(j) of the Commission's Regulations, all as amended, an Atomic Safety and Licensing Board is being established to preside over the following proceeding.

Barnett Industrial X-Ray, Inc.; Order Imposing Civil Monetary Penalty

This Board is being established pursuant to the request of Barnett Industrial X-Ray, Inc. for an enforcement hearing. The hearing request was made in response to an Order issued by the Director, Office of Enforcement, dated May 23, 1997, entitled ''Order Imposing Civil Monetary Penalty'' (62 FR 30346, June 3, 1997).

The Board is comprised of the following administrative judges:

B. Paul Cotter, Jr., Chairman, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555

Dr. Richard F. Cole, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555

Dr. Thomas S. Elleman, 704 Davidson Street, Raleigh, NC 27609

All correspondence, documents and other materials shall be filed with the Judges in accordance with 10 CFR § 2.701. /s/ B. Paul Cotter, Jr.

Issued at Rockville, Maryland, this 14th day of July 1997.

B. Paul Cotter, Jr.,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. 97–18968 Filed 7–17–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Nuclear Byproduct Material Risk Review Group

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Establishment of working group and notice of meeting.

SUMMARY: The Nuclear Byproduct Material Risk Review Group, consisting of representatives from the U.S. Nuclear Regulatory Commission and an Agreement State, has been formed in response to Commission direction in a Staff Requirements Memorandum (SRM) dated April 15, 1997. The SRM instructed the staff to reexamine the applicability of risk-informed, performance-based or risk-informed, less prescriptive approaches to regulation of nuclear material. The working group will meet at NRC Headquarters in Rockville, Maryland from July 21 through July 24, 1997, in order to refine plans for a multi-dimensional characterization of the risk associated with nuclear byproduct material and to develop a statement of work for contractor evaluation of that risk.

DATES AND TIMES: The working group will meet in closed session on July 21 and 22, 1997, from 7:30 a.m. to 4:00 p.m., to develop the statement of work. The working group will meet in open session on July 23, 1997, from 7:30 a.m. to 4:00 p.m. and on July 24, 1997, from 7:30 a.m. to 12:00 noon, to refine plans for a multi-dimensional characterization of the risk associated with nuclear byproduct material.

ADDRESSES: U.S. Nuclear Regulatory Commission, Two White Flint North, 11545 Rockville Pike, Room T10A17, Rockville, MD, 20852–2738, on Monday, July 21, Tuesday, July 22, and Thursday, July 24, 1997. U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Room O1F5, Rockville, MD, 20852–2738, on Wednesday, July 23, 1997.

FOR FURTHER INFORMATION CONTACT: Dennis I. Serig, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, MS T8F5, Washington, DC 20555, telephone (301) 415–7901, e-mail dis@nrc.gov.

SUPPLEMENTARY INFORMATION: As part of the Commission's Strategic Assessment and Rebaselining efforts, an April 15, 1997, SRM related to NRC's Direction Setting Issue 12, Risk-Informed, Performance-Based Regulation, included, in part, Commission direction that the staff reexamine the applicability of risk-informed, performance-based or risk-informed, less prescriptive approaches to regulation of nuclear material. In response to that direction, the Nuclear Byproduct Material Risk Review Group will identify and document a technical basis for a risk-informed approach to the regulation of nuclear byproduct material, and will develop plans for a graded approach to nuclear byproduct material regulation based on risk information. The working group's activities encompass areas addressed in Title 10 of the Code of Federal Regulations Parts 30–36 and 39. The group's approach will involve systematic evaluations of the ''nuclear byproduct material systems.'' Nuclear byproduct material systems will be defined as broadly as is necessary to identify the real-world risks associated with them (encompassing part 39, Licenses and radiation safety requirements for well logging.

The group's approach will involve systematic evaluations of the ''nuclear byproduct material systems''. Nuclear byproduct material systems will be defined as broadly as is necessary to identify the real-world risks associated with them (ranging from normal use of

the material, to public perceptions during and after an event). The approach will include consideration of the activities of Agreement States' regulatory programs where appropriate, and the group will consider the effects of its recommendations on Agreement States.

Committee Organization and Operations

Dennis Serig, NRC, Office of Nuclear Material Safety and Safeguards, has been selected as chairman. Other members are Elizabeth Ullrich, NRC, Region I; John Lubinski, NRC, Office of Nuclear Material Safety and Safeguards; John Randall, NRC, Office of Nuclear Regulatory Research; and Nancy Daugherty, State of Colorado.

Committee Meetings

The working group will meet at approximately monthly intervals in the Washington, DC, area, or at other locations agreed upon by the working group members. Meetings will be announced in advance through the NRC Public Meeting Notice System and, with some exceptions, will be open for public observation. Persons attending working group meetings will be welcome to provide comments to the working group for its consideration, either in written form or orally, at times specified by the working group chair.

Dated at Rockville, Maryland this 14th day of July, 1997.

For the Nuclear Regulatory Commission.

Frederick C. Combs,

Deputy Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 97–18994 Filed 7–17–97; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–244]

Rochester Gas and Electric Corporation; R.E. Ginna Nuclear Power Plant; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from certain requirements of its regulations for Facility Operating License No. DRP–18 issued to Rochester Gas and Electric Corporation (the licensee), for operation of the R.E. Ginna Nuclear Power Plant located in Wayne County, New York.

Environmental Assessment

Identification of Proposed Action

The proposed action would exempt Rochester Gas and Electric Corporation from the requirements of 10 CFR 70.24, which requires a monitoring system that will energize clear audible alarms if accidental criticality occurs in each area in which special nuclear material is handled, used, or stored. The proposed action would also exempt the licensee from the requirements to maintain emergency procedures for each area in which this licensed special nuclear material is handled, used, or stored to ensure that all personnel withdraw to an area of safety upon the sounding of the alarm, to familiarize personnel with the evacuation plan, and to designate responsible individuals for determining the cause of the alarm, and to place radiation survey instruments in accessible locations for use in such an emergency.

The proposed action is in accordance with the licensee's application for exemption dated June 5, 1997.

The Need for the Proposed Action

The purpose of 10 CFR 70.24 is to ensure that if a criticality were to occur during the handling of special nuclear material, personnel would be alerted to that fact and would take appropriate action. At a commercial nuclear power plant the inadvertent criticality with which 10 CFR 70.24 is concerned could occur during fuel handling operations. The special nuclear material that could be assembled into a critical mass at a commercial nuclear power plant is in the form of nuclear fuel; the quantity of other forms of special nuclear material that is stored on site is small enough to preclude achieving a critical mass. Because the fuel is not enriched beyond 5.0 weight percent Uranium-235 and because commercial nuclear plant licensees have procedures and design features that prevent inadvertent criticality, the staff has determined that an inadvertent criticality would not likely occur due to the handling of special nuclear material at a commercial power reactor. The requirements of 10 CFR 70.24, therefore, are not necessary to ensure the safety of personnel during the handling of special nuclear materials at commercial power reactors.

Environmental Impacts of the Proposed Action

The Commission has completed its evaluation of the proposed action and concludes that there is no significant environmental impact if the exemption is granted. Inadvertent or accidental criticality will be precluded through compliance with the R.E. Ginna Nuclear Plant Technical Specifications, the design of the fuel storage racks providing geometric spacing of fuel assemblies in their storage locations, and administrative controls imposed on fuel handling procedures. Technical Specifications requirements specify reactivity limits for the fuel storage racks and minimum spacing between the fuel assemblies in the storage racks.

Appendix A of 10 CFR Part 50, ''General Design Criteria for Nuclear Power Plants,'' Criterion 62, requires the criticality in the fuel storage and handling system shall be prevented by physical systems or processes, preferably by use of geometrically-safe configurations. This is met at Ginna, as identified in the Technical Specifications and the Updated Final Safety Analysis Report (UFSAR). Ginna Technical Specifications Section 4.3, Fuel Storage, states that the spent fuel storage racks are designed with $K_{eff} \leq 0.95$ if fully flooded with unborated water: and new fuel racks are designed with $K_{eff} \leq 0.95$ if fully flooded with unborated water; and $K_{eff} \leq 0.98$ if moderated by aqueous foam. UFSAR Section 9.1.1, New Fuel Storage, states that the spacing of new fuel assemblies ensures a Keff less than 0.95 for the accidental full water density flooding scenario and less than 0.98 for the accidental low water density (optimum moderation) flooding scenario.

The proposed exemption would not result in any significant radiological impacts. The proposed exemption would not affect radiological plant effluent nor cause any significant occupational exposures since the Technical Specifications, design controls (including geometric spacing of fuel assembly storage spaces) and administrative controls preclude inadvertent criticality. The amount of radioactive waste would not be changed by the proposed exemption.

The proposed exemption does not result in any significant nonradiological environmental impacts. The proposed exemption involves features located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect nonradiological plant effluents and has no other environmental impact. Accordingly, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the Commission has concluded that there is no measurable environmental impact associated with the proposed action, any alternatives with equal or greater environmental

impact need not be evaluated. As an alternative to the proposed exemption, the staff considered denial of the requested exemption. Denial of the request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the ''Final Environmental Statement For the R.E. Ginna Nuclear Power Plant dated December 1973.

Agencies and Persons Consulted

In accordance with its stated policy, on June 10, 1997, the staff consulted with Mr. Jack Spath of the New York State Energy Research and Development Authority, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

Based upon the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment, Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated June 5, 1997, which is available for public inspection at the Commission's Public Document Room, which is located at The Gelman Building, 2120 L Street, NW., Washington, D.C., and at the local public document room located at the Rochester Public Library, 115 South Avenue, Rochester, New York.

Dated at Rockville, Maryland, this ninth day of July 1997.

For the Nuclear Regulatory Commission.

Guy S. Vissing,

Senior Project Manager, Project Directorate I–1, Division of Reactor Projects I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 97–18993 Filed 7–17–97; 8:45 am]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–26740]

Filings Under the Public Utility Holding Company Act of 1935, as amended (''Act'')

July 11, 1997.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by August 4, 1997, to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

AEP Generating Company (70–8237)

AEP Generating Company (''Generating''), 1 Riverside Plaza, Columbus, Ohio 43215, an electric public-utility subsidiary company of American Electric Power Company, Inc. (''AEP''), a registered holding company, has filed a post-effective amendment under section 12(c) of the Act and rules 46 and 54 under the Act to its declaration filed under section 12(c) of the Act and rule 46 under the Act.

By orders dated December 10, 1993 and August 24, 1994 (HCAR Nos. 25943 and 26112, respectively), Generating was authorized to declare and pay to AEP, through December 31, 1997:

(1) dividends up to the full amount of its retained earnings; and

(2) additional dividends (''Additional Dividends'') up to $16 million out of other paid-in capital. The authorization required Generating to maintain 30% common equity to total capitalization. To date, Generating has paid $13.5 million in such dividends. As of March 31, 1997, Generating had paid-in capital of $42,235,000.

Generating now proposes to pay dividends out of paid-in capital to AEP from time to time through December 31, 2002, to the full extent permitted by applicable corporate law.[1] Generating also requests removal of the requirement that, in the payment of any dividend out of capital, it maintain a percentage of common equity to total capitalization at or above 30%.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–18921 Filed 7–17–97; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–22746; No. 812–10644]

The Lazard Retirement Series, Inc., et al.

July 11, 1997.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of Application for an Exemption pursuant to the Investment Company Act of 1940 (the ''1940 Act'').

APPLICANTS: Lazard Retirement Series, Inc. (the ''Company'') and Lazard Asset Management (''LAM'').

RELEVANT 1940 ACT SECTIONS: Order requested pursuant to Section 6(c) granting exemptions from the provisions of Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act and Rules 6e–2(b)(15) and 6e–3(T)(b)(15) thereunder.

SUMMARY OF APPLICATION: Applicants seek exemptive relief to permit shares of the Company and any other investment company that is designed to fund variable insurance products and for which LAM, or any of its affiliates, may serve as investment adviser, administrator, manager, principal underwriter or sponsor (collectively, the ''Funds'') to be sold to and held by separate accounts funding variable annuity and variable life insurance contracts issued by affiliated or unaffiliated life insurance companies (''Participating Insurance Companies'') or qualified pension and retirement plans (''Plans'') outside of the separate account context.

FILING DATE: The application was filed on May 7, 1997.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request

[1] Pursuant to Section 1701.33 of the Ohio Revised Code, the relevant state law applicable to Generating, the directors may declare dividends out of surplus. Surplus is defined to be the excess of a corporation's assets over its liabilities plus stated capital.

a hearing by writing to the Secretary of the Commission and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on August 5, 1997, and must be accompanied by proof of service on Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the requester's interest, the reason for the request and the issues contested. Persons may request notification of a hearing by writing to the Secretary of the Commission.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants, c/o Lazard Frères Asset Management, 30 Rockefeller Plaza, New York, New York 10020.

FOR FURTHER INFORMATION CONTACT: Laura A. Novack, Senior Attorney, or Kevin M. Kirchoff, Branch Chief, Office of Insurance Products (Division of Investment Management) at (202) 942–0670.

SUPPLEMENTARY INFORMATION: The following is a summary of the application; the complete application is available for a fee from the Public Reference Branch of the Commission.

Applicants' Representations

1. The Company is a Maryland corporation registered pursuant to the 1940 Act as an open-end management investment company. The Company, which was organized in February 1997, consists of nine separate series which operate as distinct investment vehicles, all of which desire to sell their shares to fund variable insurance products.

2. LAM, a division of Lazard Frères & Co. LLC, is registered under the Investment Advisers Act of 1940, and serves as the Company's investment manager.

3. Applicants desire that the Funds have the flexibility to offer their shares to insurance company separate accounts that fund variable annuity and variable life insurance contracts (including single premium, scheduled premium, modified single premium and flexible premium) (collectively, ''Variable Contracts''), which separate accounts are established by affiliated or unaffiliated insurance companies. These separate accounts may be registered as investment companies under the 1940 Act or may be exempt from registration under the 1940 Act pursuant to Section 3(c)(1) thereunder.

4. The participating Insurance Companies will establish their own separate accounts and design their own Variable Contracts. Each Participating Insurance Company will have the legal obligation of satisfying all requirements applicable to such insurance company under the federal securities laws. The role of the Funds, so far as the federal securities laws are applicable, will be limited to that of offering their shares to separate accounts of Participating Insurance Companies and to Plans, and fulfilling any conditions the Commission may impose upon granting the requested relief. Each Participating Insurance Company will enter into a fund participation agreement with the Fund in which the Participating Insurance Company invests.

5. Applicants state that Fund shares also may be offered directly to Plans outside the separate account context. The Plans may choose one or more of the Funds as the sole investment under the Plan or as one of several investments. Plan participants may or may not be given the right to select among Funds, depending on the Plans. ''Plan Participants'' include not only those participants of qualified pension or retirement plans as set forth in Treasury Regulation § 1.817–5(f)(3)(iii) and Revenue Ruling 94–62, but also include any other trust, account, contract or annuity that is determined to be within the scope of Treasury Regulation § 1.817–5(f)(3)(iii). Fund shares sold to Plans will be held, where applicable, by the trustees of such Plans as required by Section 403(a) of the Employee Retirement Income Security Act (''ERISA'').

Applicants' Legal Analysis

1. In connection with the funding of scheduled premium variable life insurance contracts issued through a separate account registered under the 1940 Act as a unit investment trust, Rule 6e–2(b)(15) provides partial exemptions from Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act. The exemptions granted by Rule 6e–2(b) are available only where the management investment company underlying the separate account offers its shares ''*exclusively* to variable life insurance separate accounts of the life insurer or any affiliated life insurance company.''

2. The use of a common management investment company as the underlying investment medium for both variable annuity and variable life insurance separate accounts of a single insurance company (or of two or more affiliated insurance companies) is referred to as ''mixed funding.'' The use of a common management investment company as the underlying investment medium for variable annuity and/or variable life insurance separate accounts of unaffiliated insurance companies is referred to as ''shared funding.'' ''Mixed and shared funding'' denotes the use of a common management investment company to fund the variable annuity and variable life insurance separate accounts of affiliated and unaffiliated insurance companies. The relief granted by Rule 6e–2(b)(15) is not available with respect to a scheduled premium variable life insurance separate account that owns shares of an underlying fund that also offers its shares to a variable annuity separate account of the same company or of any other affiliated or unaffiliated life insurance company. Therefore, Rule 6e–2(b)(15) precludes mixed and shared funding.

3. In connection with the funding of flexible premium variable life insurance contracts issued through a separate account registered under the 1940 Act as a unit investment trust, Rule 6e–3(T)(b)(15) provides partial exemptions from Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act. The exemptions granted to a separate account by Rule 6e–3(T)(b)(15) are available only where all of the assets of the separate account consist of the shares of one or more registered management investment companies which offer their shares ''*exclusively*'' to separate accounts of the life insurer, or any affiliated life insurance company, offering either scheduled premium variable life insurance contracts or flexible premium variable life insurance contracts, or both, or which also offer their shares to variable annuity separate accounts of the life insurer or of an affiliated life insurance company. Thus, Rule 6e–3(T) permits mixed funding with respect to a flexible premium variable life insurance separate account, but precludes shared funding.

4. Applicants assert that the use of the Funds as common investment media for the Variable Contracts would allow Participating Insurance Companies to benefit not only from the investment and administrative expertise of LAM, but also from the cost efficiencies and investment flexibility afforded by a large pool of funds. Applicants submit that mixed and shared funding would benefit Variable Contract owners by: (a) eliminating a significant portion of the costs of establishing and administering separate funds; (b) permitting a greater number of assets to be available for investment by the Funds, thereby promoting economies of scale, permitting greater diversification, and making the addition of new portfolios more feasible; and (c) encouraging more insurance companies to offer Variable Contracts, resulting in increased competition with respect to both the design and pricing of Variable

Contracts, which can be expected to result in greater product variation and lower charges.

5. Applicants assert that the relief granted by sub-paragraph (b)(15) of Rules 6e–2 and 6e–3(T) should not be affected by the proposed sale of Fund shares to Plans. Applicants note, however, that because the relief under sub-paragraph (b)(15) of Rules 6e–2 and 6e–3(T) is available only where shares are offered exclusively to separate accounts of life insurance companies, additional exemptive relief is necessary if shares of the Funds also are to be sold to Plans.

6. Applicants state that current tax law permits the Funds to increase their asset base through the sale of Fund shares to the Plans. Applicants state that Section 817(h) of the Internal Revenue Code of 1986, as amended (the ''Code''), imposes certain diversification requirements on the underlying assets of variable annuity contracts and variable life contracts held by the portfolios of the Funds. The Code provides that such contracts shall not be treated as an annuity contract or life insurance contract for any period (and any subsequent period) during which the investments are not adequately diversified in accordance with regulations prescribed by the Treasury Department. The regulations provide that, to meet the diversification requirements, all of the beneficial interests in the investment company must be held by the segregated asset accounts of one or more insurance companies. Treas. Reg. § 1.817–5 (1989). The regulations do, however, contain certain exceptions to this requirement, one of which allows shares in an investment company to be held by the trustee of a qualified pension or retirement plan without adversely affecting the ability of shares in the same investment company also to be held by the separate accounts of insurance companies in connection with their variable annuity and variable life contracts. Treas. Reg. § 1.817–5(f)(3)(iii).

7. Applicants state that the promulgation of Rules 6e–2 and 6e–3(T) under the 1940 Act preceded the issuance of these Treasury Regulations, and that the sale of shares of the same investment company to both separate accounts and Plans could not have been envisioned at the time of the adoption of Rules 6e–2(b)(15) and 6e–3(T)(b)(15).

8. Applicants therefore request an Order of the Commission exempting variable life insurance variable annuity separate accounts of Participating Insurance Companies (and, to the extent necessary, any investment adviser, principal underwriter and depositor of such an account) and Applicants from Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act, and sub-paragraph (b)(15) of Rules 6e–2 and 63–3(T) thereunder, when shares of the Funds are offered and sold to, and held by, such separate accounts in the mixed and shared funding context, regardless of whether shares of the Funds also are offered and sold directly to Plans.

9. Section 9(a) of the 1940 Act provides that it is unlawful for any company to serve as an investment adviser to, or principal underwriter for, any registered open-end investment company if an affiliated person of that company is subject to a disqualification enumerated in Section 9(a) (1) or (2).

10. Rules 6e–2(b)(15) and 6e–3(T)(b)(15) provide partial exemptions from Section 9(a) under certain circumstances, subject to the limitations on mixed and shared funding. The relief provided by sub-paragraph (b)(15)(i) of Rules 6e–2 and 6e–3(T) permits a person disqualified under Section 9(a) to serve as an officer, director, or employee of an insurance company or any of its affiliates, so long as that person does not participate directly in the management or administration of the underlying investment company. The relief provided by sub-paragraph (b)(15)(ii) of Rules 6e–2 and 6e–3(T) permits the life insurer to serve as the underlying fund's investment adviser or principal underwriter, provided that none of the insurer's personnel who are ineligible pursuant to Section 9(a) participate in the management or administration of the fund.

11. Applicants state that the partial relief from Section 9(a) found in sub-paragraph (b)(15) of Rules 6e–2 and 6e–3(T), in effect, limits the amount of monitoring necessary to ensure compliance with Section 9 to that which is appropriate in light of the policy and purposes of that section. Applicants state that those rules recognize that it is not necessary for the protection of investors or the purposes fairly intended by the policy and provisions of the 1940 Act to apply the provisions of Section 9(a) to the many individuals in an insurance company complex, who will have no involvement in matters pertaining to the investment company funding the separate accounts. Applicants note that the Participating Insurance Companies are not expected to play any role in the management or administration of the Funds. Therefore, Applicants assert, applying the restrictions of Section 9(a) serves no regulatory purpose. Applicants state that the relief requested should not be affected by the proposed sale of Fund shares to the Plans, because the insulation of the Funds from those individuals who are disqualified under the 1940 Act remains in place. Moreover, since the Plans are not investment companies and will not be deemed to be affiliated solely by virtue of their shareholdings, no additional relief is necessary.

12. Sections 13(a), 15(a) and 15(b) of the 1940 Act require ''pass-through'' voting with respect to underlying investment company shares held by a separate account. Subparagraph (b)(15)(iii) of Rules 6e–2 and 6e–3(T) under the 1940 Act provides partial exemptions from the pass-through voting requirements in limited situations.

13. For example, sub-paragraph (b)(15)(iii)(B) of Rule 6e–2 and sub-paragraph (b)(iii)(B) of Rule 6e–3(T) provide that the insurance company may disregard the voting instructions of its contract owners if the contract owners initiate any change in the investment company's investment policies, principal underwriter, or investment adviser. Under the Rules, voting instructions with respect to a change in investment management may be disregarded only if the insurance company makes a good faith determination that such changes would: (a) Violate state law; (b) result in investment that were not consistent with the investment objectives of the separate account; or (c) result in investments that would vary from the general quality and nature of investments and investment techniques used by other separate accounts of the company or of an affiliated life insurance company with similar investment objectives.

14. Applicants state that Rule 6e–2 recognizes that variable life insurance contracts have important elements unique to insurance contracts and are subject to extensive state regulation of insurance. Applicants maintain, therefore, that in adopting Rule 6e–2, the Commission expressly recognized that exemptions from pass-through voting requirements were necessary to assure the solvency of the life insurer and the performance of its contractual obligations by enabling an insurance regulatory authority or the life insurer to act when certain proposals reasonably could be expected to increase the risks undertaken by the life insurer. Flexible premium variable life insurance contracts and variable annuity contracts are subject to substantially the same state insurance regulatory authority, and therefore, corresponding provisions of Rule 6e–3(T) presumably were adopted in recognition of the same

considerations as the Commission applied in adopting Rule 6e–2. Applicants submit that these considerations are no less important or necessary when an insurance company funds its separate accounts in connection with mixed and shared funding, and that such funding does not compromise the goals of the insurance regulatory authorities or of the Commission.

15. Applicants further state that the sale of Fund shares to Plans does not affect the relief requested in this regard. As previously noted, Fund shares sold to Plans will be held by the trustees of such Plans as required by Section 403(a) of ERISA. Section 403(a) also provides that the trustees must have exclusive authority and discretion to manage and control the assets of the Plans with two exceptions: (a) When the Plan expressly provides that the trustees are subject to the direction of a named fiduciary who is not a trustee, in which case the trustees are subject to proper directions made in accordance with the terms of the Plan and not contrary to ERISA; and (b) when the authority to manage, acquire or dispose of assets of the Plan is delegated to one or more investment managers pursuant to Section 402(c)(3) of ERISA.

16. Unless one of the two exceptions stated in Section 403(a) applies, Plan trustees have the exclusive authority and responsibility for voting proxies. Where a named fiduciary appoints an investment manager, the investment manager has the responsibility to vote the share held unless the right to vote such shares is reserved to the trustees or to the named fiduciary. In any event, there is no pass-through voting to the participants in such Plans. Accordingly, Applicants not that, unlike the case with insurance company separate accounts, the issue of the resolution of material irreconcilable conflicts with respect to voting is not present where the Plans do not provide participants with the right to give voting instructions.

17. Applicants submit that there is no contractual or other relationship between the Participant Insurance Companies and any Plans which would affect the solvency of the life insurer, would affect the performance of the life insurer's contractual obligations, or would be expected to increase the risks undertaken by the life insurer. Accordingly, Applicants submit that where Plans provide participants with the right to give voting instructions, the purchase of shares by Plans does not present any complications not otherwise occasioned by mixed or shared funding.

18. Applicants state that no increased conflicts of interest would be presented by the granting of the requested relief. Applicants assert that share funding does not present any issues that do not already exist where a single insurance company is licensed to do business in several states. Applicants note that where different Participating Insurance Companies are domiciled in different states, it is possible that the state insurance regulatory body in a state in which one Participating Insurance Company is domiciled could require action that is inconsistent with the requirements of other insurance regulators in one or more other states in which other Participating Insurance Companies are domiciled. Applicants submit that this possibility is no different or greater than exists where a single insurer an its affiliates offer their insurance products in several states.

19. Applicants further submit that affiliation does not reduce the potential for differences in state regulatory requirements. In any event, the conditions (adapted from the conditions included in Rule 6e–3(T)(b)(15)) discusses below are designed to safeguard against any adverse effects that these differences may produce. If a particular state insurance regulator's decision conflicts with the majority of other state regulators, the affected insurer may be required to withdraw its separate account's investment in the relevant Funds.

20. Applicants also argue that affiliation does not eliminate the potential, if any exists, for divergent judgments as to when a Participating Insurance Company could disregard Variable Contract owner voting instructions. Potential disagreement is limited by the requirements that the Participating Insurance Company's disregard of voting instructions be both reasonable and based on specified good faith determinations. However, if a Participating Insurance Company's decision to disregard Variable Contract owner instructions represents a minority position or would preclude a majority vote approving a particular change, such Participating Insurance Company may be required, at the election of the relevant Fund, to withdraw its separate account's investment in that Fund. No charge or penalty will be imposed as a result of such a withdrawal.

21. Applicants submit that there is no reason why the investment policies of a Fund with mixed funding would, or should, be materially different from what those policies would, or should, be if such Fund or series thereof funded only variable annuity or variable life insurance contracts. Moreover, Applicants represent that the Funds will not be managed to favor or disfavor any particular insurer or type of insurance product.

22. Applicants note that Section 817(h) of the Code imposes certain diversification requirements on the underlying assets of variable annuity and variable life insurance contracts held in the portfolios of management investment companies. Treasury Regulation § 1.817–5(f)(3)(iii), which established diversification requirements for such portfolios, specifically permits, among other things, ''qualified pension or retirement plans'' and separate accounts to share the same underlying management investment company. Therefore, Applicants have concluded that neither the code, the Treasury Regulations, nor the Revenue Rulings thereunder present any inherent conflicts of interest if the Plans, variable annuity separate accounts and variable life insurance separate accounts all invest in the same management investment company.

23. Applicants note that while there are differences in the manner in which distributions are taxed for variable annuity contracts, variable life insurance contracts and Plans, these tax consequences do not raise any conflicts of interest. When distributions are to be made, and the separate account or the Plan is unable to net purchase payments to make the distributions, the separate account or the Plan will redeem shares of the Funds at their respective net asset value. The Plan will then make distributions in accordance with the terms of the Plan. The life insurance company will make distributions in accordance with the terms of the Variable Contract.

24. Applicants state that they do not see any greater potential for material irreconcilable conflicts arising between the interests of participants under the Plans and owners of the Variable Contracts issued by the separate accounts of Participating Insurance Companies from possible future changes in the federal tax laws than that which already exists between variable annuity contract owners and variable life insurance contract owners.

25. Applicants argue that the ability of the Funds to sell their respective shares directly to Plans does not create a ''senior security,'' as such term is defined under Section 18(g) of the 1940 Act, with respect to any Variable Contract owner as opposed to a participant under a Plan. Regardless of the rights and benefits of participants and Variable Contract owners under their respective Plans and Variable

Contracts, the Plans and the separate accounts have rights only with respect to their shares of the Funds. Such shares may be redeemed only at net asset value. No shareholder of any of the Funds has any preference over any other shareholder with respect to distributions of assets or payment of dividends.

26. Applicants state that there are no conflict of interest between Variable Contract owners and Plan Participants with respect to the state insurance commissioners' veto powers over investment objectives. The state insurance commissioners have been given the veto power to prevent, among other things, insurance companies from indiscriminately redeeming their separate accounts out of one Fund and investing in another. To accomplish such redemptions and transfers, complex and time consuming transactions must be undertaken. conversely, trustees of Plans or the participants in participant-directed Plans can make the decision quickly and implement redemption of shares from a Fund and reinvest the monies in another funding vehicle without the same regulatory impediments or, as is the case with most Plans, even hold cash pending a suitable investment. Based on the foregoing, Applicants represent that even should the interests of Variable Contract owners and the interests of Plans and Plan participants conflict, the conflicts can be resolved almost immediately in that trustees of the Plans can, independently, redeem shares out of the Funds.

27. Applicants state that, regardless of the types of Fund shareholders, a Fund's adviser is legally obligated to manage the Funds in accordance with each Fund's investment objectives, policies and restrictions as well as any guidelines established by the Fund's Board. Applicants assert that LAM does so, and, thus, would manage the Funds in the same manner as any other mutual fund.

Applicants' Conditions

Applicants have consented to the following conditions:

1. A majority of each Fund's Board shall consist of persons who are not ''interested persons'' thereof, as defined by Section 2(a)(19) of the 1940 Act and the Rules thereunder and as modified by any applicable orders of the Commission, except that if this condition is not met by reason of death, disqualification, or bona fide resignation of any Board member, then the operation of this condition shall be suspended: (a) For a period of 45 days, if the vacancy or vacancies may be filled by the Board; (b) for a period of 60 days, if a vote of shareholders is required to fill the vacancy or vacancies; or (c) for such longer period as the Commission may prescribe by order upon application.

2. Each Fund's Board will monitor the Fund for the existence of any material irreconcilable conflict between and among the interests of Variable Contract owners of all separate accounts and of Plan participants and Plans investing in the Fund, and determine what action, if any, should be taken in response to such conflicts. A material irreconcilable conflict may arise for a variety of reasons, including: (a) An action by any state insurance regulatory authority; (b) a change in applicable federal or state insurance, tax, or securities laws or regulations, or a public ruling, private letter ruling, no-action or interpretive letter, or any similar action by insurance, tax, or securities regulatory authorities; (c) an administrative or judicial decision in any relevant proceeding; (d) the manner in which the investments of the Funds are being managed; (e) a difference in voting instructions given by owners of variable annuity and variable life insurance contracts; (f) a decision by a Participating Insurance Company to disregard the voting instructions of Variable Contract owners; or (g) if applicable, a decision by a Plan to disregard the voting instructions of Plan participants.

3. LAM (or any other investment adviser of a Fund), any Participating Insurance Company and any Eligible Plan that executes a fund participation agreement upon becoming an owner of 10% or more of the assets of a Fund (collectively, ''Participants'') will report any potential or existing conflicts to the relevant Board. Participants will be obligated to assist the relevant Board in carrying out its responsibilities under these conditions by providing the Board will all information reasonably necessary for the Board to consider any issues raised. This responsibility includes, but it not limited to, an obligation by each Participating Insurance Company to inform the Board whenever Variable Contract owner voting instructions are disregarded and, if pass-through voting is applicable, an obligation by each Plan to inform the Board whenever Plan participant voting instructions are disregarded. The responsibility to report such information and conflicts and to assist the Boards will be contractual obligations of all Participating insurance Companies and Plans investing in the Funds under their agreements governing participation in the Funds, and such agreements shall provide that these responsibilities will be carried out with a view only to the interests of Variable Contract owners and, if applicable, Plan participants.

4. If a majority of a Fund's Board members, or a majority of its disinterested Board members, determine that a material irreconcilable conflict exists, the relevant Participating Insurance Companies and Plans, at their expense and to the extent reasonably practical (as determined by a majority of the disinterested Board members), shall take whatever steps are necessary to remedy or eliminate the material irreconcilable conflict. Such steps could include: (a) Withdrawing the assets allocable to some or all of the separate accounts from the Fund or any of its series and reinvesting such assets in a different investment medium, which may include another series of the Fund or another Fund; (b) in the case of a Participating Insurance Company, submitting the question as to whether such segregation should be implemented to a vote of all affected Variable Contract owners and, as appropriate, segregating the assets of any appropriate group (i.e., variable annuity or variable life insurance contract owners of one or more Participating Insurance Companies) that votes in favor of such segregation, or offering to the affected Variable Contract owners the option of making such a change; and (c) establishing a new registered management investment company or managed separate account. If a material irreconcilable conflict arises because of a Participating Insurance Company's decision to disregard contract owner voting instructions and that decision represents a minority position or would preclude a majority vote, the Participating Insurance Company may be required, at the election of the Fund, to withdraw its separate account's investment in such Fund, and no charge or penalty will be imposed as a result of such withdrawal. If a material irreconcilable conflict arises because of a Plan's decision to disregard Plan participant voting instructions, if applicable, and that decision represents a minority position or would preclude a majority vote, the Plan may be required, at the election of the Fund, to withdraw its investment in such Fund, and no charge or penalty will be imposed as a result of such withdrawal.

The responsibility to take remedial action in the event of a Board determination of a material irreconcilable conflict and to bear the cost of such remedial action will be a contractual obligation of all

Participating Insurance Companies and Plans under their agreements governing participating in the Funds. These responsibilities shall be carried out with a view only to the interests of Contract owners and, as applicable, Plan participants.

5. For purposes of Condition 4, a majority of the disinterested members of the applicable Board shall determine whether any proposed action adequately remedies any material irreconcilable conflict. In no event will a Fund or LAM (or any other investment adviser of the Funds) be required to establish a new funding medium for any Variable Contract. No Participating Insurance Company shall be required by Condition 4 to establish a new funding medium for any Variable Contract if a majority of Variable Contract owners materially and adversely affected by the material irreconcilable conflict, vote to decline such offer. No Plan shall be required by Condition 4 to establish a new funding medium for such plan if: (a) A majority of Plan participants materially and adversely affected by the material irreconcilable conflict vote to decline such offer; or (b) pursuant to governing plan documents an applicable law, the Plan makes such decision without a vote by Plan Participants.

6. Participants will be informed promptly in writing of a Board's determination of the existence of a material irreconcilable conflict and its implications.

7. Participating Insurance Companies will provide pass-through voting privileges to all Variable Contract owners so long as the Commission continues to interpret the 1940 Act as requiring pass-through voting privileges for Variable Contract owners. Accordingly, such Participating Insurance Companies, where applicable, will vote shares of the Fund held in its separate accounts in a manner consistent with voting instructions timely received from Variable Contract owners. In addition, each Participating Insurance Company will vote shares of a Fund held in its separate accounts for which it has not received timely voting instructions, as well as shares it owns, in the same proportion as those shares for which it has received voting instructions. Participating Insurance Companies will be responsible for assuring that each of their separate accounts investing in a Fund calculates voting privileges in a manner consistent with all other Participating Insurance Companies. The obligation to vote a Fund's shares and calculate voting privileges in a manner consistent with all other separate accounts investing in the Fund will be a contractual obligation of all Participating Insurance Companies under the agreements governing their participation in the Fund. Each Plan will vote as required by applicable law and governing Plan documents.

8. All reports of potential or existing conflicts of interest received by a Board, and all Board action with regard to: (a) Determining the existence of a conflict; (b) notifying Participants of a conflict; and (c) determining whether any proposed action adequately remedies a conflict, will be properly recorded in the minutes of the relevant Board or other appropriate records. Such minutes or other records shall be made available to the Commission upon request.

9. Each Fund will notify all Participating Insurance Companies that separate account prospectus disclosure regarding potential risks of mixed and shared funding may be appropriate. Each Fund shall disclose in its prospectus that: (a) Its shares may be offered to insurance company separate accounts that fund both variable annuity and variable life insurance contracts, and to Plans; (b) differences in tax treatment or other considerations may cause the interests of various Variable Contract owners participating in the Fund and the interests of Plans investing in the Fund to conflict; and (c) the Board will monitor the Fund for any material conflicts and determine what action, if any, should be taken.

10. Each Fund will comply with all the provisions of the 1940 Act requiring voting by shareholders (for these purposes, the persons having a voting interest in the shares of the Funds). In particular, each such Fund either will provide for annual meetings (except to the extent that the Commission may interpret Section 16 of the 1940 Act not to require such meetings) or comply with Section 16(c) of the 1940 Act (although none of the Funds shall be one of the trusts described in Section 16(c) of the 1940 Act) as well as Section 16(a) and, if applicable, Section 16(b) of the 1940 Act. Further, each Fund will act in accordance with the Commission's interpretation of the requirements of Section 16(a) with respect to periodic elections of Board members and with whatever rules the Commission may promulgate with respect thereto.

11. If and to the extent Rule 6e–2 or Rule 6e–3(T) is amended, of if Rule 6e–3 under the 1940 Act is adopted, to provide exemptive relief from any provisions of the 1940 Actor the rules thereunder with respect to mixed and shared funding on terms and conditions materially different from any exemptions granted in the order requested by Applicants, then the Funds and/or the Participants, as appropriate, shall take such steps as may be necessary to comply with Rule 6e–2 or Rule 6e–3(T), as amended, and Rule 6e–3, as adopted, to the extent such rules are applicable.

12. No less than annually, the Participants shall submit to each Board such reports, materials or data as each Board may reasonably request so that such Boards may carry out fully the obligations imposed upon them by the conditions stated in this application. Such reports, materials and data shall be submitted more frequently if deemed appropriate by the Boards. The obligations of Participating Insurance Companies and Plans to provide these reports, materials and data upon reasonable request of a Board shall be a contractual obligation of all Participating Insurance Companies and Plans under the agreements governing their participation in the Funds.

13. If a Plan or Plan participant should become an owner of 10% or more of the assets of a Fund, such Plan or Plan participant will execute a participation agreement with such Fund which includes the conditions set forth herein to the extent applicable. A Plan or Plan participant will execute an application containing an acknowledgement of this condition upon such Plan's initial purchase of the shares of any Fund.

Conclusion

For the reasons summarized above, Applicants represent that the exemptions requested are necessary and appropriate in the public interest and consistent with the protection of investors and purposes fairly intended by the policy and provisions of the 1940 Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–18920 Filed 7–17–97; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–22745; 811–3881]

PIMCO Advisors Funds; Notice of Application

July 11, 1997.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of Application for Deregistration under the Investment Company Act of 1940 (the ''Act'').

APPLICANT: PIMCO Advisors Funds.

RELEVANT ACT SECTION: Order requested under section 8(f).

FILING DATES: The application was filed on March 10, 1997, and amended on June 19, 1997.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personnally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on August 5, 1997, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, N.W., Washington, D.C. 20549. Applicant, 2187 Atlantic Street, Stamford, Connecticut 06902.

FOR FURTHER INFORMATION CONTACT: Lawrence W. Pisto, Senior Counsel, at (202) 942–0527, or Christine Y. Greenlees, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is a registered, open-end, management investment company organized as a Massachusetts business trust. On October 17, 1983, applicant (then called Thomson McKinnon Trust) [1] registered under section 8(a) of the Act and filed a registration statement on Form N–1A pursuant to section 8(b) of the Act and the Securities Act of 1933, covering an indefinite number of shares of common stock. The registration statement became effective and the initial public offering commenced on December 30, 1983. Applicant is comprised of sixteen series (each a ''Fund'').[2] Each Fund offers three classes of shares: Class A, Class B, and Class C.

2. On September 17, 1996, applicant's Board on Trustees (the ''Trustees'') authorized each Fund to enter into an Agreement and Plan of Reorganization (each a ''Plan'') with a series of either PIMCO Funds: Multi-Manager Series (''PFEAS'') or PIMCO Funds (''PIMS'') (each an ''Acquiring Fund'').[3] Pursuant to each Plan, the assets and liabilities of each Fund would be transferred to a corresponding Acquiring Fund in exchange for Class A, Class B, and Class C shares of such Acquiring Fund.

3. In recommending the reorganization, the Trustees identified certain potential benefits likely to result from the reorganization: (a) Economies of scale; (b) unified fee structure; (c) more diversified investment opportunities; (d) continued investment in a mutual fund without recognition of gain or loss for federal income tax purposes; and (e) a larger, more integrated fund complex.

4. In accordance with rule 17a-8 under the Act,[4] the trustees of the representive Funds and Acquiring Funds determined that (a) participation in the transaction would be in the best interests of the particular Fund or Acquiring Fund's shareholders; and (b) the current interests of such shareholders would not be diluted as a result of the transaction.

5. On or about November 4, 1996, proxy materials were sent to applicant's shareholders. On December 20, 1996, the shareholders of each Fund approved the Plan for such Fund.

6. On January 16 or 17, 1997, as applicable, Value Fund, High Income Fund, Total Return Fund, U.S. Government Fund, Short Intermediate Fund and Money Market Fund each paid a dividend which, together with all previous such dividends, had the effect of distributing each such Fund's investment company taxable income and net realized capital gain, if any, through January 17, 1997 (the ''Exchange Date'').

7. On the Exchange Date, all of the assets and liabilities of each Fund were transferred to an Acquiring Fund in exchange for shares of such Acquiring Fund based on net asset value. Certain of the Acquiring Funds had no assets or liabilities prior to the transactions. The Funds and their respective Acquiring Funds are: (a) The Value Fund and the PIMCO Value Fund; (b) the Discovery Fund and the PIMCO Mid Cap Growth Fund; (c) the Equity Income Fund and the PIMCO Renaissance Fund; (d) the Growth Fund and the PIMCO Growth Fund; (e) the Innovation Fund and the PIMCO Innovation Fund; (f) the International Fund and the PIMCO International Fund; (g) the Opportunity Fund and the PIMCO Fund; (h) the Precious Metal Fund and the PIMCO Precious Metals Opportunity Fund; (i) the Target Fund and the PIMCO Target Fund; (j) the Tax Exempt Fund and the PIMCO Tax Exempt Fund; (k) the High Income Fund and the PIMCO High Yield Fund; (l) the Total Return Income Fund and the PIMCO Total Return Fund; (m) the U.S. Government Fund and the PIMCO Total Return Fund; (n) the Short-Intermediate Fund and the PIMCO Low Duration Fund; (o) the Money Market Fund and the PIMCO Money Market Fund; and (p) the Global Income Fund and the PIMCO Global Bond Fund II.

8. Immediately upon consumption of this transaction, applicant distributed the Class A, Class B and Class C shares of the Acquiring Funds received by applicant to the Class A, Class B and Class C shareholders of the corresponding Fund. Each Class A, Class B and Class C shareholder of each Fund received that proportion of the shares of the corresponding class of the corresponding Acquiring Fund received by applicant which the number of shares of beneficial interest of such class of Fund owned by such shareholder bore to the number of such shares of such class of Fund outstanding on the Exchange Date.

9. Expenses included legal and accounting fees, printing and mailing costs, and costs of proxy solicitation, and were preliminarily allocated among each Fund and each Acquiring Fund, based in part on the number of share holders to whom mailings were made. Each Fund and each Acquiring Fund bore its share of the overall expenses of the transactions in accordance with this allocation, except that PIMCO advisors L.P. bore any expenses preliminarily allocated to a Fund or to an Acquiring Fund to the extent that such allocated

[1] On November 15, 1994, applicant changed its name to PIMCO Advisors Funds.

[2] The Funds are: Value Fund, Discovery Fund, Equity Income Fund, Growth Fund, Innovation Fund, International Fund, Opportunity Fund, Precious Metals Fund, Target Fund, Tax Exempt Fund, High Income Fund, Total Return Income Fund, U.S. Government Fund, Short-Intermediate Fund, Money Market Fund, and Global Income Fund.

[3] The PFEAS Acquiring Funds are: PIMCO Value Fund, PIMCO MidCap Growth Fund, PIMCO Renaissance Fund, PIMCO Growth Fund, PIMCO Innovation Fund, PIMCO International Fund, PIMCO Opportunity Fund, PIMCO Precious Metals Fund, PIMCO Target Fund, and PIMCO Tax Exempt Fund. The PIMS Acquiring Funds are: PIMCO High Yield Fund, PIMCO Total Return Fund, PIMCO Low Duration Fund, PIMCO Money Market Fund, and PIMCO Global Bond Fund II.

[4] Rule 17a–8 provides relief from the affiliated transaction prohibition of section 17(a) of the Act for a merger of investment companies that may be affiliated persons of each other solely by reason of having a common investment adviser, common directors, and/or common officers.

expenses exceeded specified expense exceeded specified expense caps for each Fund and each Acquiring Fund. Total expanses of $500,000 was borne by the Funds. The preliminary allocations and expense caps for each Fund and each Acquiring Fund were approved by the trustees of the respective Funds and Acquiring Funds.

10. Applicant has no assets, debts or liabilities. As of the date of the application, applicant has no securityholders. Applicant is not a party to any litigation or administrative proceeding. Applicant is not engaged, nor does it propose to engage, in any business activities other than those necessary for the winding up of its affairs.

11. Applicant intends to file the necessary documentation with the Commonwealth of Massachusetts to effect its dissolution as a Massachusetts business trust.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–18922 Filed 7–17–97; 8:45 am]

BILLING CODE 8010–01–M

UNITED STATES SENTENCING COMMISSION

Rules of Practice and Procedure

AGENCY: United States Sentencing Commission.

ACTION: Notice of promulgation of rules of practice and procedure.

SUMMARY: Pursuant to its authority under section 995(a)(1) of title 28, United States Code, the Sentencing Commission has established rules of practice and procedure relating to the manner in which it conducts its business. The Commission hereby gives notice of the adoption of these rules.

EFFECTIVE DATE: These rules are effective as of their adoption by the Commission on July 11, 1997.

ADDRESSES: Inquiries about any matter covered by the rules should be sent to: United States Sentencing Commission, One Columbus Circle, NE., Suite 2–500, South Lobby, Washington, DC 20002–8002, Attention: Office of Legislative and Public Affairs.

FOR FURTHER INFORMATION CONTACT: Michael Courlander, Public Information Specialist, Telephone: (202) 273–4590.

SUPPLEMENTARY INFORMATION: Section 995(a)(1) of title 28 authorizes the U.S. Sentencing Commission, an independent agency in the judicial branch of the United States Government, to establish general policies and promulgate rules and regulations for the Commission as necessary to carry out the purposes of the Sentencing Reform Act of 1984. The rules of practice and procedure are designed to facilitate public understanding and participation in the work of the Sentencing Commission. For the most part, these rules do not represent a substantive change in the way the Commission has traditionally conducted its business. These rules are not intended to enlarge the rights of any person sentenced under the guidelines promulgated by the Commission or otherwise create any private right of action. The rules were published for comment on July 29 and October 8, 1996. 61 FR 39493–96, 61 FR 52825–26. The Commission received public comment from a number of persons and groups. The Commission also conducted an informational hearing on June 4, 1997, at which time it received additional comment. The adopted rules reflect a variety of changes suggested by the public comment and hearing participants.

Authority: 28 U.S.C. 995(a)(1).

Richard P. Conaboy,

Chairman.

Rules of Practice and Procedure

Part I—Purpose of Rules; Rules Amendment Procedure

Rule 1.1 Application and Purpose

Pursuant to 28 U.S.C. 995(a)(1) and other applicable provisions of its organizational statute, the United States Sentencing Commission (''the Commission'') has established these rules governing its usual operating practices. The Commission, an agency within the judicial branch of government, is subject to only that provision of the Administrative Procedure Act, section 553 of title 5, United States Code, relating to publication in the **Federal Register** and a public hearing procedure, with regard to proposed sentencing guidelines or amendments thereto. *See* 28 U.S.C. 994(x). The Commission is not subject to a variety of other statutes, such as the Federal Advisory Committee Act, the Sunshine Act, and the Freedom of Information Act, typically applicable to rulemaking agencies in the executive branch. The Commission nevertheless desires to involve interested members of the public in its work to the maximum extent practicable. Accordingly, these rules are issued for the purpose of more fully informing interested persons of opportunities and procedures for becoming aware of and participating in the public business of the Commission. These rules are not intended to enlarge the rights of any person sentenced under the guidelines promulgated by the Commission or to otherwise create any private right of action.

Rule 1.2 Rules Amendment Procedure

(a) Except as provided in subsection (b), amendment of these rules shall require the affirmative vote in a public meeting of a majority (and not less than three) of the voting members then serving. Any such amendment shall be adopted only after notice and reasonable opportunity for public comment.

(b) The Commission temporarily may suspend any rule contained herein and/or adopt a supplemental or superseding rule by affirmative vote in a public meeting of a majority of the voting members then serving.

Part II—Action by the Commission

Rule 2.1 Members

For purposes of the voting procedures set forth in these rules, ''member'' of the Commission shall mean a voting member and shall not include an *ex-officio,* non-voting member. *Ex-officio* members may not vote or make or second motions.

Rule 2.2 Voting Rules for Action by the Commission

Except as otherwise provided in these rules or by law, action by the Commission requires the affirmative vote of a majority of the members at a public meeting at which a quorum is present. A quorum shall consist of a majority of the members then serving. Members shall be deemed ''present'' and may participate and vote in public meetings from remote locations by electronic means, including telephone, satellite, and video conference devices.

Promulgation of guidelines, policy statements, official commentary, and amendments thereto shall require the affirmative vote of at least four members at a public meeting. *See* 28 U.S.C. 994(a).

Publication for comment of proposed amendments to guidelines, policy statements, or official commentary shall require the affirmative vote of at least three members at a public meeting. The decision to instruct staff to prepare a retroactivity impact analysis for a proposed amendment shall require the affirmative vote of at least three members at a public meeting.

Action on miscellaneous matters may be taken without a meeting based on the affirmative vote, by written or oral communication, of a majority of the

members then serving. Such matters may include, the approval of budget requests, legal briefs, staff reports, analyses of legislation, and administrative and personnel issues.

A motion to reconsider Commission action may be made only by a commissioner on the prevailing side of the vote for which reconsideration is sought, or who did not vote on the matter. Four votes are necessary to reconsider a Commission vote on any question on which a four-vote majority is required.

Part III—Meetings and Hearings

Rule 3.1 Meetings

The Chair shall call and preside at Commission meetings. In the absence of the Chair, the Chair will designate a Vice Chair to preside.

Rule 3.2 Public Meetings

The Commission shall meet on at least two occasions in each calendar quarter to conduct business.

To the extent practicable, the Chair shall issue, through the Office of Staff Director, a public notice of any public meeting at least seven days prior to the date of the meeting. The public notice, to the extent practicable, shall indicate the general purpose(s) of the meeting and include an agenda and any related documents approved for public release.

At the discretion of the Chair, members of the public may be afforded an opportunity to comment on any issue on the agenda of a public meeting.

Rule 3.3 Executive Sessions

The Commission may hold executive sessions closed to the public to transact business of the Commission that is not appropriate for a public meeting, *e.g.*, discussion and resolution of personnel and budget issues.

Rule 3.4 Briefing Sessions

The Commission may hold briefing sessions that are not open to the public generally to receive in-depth information from staff and other persons. The Office of Legislative and Public Affairs will make available a list of issues upon which the Commission was briefed.

Rule 3.5 Public Hearings

The Commission may convene a public hearing on any matter involving the promulgation of sentencing guidelines or any other matter affecting the Commission's business. A request for comment on a proposed matter does not necessarily mean that a public hearing will be held on the matter or that a public hearing, if scheduled, will pertain to all issues raised in the request for comment.

Notice of a public hearing shall be given as soon as practicable. The notice shall include, as applicable, information regarding a procedure for requesting an opportunity to testify, and the availability of documents or reports relevant to the subject of the hearing.

The Commission may specify the format for public hearings, invite witnesses, choose witnesses from among those who request the opportunity to testify, and require that written testimony be submitted in advance of the hearing.

The Commission may exclude from such a hearing any electronic devices that record the voice or image of any or all witnesses, as well as cameras of any kind.

At the request of any witness to turn off any such electronic device(s) during that person's testimony, the Chair of the Commission may order, at his or her discretion, that use of such devices be discontinued during the testimony of that witness.

Rule 3.6 Written Record of Meetings and Hearings

The Commission shall prepare and maintain written minutes of public meetings and make them publicly available after their approval by the Commission. The Commission shall tape record public meetings and make the recordings publicly available after the approval of the minutes of such meeting. No such recording shall be copied or removed from the Commission's offices.

The Commission shall maintain a written transcription of public hearings that shall be publicly available for inspection.

Part IV—Guideline Amendment Process

Rule 4.1 Promulgation of Amendments

The Commission may promulgate and submit to Congress amendments to the guidelines after the beginning of a regular session of Congress and not later than May 1 of that year. Amendments shall be accompanied by an explanation or statement of reasons for the amendments. Unless otherwise specified, or unless Congress legislates to the contrary, amendments submitted for review shall take effect on the first day of November of the year in which submitted. 28 U.S.C. 994(p).

At other times, pursuant to special statutory enactment, the Commission may promulgate amendments to accomplish identified congressional objectives.

Amendments to policy statements and commentary may be promulgated and put into effect at any time. However, to the extent practicable, the Commission shall endeavor to include amendments to policy statements and commentary in any submission of guideline amendments to Congress and put them into effect on the same November 1 date as any guideline amendments issued in the same year.

Generally, promulgated amendments will be given prospective application only. However, in those cases in which the Commission considers an amendment for retroactive application to previously sentenced, imprisoned defendants, it shall decide whether to make the amendment retroactive at the same meeting at which it decides to promulgate the amendment. Prior to final Commission action on the retroactive application of an amendment, the Commission shall review the retroactivity impact analysis prepared pursuant to Rule 2.2, *supra.*

Rule 4.2 Prison Impact of Amendments

Prior to promulgating amendments to the guidelines, the Commission shall consider the impact of any amendment on available penal and correctional resources, and on other facilities and services and shall make such information available to the public.

Rule 4.3 Notice and Comment on Proposed Amendments

In proposing and promulgating guidelines and amendments thereto, the Commission shall comply with the requirements of section 553 of title 5, United States Code, relating to publication in the **Federal Register** and public hearing procedure. 28 U.S.C. 994(x).

The Commission may promulgate commentary and policy statements, and amendments thereto, without regard to the provisions of 28 U.S.C. 994(x). Nevertheless, the Commission will endeavor to provide, to the extent practicable, comparable opportunities for public input on proposed policy statements and commentary considered in conjunction with guideline amendments.

Rule 4.4 Federal Register Notice of Proposed Amendments

A vote to publish a proposed amendment to a guideline, policy statement, or official commentary in the **Federal Register** shall be deemed to be a request for public comment on the proposed amendment. At the same time the Commission votes to publish proposed amendments for comment, it

shall request public comment on whether to make any amendments retroactive.

The notice of proposed amendments also shall provide, to the extent appropriate and practicable, reasons for consideration of amendments and a summary of or reference to publicly available information that is relevant to the issue(s). In addition, the publication notice shall include a deadline for public comment and may include a notice of any scheduled public hearing(s) or meetings on the issue(s).

In the case of proposed amendments to guidelines or issues for comment that form the basis for possible guidelines amendments, the Commission shall allow, to the extent practicable, a minimum period of public comment of at least 60 calendar days prior to final Commission action on the proposed amendments.

Rule 4.5 Public Hearing on Proposed Amendments

In the case of ''emergency'' amendments issued pursuant to special statutory authorization, the Commission ordinarily will not conduct a public hearing on the proposed amendments but will afford such opportunity for written comment as time allows.

In the case of other amendments to guidelines or policy statements issued pursuant to 28 U.S.C. 994, the Commission shall conduct a public hearing on the proposed amendments, unless the Commission determines that time does not permit a hearing or that a hearing will not substantially assist the amendment process. Notice of the hearing shall be given in the **Federal Register** and by other means designed to inform persons likely to be interested in participating in such a hearing.

Part V—Public Participation in Guideline Amendment Process

Rule 5.1 Public Comment File

The Office of Legislative and Public Affairs shall receive and maintain public comment and public hearing testimony received by the Commission. This public comment file will be available during normal business hours for public inspection pursuant to written or telephonic request and with reasonable notice.

Rule 5.2 Notice of Priorities

The Commission shall publish annually in the **Federal Register** and make available to the public a notice of the tentative priorities for future Commission inquiry and possible action, including areas for possible amendments to guidelines, policy statements, and commentary. Any such notice shall include an invitation to, and deadline for, the submission of written public comment on the proposed priorities.

Rule 5.3 Data and Reports Relevant to the Amendment Process

To fulfill Commission priorities and inform consideration of potential amendments, the Staff Director shall direct the preparation of relevant data and reports for consideration by the Commission. Upon authorization, the Office of Legislative and Public Affairs shall make the data and reports available to the public as soon as practicable.

Rule 5.4 Advisory Groups

Upon authorization of the Commission, the Staff Director may facilitate the creation, membership, and periodic meeting at the Commission offices and elsewhere, of advisory groups of defense attorneys, academics, probation officers, judges, prosecutors, and others, to facilitate formal and informal input to the Commission.

Two types of advisory groups are authorized: standing and ad hoc. The following groups are standing advisory groups: the Practitioners' Advisory Group and the Probation Officers' Advisory Group.

Upon creating an advisory group, the Commission may prescribe such policies regarding the conduct of meetings and operation of the group as the Commission deems necessary or appropriate. The Commission also may delegate to an advisory group the responsibility for developing such policies.

In addition, the Commission expects to solicit input, from time to time, from outside groups representing the federal judiciary, prosecutors, defense attorneys, crime victims, and other interested groups.

Part VI—Information About the Commission

Rule 6.1 Office(s)

The offices of the Commission are located in the Thurgood Marshall Federal Judiciary Building, Suite 2–500, South Lobby, One Columbus Circle, NE., Washington, DC. 20002–8002.

The office can be reached by telephone between 8:30 a.m. and 5:30 p.m., Monday through Friday. The main telephone number is (202) 273–4500. The fax number is (202) 273–4529.

Rule 6.2 Office of Legislative and Public Affairs

The Office of Legislative and Public Affairs administers the Commission's policy on Public Access to Sentencing Commission Documents and Data. *See* 54 FR 51279 (1989). This office also maintains *A Guide to Publications & Resources* that lists all publications and datasets available from the Commission. This document is available on request.

Generally, the Office of Legislative and Public Affairs will maintain for public inspection by appointment official Commission documents, meetings and hearing schedules and agendas, approved minutes of Commission meetings and transcripts of public hearings, public comment submissions, and other documents (or citations thereto) that inform Commission decisions or actions.

Rule 6.3 Internet Site

The Commission maintains and updates information and documents on an Internet web site. The web site is found at: *http://www.ussc.gov*.

This resource includes general information, such as background information about the Commission and Commissioners, notices for scheduled meetings and hearings, minutes of recent meetings, transcripts of public hearings, listings of Commission priorities and projects, outstanding public comment solicitations, recently promulgated amendments, the text of numerous reports and resources available from the Commission, and the text of the *Guidelines Manual* and Commission reports.

Rule 6.4 Information at Federal Depository Libraries

Commission publications printed by the Government Printing Office, and other selected documents, are available in hard copy or microfiched form through the Government Printing Office's Depository Library system. The location of the nearest Federal Depository Library can be determined in several ways: (1) By requesting a free copy of the *Directory of Depository Libraries* from the U.S. Government Printing Office, Library Programs Services, Stop: SLLD, Washington, DC 20401; (2) by asking at any local library for the address of the nearest Federal Depository Library; or (3) by using the Internet at *http://www.access.gpo.gov/su__docs*; ''Information Available for Free Public Use in Federal Depository Libraries'' should be selected. The listing may be searched by state or by area code.

Rule 6.5 Access to Commission Data Research Consortium

The Commission provides its various databases, excluding individual identifiers, to the University of

Michigan's Inter-University Consortium for Political and Social Research (ICPSR). Researchers interested in studying federal sentencing practices through quantitative methods can access Commission sentencing data through this means. Contact ICPSR, PO Box 1248, Ann Arbor, MI 48106; or call 1–800–999–0960; or use the following Internet address: *http://www.ICPSR.umich.edu/NACJD/home.html.*

[FR Doc. 97–18959 Filed 7–17–97; 8:45 am]

BILLING CODE 2210–40–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms and Recordkeeping Requirements; Agency Information Collection Activity Under OMB Review

AGENCY: Office of the Secretary, DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** notice with a 60-day comment period soliciting comments on the following collection of information was published on April 9, 1997 (62 FR 17277).

DATES: Comments must be submitted on or before August 18, 1997.

FOR FURTHER INFORMATION CONTACT: Ms. Judith Street, Federal Aviation Administration, Corporate Information Division, ABC–100, 800 Independence Ave., SW., (202) 267–9895, Washington, DC 20591.

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: Passenger Facility Charge (PFC) Application.

Type of Request: Extension of a currently approved information collection.

OMB Control Number: 2120–0557.

Affected Public: Air Carriers and Public Agencies.

Abstract: The Aviation Safety and Capacity Expansion Act of 1990 (Pub. L. 101–508) authorizes airports to impose passenger facility charges. This collection is necessary in order to implement the Statute and carry out a passenger facility charge as required by Section 9113 of the Aviation Safety and Capacity Expansion Act of 1990.

Estimated Annual Burden Hour: 26,742.

Number of Respondents: 450.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street, NW., Washington, DC 20503, Attention DOT Desk Officer.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on July 14, 1997.

Vanester M. Williams,

Clearance Officer, United States, Department of Transportation.

[FR Doc. 97–18987 Filed 7–17–97; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Federal Transit Administration

Participation in the National Advanced Rural Transportation Systems' Traveler Information Services in Tourism Areas Field Operational Test

AGENCIES: Federal Highway Administration (FHWA) and Federal Transit Administration (FTA), Department of Transportation (USDOT).

ACTION: Notice; request for participation.

SUMMARY: The USDOT is interested in evaluating the benefits associated with the application of traveler information services in rural tourism areas. This request for participation solicits applications from both public-public (e.g., State DOT–Chamber of Commerce) and public-private (e.g., National Park Service-private industry) partnerships to conduct a field operational test. The purpose of this test would be to evaluate the benefits of using advanced traveler information systems in rural tourist areas involving State or national parks, or other tourist areas (public or private) that experience seasonal or annual traffic flow congestion.

DATES: Responses to this announcement must be submitted by 4 p.m., e.t., on or before August 15, 1997.

ADDRESSES: Responses to this solicitation must be submitted directly to the Federal Highway Administration, Office of Traffic Management and ITS Applications, Rural Action Team, HTV–3, 400 Seventh St., SW., Room 3401, Washington, D.C. 20590.

FOR FURTHER INFORMATION CONTACT: Mr. R. Dale Thompson, FHWA, Office of Traffic Management and ITS Applications, Rural Action Team, (202) 366–0640; or Mr. Ronald Boenau, FTA, Office of Mobility Innovation , Rural Action Team, (202) 366–0195; or Mr. Raymond Resendes, ITS Joint Program Office, Rural Action Team, (202) 366–2182; or Ms. Beverly Russell, FHWA, Office of the Chief Counsel (202) 366–1355, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., Eastern Time, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Availability of the Plan and Electronic Access

Copies of the Advanced Rural Transportation Systems Strategic Plan, which describes the program goals and the critical program areas, are available from ITS America, 400 Virginia Avenue, SW., Suite 800, Washington, DC 20024, telephone (202) 484–4847. Electronic copies are available on the ITS America Internet Home Page, http://www.itsa.org.

Background

Title VI, part B of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), Pub. L. 102–240, 105 Stat. 1914, 2189, provided the Intelligent Vehicle Highway Systems Act which set the foundation for the National Intelligent Transportation Systems (ITS) Program. Under ISTEA, the USDOT has taken the lead in conducting ITS research, development, and operational testing activities to lay the foundation for the application of existing and emerging technologies and systems to improve the efficiency of the surface transportation system.

Early ITS efforts were driven by the desire to address growing transportation problems in urban areas and in inter-urban corridors. While many of the technologies and systems aimed at solving these problems also have application outside urban settings, the market structure, application logistics, and motivating factors underlying their deployment vary considerably from urban to rural areas. The Federal ITS

Program recognized these differences and, in the past year, has initiated the development of an ITS program component with a uniquely rural focus: the Advanced Rural Transportation Systems Program.

During 1996, the USDOT developed an Advanced Rural Transportation Systems Strategic Plan which covers the Federal role in developing and fostering the application of intelligent transportation systems in rural areas. The Strategic Plan describes the vision, mission, goals, objectives, and measures which provide the foundation upon which the Federal Advanced Rural Transportation Systems Program is built. The goals of the Advanced Rural Transportation Systems Program are closely tied to those of the overall ITS Program. Priority is given to those goals that meet the more critical needs of travelers and transporters of goods in rural areas. Consequently, the primary goals of the Advanced Rural Transportation Systems Program are safety and efficient mobility, versus those of the metropolitan systems which are congestion mitigation and increased throughput.

Because of the diversity of needs and settings in Rural America, the Advanced Rural Transportation Systems Strategic Plan specifies seven critical program areas, or clusters, which provide areas of common interest and focus within the overall rural ITS program. The companion Program Plan, currently under development, describes what is known and unknown within each cluster, sets the strategic priorities, and lays out the program (projects by year) to solve the unknowns. Together the Advanced Rural Transportation Systems Strategic and Program Plans provide the road map for the Federal Advanced Rural Transportation Systems program through the year 2003.

While rural settings differ greatly, there is general agreement on the classes of needs that exist within each setting and the principal users of ITS. The critical program areas, therefore, were developed around identifiable needs and service categories and are as follows:

1. Traveler Safety and Security;
2. Emergency Services;
3. Tourism and Travel Information Services;
4. Public Traveler Services/Public Mobility Services;
5. Infrastructure Operating and Maintenance;
6. Fleet Operating and Maintenance; and
7. Commercial Vehicle Operations.

For example, the Tourism and Travel Information Services category mentioned above refers to the needs and services that a visitor (both driver and passenger) unfamiliar with a rural area may require. These services will also address the needs of the Visitors and Tourism Bureaus, transit service providers, information providers, etc., that provide the services to meet tourists' needs. In a rural tourist area, this may be the main focus of the ITS program. Likewise, the Public Traveler Services/Public Mobility Services focuses on reducing the isolation of the transportation disadvantaged and increasing the mobility of all. Constituents of this critical program area include both the potential travelers and service providers. As ITS services are shown to reduce costs and improve efficiency, these areas and the organizations responsible for them become natural constituents and advocates for the programs.

I. Objective and Hypotheses

The objective of this field operational test is to evaluate the use of advanced technologies to collect and disseminate traveler information in rural tourist areas with limited traditional transportation options available so as to: (1) Improve mobility; (2) increase access; (3) relieve traffic congestion caused by high travel demands and the limited capacity of roadways and parking facilities; and (4) stimulate economic development.

The hypotheses for this field operational test are: (1) The Traveler Information System in a rural tourism area will improve mobility compared to mobility without the Traveler Information System; (2) tourists surveyed about the access to selected rural attractions will rate the access higher after the Traveler Information System is installed and operational; (3) the Traveler Information System will relieve congestion at the selected rural attraction(s) and tourists will perceive the reduction in congestion; and (4) the Traveler Information System will stimulate economic development.

II. Scope

Definitions

1. ''Rural tourist area,'' for purposes of this field operational test, is defined as a State or national park, or other tourist area in a rural location with a permanent population of roughly 50,000 or less with limited access to and from the area, limited roadway capacity in and out of the area that contributes to the high levels of seasonal congestion during periods of high demand, and limited parking access and capacity that reaches saturation levels at periods of high demand, as well as limited integration of transit systems.

2. A ''Traveler Information System,'' for purposes of this field operational test, is a system typical of other advanced traveler information systems deployed in metropolitan areas to disseminate traveler information to the traveling public and transportation managers. The Traveler Information System focuses on the unique needs of a rural tourist area, which may differ from one tourist area to another. Examples of typical equipment and systems deployed to support such a system are listed below. A Traveler Information System may have any one or more of these listed features, as well as others not listed. An important point is that the individual systems are integrated, or at a minimum, are capable of being integrated to provide traveler information to the general public, as well as to local and regional transportation managers. The Traveler Information System components may include, but are not limited to:

A. Cable TV;
B. Changeable Message Signs/Variable Message Signs;
C. Radio Traveler Information Reports such as Highway Advisory Radio;
D. Dedicated Telephone Traveler Information System;
E. Kiosks;
F. Internet;
G. Hand-held Devices;
H. In-vehicle Devices; and
I. Others.

Typical information collected and disseminated to travelers may include, but is not limited to:

A. Local Area Information;
B. Tourist Area Information;
C. Weather Conditions;
D. Transit Schedules and Routes;
E. Real-time Transit Information;
F. Employee Ride-share Information;
G. Real-time Traffic Information;
H. Traffic Conditions;
I. Roadway Conditions;
J. Work-zone Information;
K. Incident Information;
L. Alternate Route Information;
M. Emergency Management Information;
N. Yellow Pages Information (hotels, restaurants, local businesses, private transportation services, other public and private services, local information, points of interest, maps and directions, etc.);
O. Tourist Attraction and Park Information; and
P. Others.

III. Partnerships

The USDOT will generally work with the lead public agency participating in the partnership (State, city, or regional agency, depending on the site) to ensure an up front commitment to provide the needed support to achieve the evaluation objectives of this field

operational test. The USDOT will also ensure that needed institutional and partnership arrangements are in place and required funding is available.

All necessary partnership arrangements and institutional agreements to support the project should be documented. Signed copies of completed Memorandums of Understanding (MOUs) that clearly define responsibilities and relationships should be included in the proposal. Partners are also strongly encouraged to seek participation from certified minority business enterprise firms, women business enterprise firms, disadvantaged business enterprise firms, historically black colleges and universities, Hispanic serving institutions, and other minority institutions.

IV. National ITS System Architecture

Proposals shall provide a ''Statement of Intent'' to implement a system that is consistent with the National ITS Architecture, including any national ITS standards, protocols, or standards requirements as these emerge from the National ITS Architecture Development Program. Copies of the Architecture Definition Documents, the draft Standards Requirements Document, and the Standards Development Program from the Architecture Development Program are available from ITS America, 400 Virginia Avenue, SW., Suite 800, Washington, DC 20024, telephone (202) 484–4847. Electronic copies are available on the ITS America Internet Home Page, http://www.itsa.org. These documents provide insight into the definition of the National ITS Architecture, and the emerging approaches being taken toward standardizing interfaces that would support the integration of transportation management components.

V. Project Evaluation Activities

Evaluation is an integral part of each field operational test and is critical to the success of the National ITS Program. As such, the USDOT ITS Joint Program Office will conduct a rigorous, independent evaluation of traveler information services and products supported by a Traveler Information System in a rural tourist area. The independent evaluation may be conducted using existing USDOT resources, or, as part of another solicitation. Applicants are not required to perform this evaluation; however, they are required to support the independent evaluation.

The field operational test partners will be involved in specific phases of the evaluation. At a minimum, the partners are expected to be part of the process to develop the goals and objectives of the individual tests and the overall evaluation plan. Partners are also expected to be involved in much of the technical, legal, and institutional data collection, archiving, and reporting. Nothing in these guidelines shall preclude the non-Federal partners from conducting additional evaluations for their specific needs.

The non-Federal project coordination evaluation activities will include assisting the USDOT Evaluation Team in developing an evaluation report that summarizes findings/lessons learned resulting from the deployment of this Traveler Information System. Partners are expected to review and comment on this report; however, the independent evaluator is obligated to perform an independent analysis of the data and an unbiased report of results compared to partner-identified goals, objectives, and hypotheses.

VI. Funding

The total maximum amount of Federal ITS funding in this solicitation is $600,000. In accordance with sec. 6058 of the ISTEA, the maximum share of a project funded from Federal funds, including ITS funds, cannot exceed 80 percent. For this project, the Agency is requiring a 50% cost share from perspective partners. At least 40% of the required cost share amount must be derived from non-Federal sources in order that the Federal maximum share of 80% mandated in section 6058 not be exceeded.

The statutorily required 20 percent cost share must be from non-federally derived funding sources and must consist of either cash, substantial equipment contributions that are wholly utilized as an integral part of the project, or personnel services dedicated full-time to the project for a substantial period, as long as such personnel are not otherwise supported with Federal funds. The non-federally derived funding may come from State, local government, or private sector partners.

In an ITS partnership, as with other USDOT cost-share contracts, it is inappropriate for a fee to be included in the proposed budget as part of a partner's contribution to the project. This does not prohibit appropriate fee payments to vendors or others who may provide goods or services to the partnership. It also does not prohibit business relationships with the private sector which result in revenues from the sale or provision of ITS products or services.

The USDOT, the Comptroller General of the United States, and, if appropriate, individual States have the right to access all documents pertaining to the use of Federal ITS funds and non-Federal contributions. Non-Federal partners must submit sufficient documentation during final negotiations and on a regular basis during the life of the project to substantiate these costs. Such items as direct labor, fringe benefits, material costs, consultant costs, subcontractor costs, and travel costs should be included in that documentation.

VII. Schedule

A system in a summer or year-round tourist area must be operational by May 1, 1998. A system in a winter tourist area must be operational by November 1, 1998. The system must remain operational for a period long enough to obtain valid evaluation data. Depending on the degree of system stability during the data collection period, the nominal data collection period will be five months from the declaration of the system as ''operational.'' After the end of data collection, there shall be a six-month period of data analysis and report coordination before the final independent evaluation report is submitted. The system shall remain operational until the final evaluation report has been received and accepted by USDOT.

VIII. Evaluation of Applications

The USDOT will select one rural site to evaluate the potential and realized benefits of a Traveler Information System focusing on the objectives previously stated. However, the USDOT reserves the right to make multiple awards. Applications shall, where possible, focus on the use of currently available technologies, existing communications and infrastructure, and strengthened institutional ties to support evaluation objectives with the limited Federal ITS funding available in this effort. Applications that offer the greatest potential for demonstrating and evaluating the benefits of a Traveler Information System in a rural tourist area (including both the institutional and technological aspects) for the least Federal ITS dollars will be considered the most desirable.

Interested parties are invited to submit a proposal containing sufficient information to enable an evaluation of the proposal based on the selection criteria set forth below. A proposal shall not exceed 30 pages in length including title, index, tables, maps, appendices, abstracts, resumes and other supporting materials. A page is defined as one side of an 8½ by 11 inch paper, line spacing no smaller than 1.5, with a type font no

smaller than 12 point. Proposals greater than 30 pages will not be accepted. Ten copies plus an unbound reproducible copy of the proposal shall be submitted. The cover sheet or front page of the proposal shall include the name, address, and phone number of an individual to whom correspondence and questions about the application may be directed. Proposals shall include a ''Technical Plan,'' a ''Financial Plan,'' and a ''Management and Staffing Plan'' that describe how the proposed objectives will be met within the specified time frame and budget. The plans should be structured such that they contain the following information.

Technical Plan

1. General Requirements

A. General description of the targeted tourist site or area. Include information on the local area, State or national parks, or other tourist sites involved, roadways into and out of the area, historical data on traffic volumes and congestion or weather related problems, seasonal data applicable to congestion levels or mobility/access, any multimodal aspects of the transportation system, and the public/private agencies involved in the project such as local or State Bureau of Tourism, Chamber of Commerce, transportation agencies, park agencies, etc.

B. Interagency, interjurisdictional and public/private/academic cooperative arrangements currently in place to support the overall field test and evaluation effort.

C. Provide letters of commitment/signed Memorandums of Understanding by local public/private/academic partners.

2. Concept Overview

A. Define the current infrastructure or support systems in place to be used as a foundation for evaluating the Traveler Information System, e.g., communication systems, sources and current availability of traffic data, weather data, public and private transportation services, etc.

B. Define the Traveler Information System and the infrastructure that will be expanded and used to support the proposed system.

C. Describe the proposed rural traveler information system components and how they will be linked into the overall system.

D. Summarize the expectations of the proposed system, e.g., benefits, operations and maintenance issues, plans and system support beyond the test period.

3. Technical Approach

A. Describe system design concept discussing extent of system integration and information packaging.

B. Describe how the traveler information data will be collected, packaged into useful information, and provided to the traveling public.

C. Describe implementation of the system in probable phases with funding for each phase.

D. Describe technical approach by which the system design concept will be refined, developed, operationally tested, evaluated, and documented.

E. Document schedule of work, assumptions, and technical uncertainties, and propose specific approaches to resolve any uncertainties.

F. Show evidence that the project team has thought through the service delivery part of the project design: (1) Who will use the system?; (2) What problems will it solve for the user?; (3) Where in their trip will users find the information most useful?; and (4) How will the project team market the system?

4. Draft Project Evaluation Plan

A. Proposals shall include a draft project evaluation plan that demonstrates an understanding of the importance of building automatic data collection into the system. The proposed system shall provide feature usage and other evaluation data needed to measure the degree to which hypotheses are supported.

B. Proposals shall describe methods to ensure that benefits and costs are measurable.

C. A demonstrated understanding of the role of the evaluation should be evident in the organizational and management approach of the proposal.

D. Proposals shall describe how the proposed partnership will provide information for a with-the-system/without-the-system evaluation analysis as well as identify existing data sources available and methods to obtain such data. A discussion of the availability and potential utility of baseline information shall be included. Existing survey data bases shall be described.

E. Proposals shall describe how the proposed partnership will convey to the independent evaluation team evaluation data automatically collected by the system.

Note: Refinement of the draft project evaluation plan, and the actual data collection will be the responsibility of the independent evaluator in coordination with the project team.

Management and Staffing Plan

1. Provide names and positions of all personnel related to managing the project.
2. Identify key management and control responsibilities for the system data base and the overall system.
3. Provide a time line and define key milestones for the project.
4. Provide estimated professional and technical staffing in staff-months and staff-hours.
5. Demonstrate that the project manager is capable, available, and able to commit to a level of involvement that ensures project success.
6. Include biographical data on key management personnel.

Financial Plan

1. Provide description of total project costs and sources of matching funds.
2. Provide a system budget identifying costs for system design, development, implementation, project management, operations and maintenance, and evaluation support.
3. Applicants' evaluation support costs shall include the following information.

A. Labor costs of a single project evaluation coordinator who integrates and represents evaluation interests of all partners and stakeholders to the independent evaluator and critically reviews and provides comments on evaluation plans and products.

B. Incidental labor costs of individual partners and stakeholders who will review evaluation deliverables.

C. Labor, hardware, and software costs for ensuring automatic collection of evaluation data (e.g., recording of kiosk or web feature usage.)

D. Cost of periodic transfer of evaluation data base information to the independent evaluator.

Note: Funds identified to support this effort shall not be spent for other portions of the operational tests. The USDOT shall negotiate with the project partners during the initial operational test definition to ensure an adequate estimate of resources is committed to support the national evaluation objectives. The USDOT reserves the right to require that additional data be collected and made available to allow the USDOT to make comparative analyses with similar functions or features associated with other national operational tests.

4. Break costs down identifying them by non-Federal (public and private) and Federal (ITS and Federal-aid) sources.
5. Provide cost estimates by phase as defined in the Technical Plan.
6. All financial commitments to the project from both public and private sectors shall be documented in signed MOUs and included in the proposal.

The application shall provide an in-depth description and assessment of the total cost of achieving the objectives of the Traveler Information System field operational test, and the partnership's plans for raising the matching funds required by this solicitation. The ''Financial Plan'' should describe a phased approach that delineates what will be accomplished with the project funding.

The application should provide a comprehensive but concise plan for design, acquisition (including innovative contracting procedures such as design-build), construction, and other procurement actions to improve the systems integration of the functions needed to support a Traveler Information System.

The budget shall show the requested Federal ITS funding and proposed partnership match funding for the activities shown in the table below. The matching funds should be further divided into public and private contribution amounts in the table, as well as the source and type of contribution described in the application.

TOTAL TRAVELER INFORMATION SYSTEM—FIELD OPERATIONAL TEST FUNDING

Activities	Total amount		Source and description of matching funds	
	Federal ITS funds	Matching funds	Public	Private
Design				
Current System Expansion				
New Systems				
Operation/Maintenance				
Evaluation Support				
Project Management				
Outreach/Marketing				
Total				

IX. Proposal Evaluation Criteria

Applicants must submit an acceptable ''Technical Plan,'' ''Financial Plan,'' *and* ''Management and Staffing Plan'' that provide sound evidence that the proposed partnership can successfully meet the objectives of the Traveler Information System field operational test. The ''Technical Plan'' and ''Financial Plan'' will be weighed equally and more than the ''Management and Staffing Plan.''

(**Authority:** 23 U.S.C. 307 note and 315; Secs. 6051–6059, Pub. L. 102–240, 105 Stat. 1914, 2189; and 49 CFR 1.48).

Issued on: July 14, 1997.

Jane F. Garvey,

Federal Highway Administrator (Acting).

Gordon J. Linton,

Federal Transit Administrator.

[FR Doc. 97–18983 Filed 7–17–97; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. M–037]

Information Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Maritime Administration's (MARAD's) intentions to request extension of approval for three years of a currently approved information collection entitled Request for Transfer of Ownership, Registry, and Flag, or Charter, Lease, or Mortgage of U.S. Citizen Owned Documented Vessels.

DATES: Comments should be submitted on or before September 16, 1997.

FOR FURTHER INFORMATION CONTACT: Frances Olsen, Division of Vessel Transfer and Disposal, Office of Sealift Support, MAR–631, Room 7307, 400 Seventh Street, S.W., Washington, D.C. 20590. Telephone (202)366–2260 or fax (202) 493–2180. Copies of this collection can also be obtained from that office.

SUPPLEMENTARY INFORMATION:

Title of Collection: Request for Transfer of Ownership, Registry, and Flag, or Charter, Lease, or Mortgage of U.S. Citizen Owned Documented Vessels.

Type of Request: Extension of currently approved information collection.

OMB Control Number: 2133–0006.

Form Number: MA–29, MA–29A, MA–29B (Note: MA–29A is used only in cases of a National Emergency).

Expiration Date of Approval: November 30, 1997.

Summary of Collection of Information: MARAD is required to approve the sale, transfer, charter, lease, or mortgage of U.S. documented vessels to non-citizens, or the transfer of such vessels to foreign registry and flag, or the transfer of foreign flag vessels by their owners as required by various contractual requirements. These provisions are implemented by 46 CFR part 221.

Need and Use of the Information: This information collection requires a vessel owner to submit an application for a prospective foreign transfer of a U.S.-flag vessel. This information will assist in the determination of whether the vessel proposed for transfer will initially require retention under the U.S.-flag statutory regulation. In such instances, the application is reviewed and cleared for approval by specialists within MARAD, Department of Commerce, and Department of Defense.

Description of Respondents: Respondents are vessel owners who have applied for foreign transfer of U.S.-flag vessels.

Annual Responses: 220.

Annual Burden: 440 hours.

Comments: Send all comments regarding this information collection to Joel C. Richard, Department of Transportation, Maritime Administration, MAR–120, Room 7210, 400 Seventh Street, SW., Washington, DC 20590. Send comments regarding whether this information collection is necessary for proper performance of the function of the agency and will have practical utility, accuracy of the burden estimates, ways to minimize this burden, and ways to enhance quality, utility, and clarity of the information to be collected.

By Order of the Maritime Administrator.

Dated: July 15, 1997.

Joel C. Richard,

Secretary.

[FR Doc. 97–18996 Filed 7–17–97; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

[Notice No. 97–7]

International Standards on the Transport of Dangerous Goods; Public Meeting

AGENCY: Research and Special Programs Administration (RSPA), Department of Transportation.

ACTION: Notice of public meeting.

SUMMARY: This notice is to advise interested persons that RSPA will conduct a public meeting to report on the results of the thirteenth session of the United Nation's Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCOE) and to discuss the work program for U.S. participation in future meetings of the UN Sub-Committee of Experts on the Transport of Dangerous Goods during the 1997–1998 biennium.

DATES: July 23, 1997 at 9:30 a.m.

ADDRESSES: Room 6200, Nassif Building, 400 Seventh Street SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Frits Wybenga, International Standards Coordinator, Office of Hazardous Materials Safety, Department of Transportation, Washington, DC 20590; (202) 366–0656.

SUPPLEMENTARY INFORMATION: The primary purpose of this meeting will be to (1) review the outcome of the thirteenth session of the UNSCOE held from July 7–17, 1997 in Geneva Switzerland and to begin preparation for U.S. participation in the fourteenth session of the SCOE. Topics to be covered during the public meeting include matters related to reformatting the UN Recommendations on the Transport of Dangerous Goods into a model rule, criteria for environmentally hazardous substances, review of intermodal portable tank requirements, review of the requirements applicable to small quantities of hazardous materials in transport (limited quantities), classification of individual substances, requirements for bulk and non-bulk packagings used to transport hazardous materials, requirements for inhalation toxicity materials, and international harmonization of classification criteria and labeling.

The public is invited to attend without prior notification.

Documents

Copies of documents submitted to the thirteenth session of the UNSCOE meeting may be obtained from RSPA. Copies of UNSCOE proposals are available by linking to the UN Transport web site at http://www.itu.int/itudoc/un/editrans/dgdb/dgscomm.html. This site can be accessed through the RSPA Homepage at http://www.volpe.dot.gov/ohm. Documents and a summary of U.S. positions may also be ordered by contacting RSPA's Dockets Unit (202–366–5046).

Issued in Washington, DC, on July 14, 1997.

Robert A. McGuire,

Deputy Associate Administrator for Hazardous Materials Safety.

[FR Doc. 97–18988 Filed 7–17–97; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0377]

Proposed Information Collection Activity: Proposed Collection; Comment Request; Reinstatement

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs, is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on requirements relating to a claim for repurchase of loan.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before September 16, 1997.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20S52), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420. Please refer to ''OMB Control No. 2900–0377'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–8310 or FAX (202) 275–4884.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C., 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Claim for Repurchase of Loan, VA Form 26–8084.

OMB Control Number: 2900–0377.

Type of Review: Extension of a currently approved collection.

Abstract: Under 38 CFR 36.4600(d), the holder of a delinquent vendee account is legally entitled to repurchase of the loan by VA when the loan has been continuously in default for 3 months and the amount of the delinquency equals or exceeds the sum of 2 monthly installments. When requesting repurchase of a loan, the holder uses VA Form 26–8084. Upon receipt of a holder's VA Form 26–8084, the supporting documents are examined to see that all of the documents required have been submitted and that they are sufficient to complete the repurchase. VA Form 26–8084 is compared with the settlement sheet prepared when the loan was sold and examined closely to establish that there are no errors in the holder's methods of computation. Following repurchase by VA, the obligor(s) are notified in writing that VA has repurchased the loan, and the vendee account is serviced and maintained by VA thereafter.

Affected Public: Business or other for-profit.

Estimated Annual Burden: 421 hours.

Estimated Average Burden Per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 842.

Dated: June 27, 1997.

By direction of the Secretary.

Sandra S. McIntyre,

Management Analyst, Information Management Service.

[FR Doc. 97–18937 Filed 7–17–97; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0455]

Proposed Information Collection Activity: Proposed Collection; Comment Request; Reinstatement

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs, is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement, without change, of a previously approved collection for which approval has expired, and allow 60 days for public comment in response to the notice. This notice solicits comments on requirements relating to VBA's equal opportunity compliance review report.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before September 16, 1997.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20S52), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420. Please refer to ''OMB Control No. 2900–0455'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–8310 or FAX (202) 275–4884.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Public Law 104–13; 44 U.S.C., 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Equal Opportunity Compliance Review Report, VA Form 20–8734, and Supplement to Equal Opportunity Compliance Review Report, VA Form 20–8734a.

OMB Control Number: 2900–0455.

Type of Review: Reinstatement, without change, of a previously approved collection for which approval has expired.

Abstract: Executive Order 12250, Leadership and Coordination of Nondiscrimination Laws, delegated authority to the Attorney General to coordinate the implementation and enforcement by Executive agencies of various equal opportunity laws. Government-wide guidelines issued by the U.S. Department of Justice (DOJ) in 28 CFR 42.406 instructs funding agencies to ''provide for the collection of data and information from applicants for and recipients of Federal assistance sufficient to permit effective enforcement of Title VI.'' Executive, Order 12250 extended the delegation to cover Title IX of the Education Amendments of 1972, and Section 504 of the Rehabilitation Act of 1973, as amended.

VA's requirements to effectuate our external civil rights requirements are contained on 38 CFR, Part 18. These regulations, in part, provide that the responsible agency official or designee shall from time to time review the practices of recipients to determine whether they are complying with the equal opportunity provisions. VA Form 20–8734 is used to gather information from post-secondary proprietary schools below college level. The information is used to assure that VA Federally-funded programs are in compliance with equal opportunity laws. VA Form 20–8734a, is used to gather information from students and instructors at post-secondary proprietary schools below college level. The information is used to assure equal access and equal treatment to participants in VA Federally-funded programs.

Education Compliance Survey Specialists in VA field stations use VA Forms 20–8734 and 20–8734a during regular scheduled educational compliance survey visits, as well as during investigations of equal opportunity complaints, to identify areas which may indicate whether there is disparate treatment of members of protected groups. The information obtained on these forms is analyzed and maintained on file at the regional office. If this information were not collected, VA would be unable to carry out its civil rights enforcement responsibilities established in the DOJ's instructions.

Affected Public: Individual, or households and Business or other for-profit.

Estimated Annual Burden and Average Burden Per Respondent: Based on past experience, VBA estimates that 76 interviews will be conducted with recipients using VA Form 20–8734 at an average of 1 hour and 45 minutes per interview (133 hours). This includes one hour for an interview with the principal facility official, plus 45 minutes for reviewing records and reports and touring the facility. It is also estimated that 76 interviews will be conducted with students using VA Form 20–8734a at an average of 30 minutes per interview (38 hours) and with instructors at an average of 30 minutes per interview (38 hours) with a total of 76 hours. Interviews are also conducted with 76 students without instructors at an average time of 30 minutes.

VBA estimates that it will take 1 hour to conduct an interview with the recipients (76 hours) and 30 minutes with the instructors (38 hours). The total number of hours for interviewing recipients and instructors are estimated at 114.

Frequency of Response: On occasion.

Estimated Number of Respondents: 228.

Dated: June 27, 1997.

By direction of the Secretary.

Sandra S. McIntyre,

Management Analyst, Information Management Service.

[FR Doc. 97–18938 Filed 7–17–97; 8:45 am]

BILLING CODE 8320–01–P

federal register

Friday
July 18, 1997

Part II

Environmental Protection Agency

40 CFR Part 50

National Ambient Air Quality Standards for Particulate Matter; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[AD–FRL–5725–2]

RIN 2060–AE66

National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document describes EPA's decision to revise the national ambient air quality standards (NAAQS) for particulate matter (PM) based on its review of the available scientific evidence linking exposures to ambient PM to adverse health and welfare effects at levels allowed by the current PM standards. The current primary PM standards are revised in several respects: Two new $PM_{2.5}$ standards are added, set at 15 μg/m^3, based on the 3-year average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors, and 65 μg/m^3, based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area; and the current 24-hour PM_{10} standard is revised to be based on the 99th percentile of 24-hour PM_{10} concentrations at each monitor within an area. The new suite of primary standards will provide increased protection against a wide range of PM-related health effects, including premature mortality and increased hospital admissions and emergency room visits, primarily in the elderly and individuals with cardiopulmonary disease; increased respiratory symptoms and disease, in children and individuals with cardiopulmonary disease such as asthma; decreased lung function, particularly in children and individuals with asthma; and alterations in lung tissue and structure and in respiratory tract defense mechanisms. The current secondary standards are revised by making them identical in all respects to the new suite of primary standards. The new secondary standards, in conjunction with a regional haze program, will provide appropriate protection against PM-related public welfare effects including soiling, material damage, and visibility impairment. In conjunction with the new $PM_{2.5}$ standards, a new reference method has been specified for monitoring PM as $PM_{2.5}$.

EFFECTIVE DATE: This action is effective September 16, 1997.

ADDRESSES: A docket containing information relating to the EPA's review of the PM primary and secondary standards (Docket No. A–95–54) is available for public inspection in the Central Docket Section of the U.S. Environmental Protection Agency, South Conference Center, Rm. 4, 401 M St., SW., Washington, DC. This docket incorporates the docket established for the air quality Criteria Document (Docket No. ECAO–CD–92–0671). The docket may be inspected between 8 a.m. and 3 p.m., Monday through Friday, except legal holidays, and a reasonable fee may be charged for copying. The information in the docket constitutes the complete basis for the decision announced in this document. For the availability of related information, see ''SUPPLEMENTARY INFORMATION.''

FOR FURTHER INFORMATION CONTACT: John H. Haines, MD–15, Air Quality Strategies and Standards Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone: (919) 541–5533; e-mail: haines.john@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Related Final Rules on PM Monitoring

In a separate document published elsewhere in this issue of the **Federal Register**, EPA is amending its ambient air quality surveillance requirements (40 CFR part 58) and its ambient air monitoring reference and equivalent methods (40 CFR part 53) for PM.

Availability of Related Information

Certain documents are available from the U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. Available documents include:

(1) Air Quality Criteria for Particulate Matter (Criteria Document) (three volumes, EPA/600/P–95–001aF thru EPA/600/P–95–001cF, April 1996, NTIS #PB–96–168224, $234.00 paper copy).

(2) Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information (Staff Paper) (EPA–452/R–96–013, July 1996, NTIS #PB–97–115406, $47.00 paper copy and $19.50 microfiche). (Add a $3.00 handling charge per order.)

A limited number of copies of other documents generated in connection with this standard review, such as technical support documents pertaining to air quality, monitoring, and health risk assessment, can be obtained from: Environmental Protection Agency Library (MD–35), Research Triangle Park, NC 27711, telephone (919) 541–2777. These and other related documents are also available for inspection and copying in the EPA docket at the address under ''ADDRESSES,'' at the beginning of this document.

Electronic Availability

The Staff Paper and human health risk assessment support documents are available on the Agency's Office of Air Quality Planning and Standards' (OAQPS) Technology Transfer Network (TTN) Bulletin Board System (BBS) in the Clean Air Act Amendments area, under Title I, Policy/Guidance Documents. To access the bulletin board, a modem and communications software are necessary. To dial up, set your communications software to 8 data bits, no parity and one stop bit. Dial (919) 541–5742 and follow the on-screen instructions to register for access. After registering, proceed to choice ''<T> Gateway to TTN Technical Areas'', then choose ''<E> CAAA BBS''. From the main menu, choose ''<1> Title I: Attain/Maint of NAAQS'', then ''<P> Policy Guidance Documents.'' To access these documents through the World Wide Web, click on ''TTN BBSWeb'', then proceed to the Gateway to TTN Technical areas, as above. If assistance is needed in accessing the system, call the help desk at (919) 541–5384 in Research Triangle Park, NC.

Implementation Strategy For Revised Air Quality Standards

On Wednesday, July 16, 1997, President Clinton signed a memorandum to the Administrator specifying his goals for the implementation of the O_3 and PM standards. Attached to the President's memorandum is a strategy prepared by an interagency Administration group outlining the next steps that would be necessary for implementing these standards. The EPA will prepare guidance and proposed rules consistent with the President's memorandum. Copies of the Presidential document are available in paper copy by contacting the U.S. Environmental Protection Agency Library at the address under ''Availability of Related Information'' and in electronic form as discussed above in ''Electronic Availability.''

The following topics are discussed in this preamble:

I. Background
  A. Legislative Requirements
  B. Related Control Requirements
  C. Review of Air Quality Criteria and Standards for PM
  D. Summary of Proposed Revisions to the PM Standards
II. Rationale for the Primary PM Standards
  A. Introduction
  B. Need for Revision of the Current Primary PM Standards

C. Indicators of PM
D. Averaging Time of $PM_{2.5}$ Standards
E. Form of $PM_{2.5}$ Standards
F. Levels for the Annual and 24-Hour $PM_{2.5}$ Standards
G. Conclusions Regarding the Current PM_{10} Standards
H. Final Decisions on Primary PM Standards
III. Rationale for the Secondary Standards
A. Need for Revision of the Current SecondaryStandards
B. Decision on the Secondary Standards
IV. Other Issues
A. Consideration of Costs
B. Margin of Safety
C. Data Availability
D. 1990 Amendments
V. Revisions to 40 CFR Part 50, Appendix K—Interpretation of the PM NAAQS
A. $PM_{2.5}$ Computations and Data Handling Conventions
B. PM_{10} Computations and Data Handling Conventions
C. Changes that Apply to Both $PM_{2.5}$ and PM_{10} Computations
VI. Reference Methods for the Determination of Particulate Matter as PM_{10} and $PM_{2.5}$ in the Atmosphere
A. Revisions to 40 CFR Part 50, Appendix J—Reference Method for PM_{10}
B. 40 CFR Part 50, Appendix L—New Reference Method for $PM_{2.5}$
VII. Effective Date of the Revised PM Standards and Applicability of the Existing PM_{10} Standards
VIII. Regulatory and Environmental Impact Analyses
A. Executive Order 12866
B. Regulatory Flexibility Analysis
C. Impact on Reporting Requirements
D. Unfunded Mandates Reform Act
E. Environmental Justice
F. Submission to Congress and the Comptroller General
IX. Response to Petition for Administrator Browner's Recusal
X. References

I. Background

A. Legislative Requirements

Two sections of the Clean Air Act (Act) govern the establishment, review, and revision of NAAQS. Section 108 of the Act (42 U.S.C. 7408) directs the Administrator to identify certain pollutants which ''may reasonably be anticipated to endanger public health and welfare'' and to issue air quality criteria for them. These air quality criteria are to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air * * *.''

Section 109 of the Act (42 U.S.C. 7409) directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants identified under section 108 of the Act. Section 109(b)(1) of the Act defines a primary standard as one ''the attainment and maintenance of which in the judgment of the Administrator, based on [the] criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' The margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting, as well as to provide a reasonable degree of protection against hazards that research has not yet identified. Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, by selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that she finds may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The Act does not require the Administrator to establish a primary NAAQS at a zero-risk level, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Ass'n* v. *EPA*, 647 F.2d 1130, 1161–1162 (D.C. Cir.1980).

A secondary standard, as defined in section 109 (b)(2) of the Act, must ''specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on [the] criteria, [are] requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.'' Welfare effects as defined in section 302(h) of the Act (42 U.S.C. 7602(h)) include, but are not limited to, ''effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

Section 109(d)(1) of the Act requires periodic review and, if appropriate, revision of existing air quality criteria and NAAQS. Section 109(d)(2) of the Act requires appointment of an independent scientific review committee to review criteria and standards and recommend new standards or revisions of existing criteria and standards, as appropriate. The committee established under section 109(d)(2) of the Act is known as the Clean Air Scientific Advisory Committee (CASAC), a standing committee of EPA's Science Advisory Board.

B. Related Control Requirements

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the Act (42 U.S.C. 7410) and related provisions, States are to submit, for EPA approval, State implementation plans (SIP's) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with EPA, also administer the prevention of significant deterioration program (42 U.S.C. 7470–7479) for these pollutants. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants through the Federal Motor Vehicle Control Program under Title II of the Act (42 U.S.C. 7521–7574), which involves controls for automobile, truck, bus, motorcycle, nonroad engine, and aircraft emissions; the new source performance standards under section 111 of the Act (42 U.S.C. 7411); and the national emission standards for hazardous air pollutants under section 112 of the Act (42 U.S.C. 7412).

C. Review of Air Quality Criteria and Standards for PM

Particulate matter is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes. Particles originate from a variety of anthropogenic stationary and mobile sources as well as from natural sources. Particles may be emitted directly or formed in the atmosphere by transformations of gaseous emissions such as sulfur oxides (SO_x), nitrogen oxides (NO_x), and volatile organic compounds (VOC). The chemical and physical properties of PM vary greatly with time, region, meteorology, and source category, thus complicating the assessment of health and welfare effects.

The last review of PM air quality criteria and standards was completed in July 1987 with notice of a final decision to revise the existing standards published in the **Federal Register** (52 FR 24854, July 1, 1987). In that decision, EPA changed the indicator for PM from total suspended particles (TSP) to

PM_{10}.[1] Identical primary and secondary PM_{10} standards were set for two averaging times: 50 μg/m³, expected annual arithmetic mean, averaged over 3 years, and 150 μg/m³, 24-hour average, with no more than one expected exceedance per year.[2]

The EPA initiated this current review of the air quality criteria and standards for PM in April 1994 by announcing its intention to develop a revised Air Quality Criteria Document for Particulate Matter (henceforth, the ''Criteria Document''). Thereafter, the EPA presented its plans for review of the criteria and standards for PM under a highly accelerated, court-ordered schedule[3] at a public meeting of the CASAC in December 1994. Several workshops were held by EPA's National Center for Environmental Assessment (NCEA) to discuss important new health effects information in November 1994 and January 1995. External review drafts of the Criteria Document were made available for public comment and were reviewed by CASAC at public meetings held in August and December 1995 and February 1996. The CASAC came to closure in its review of the Criteria Document, advising the Administrator in a March 15, 1996 closure letter (Wolff, 1996a) that ''although our understanding of the health effects of PM is far from complete, a revised Criteria Document which incorporates the Panel's latest comments will provide an adequate review of the available scientific data and relevant studies of PM.'' CASAC and public comments from these meetings, and from subsequent written comments and the closure letter, were incorporated as appropriate in the final Criteria Document (U.S. EPA, 1996a).

External review drafts of a Staff Paper prepared by the Office of Air Quality Planning and Standards (OAQPS), Review of the National Ambient Air Quality Standards for Particulate Matter: Assessment of Scientific and Technical Information (henceforth, the ''Staff Paper''), were made available for public comment and were reviewed by CASAC at public meetings in December 1995 and May 1996.[4] The CASAC came to closure in its review of the Staff Paper, advising the Administrator in a June 13, 1996 closure letter (Wolff, 1996b) that ''the Staff Paper, when revised, will provide an adequate summary of our present understanding of the scientific basis for making regulatory decisions concerning PM standards.'' CASAC and public comments from these meetings, subsequent written comments, and the CASAC closure letter were incorporated as appropriate in the final Staff Paper (U.S. EPA, 1996b).

On November 27, 1996, EPA announced its proposed decision to revise the NAAQS for PM (61 FR 65638, December 13, 1996) (hereafter ''proposal'') as well as its proposed decision to revise the NAAQS for ozone (O_3)(61 FR 65716, December 13, 1996). In the proposal, EPA identified proposed revisions, based on the air quality criteria for PM, and solicited public comments on alternative primary standards and on the proposed forms of the standards.

To ensure the broadest possible public input on the PM and O_3 proposals, EPA took extensive and unprecedented steps to facilitate the public comment process beyond the normal process of providing an opportunity to request a hearing and receiving written comments submitted to the rulemaking docket. The EPA established a national toll-free telephone hotline to facilitate public comments on the proposed revisions to the PM and O_3 NAAQS, and on related notices dealing with the implementation of revised PM and O_3 standards, as well as a system for the public to submit comments on the proposals electronically via the Internet. Over 14,000 calls and over 4,000 electronic mail messages were received through these channels. The public could also access key supporting documents (including the Criteria Document, Staff Paper, related technical documents and fact sheets) via the Internet.

The EPA also held several public hearings and meetings across the country to provide direct opportunities for public comment on the proposed revisions to the PM and O_3 NAAQS and to disseminate information to the public about the proposed standard revisions. On January 14 and 15, 1997, EPA held concurrent, 2-day public hearings in Boston, MA, Chicago, IL, and Salt Lake City, UT. A fourth public hearing, which focused primarily on PM monitoring issues, was held in Durham, NC on January 14, 1997. Over 400 citizens and organizations testified during these public hearings. EPA also held two national satellite telecasts to answer questions on the standards and participated in meetings sponsored by the Air and Waste Management Association on the proposed revisions to the standards at more than 10 locations across the country. Beyond that, several EPA regional offices held public meetings and workshops and participated in hearings that States and cities held around the country.

As a result of this intensive effort to solicit public input, over 50,000 written and oral comments were received on the proposed revisions to the PM NAAQS by the close of the public comment period on March 12, 1997. Major issues raised in the comments are discussed throughout the preamble of this final decision. A comprehensive summary of all significant comments, along with EPA's response to such comments (hereafter ''Response to Comments''), can be found in the docket for this rulemaking (Docket No. A–95–54).

The principal focus of this current review of the air quality criteria and standards for PM is on recent epidemiological evidence reporting associations between ambient concentrations of PM and a range of serious health effects. Particular attention has been given to several size-specific classes of particles, including PM_{10} and the principal fractions of PM_{10}, referred to as the fine ($PM_{2.5}$)[5] and coarse ($PM_{10-2.5}$)[6] fractions. As discussed in the Criteria Document, fine and coarse fraction particles can be differentiated by their sources and formation processes and their chemical and physical properties, including behavior in the atmosphere. Detailed discussions of atmospheric formation, ambient concentrations, and health and welfare effects of PM, as well as quantitative estimates of human health risks associated with exposure to PM, can be found in the Criteria Document and in the Staff Paper.

[1] PM_{10} refers to particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers. Technical details further specifying the measurement of PM_{10} are contained in 40 CFR part 50, Appendices J and M.

[2] A more complete history of the PM NAAQS is presented in section II.B of the OAQPS Staff Paper, Review of National Ambient Air Quality Standards for Particulate Matter: Assessment of Scientific and Technical Information (U.S. EPA, 1996b).

[3] A court order entered in *American Lung Association* v. *Browner,* CIV–93–643–TUC–ACM (D. Ariz.,October 6, 1994), as subsequently modified, requires publication of EPA's final decision on the review of the PM NAAQS by July 19, 1997.

[4] The Staff Paper evaluates policy implications of the key studies and scientific information in the Criteria Document, identifies critical elements that EPA staff believes should be considered, and presents staff conclusions and recommendations of suggested options for the Administrator's consideration.

[5] $PM_{2.5}$ refers to particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers, as further specified in 40 CFR part 50, Appendix L in this document.

[6] $PM_{10-2.5}$ refers to those particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers but greater than 2.5 micrometers. In other words, it refers to the inhalable particles that remain if fine ($PM_{2.5}$) particles are removed from a sample of PM_{10} particles.

D. Summary of Proposed Revisions to the PM Standards

For reasons discussed in the proposal, the Administrator proposed to revise the current primary standards for PM (as indicated by PM_{10}), by adding two new primary $PM_{2.5}$ standards set at 15 μg/m³, annual mean, and 50 μg/m³, 24-hour average. The proposed annual $PM_{2.5}$ standard would be based on the 3-year average of the annual arithmetic mean $PM_{2.5}$ concentrations, spatially averaged across an area. The proposed 24-hour $PM_{2.5}$ standard would be based on the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area. The proposal solicited comment on two alternative approaches for selecting the levels of $PM_{2.5}$ standards. The Administrator also proposed to revise the current 24-hour primary PM_{10} standard of 150 μg/m³ by replacing the 1-expected-exceedance form with a 98th percentile form, averaged over 3 years at each monitor within an area, solicited comment on an alternative proposal to revoke the 24-hour PM_{10} standard, and proposed to retain the current annual primary PM_{10} standard of 50 μg/m³. The proposal also solicited comment on proposed revisions to 40 CFR part 50, Appendix K to establish new data handling conventions for calculating 98th percentile values and spatial averages, revisions to 40 CFR part 50, Appendix J to modify the reference method for monitoring PM as PM_{10}, and a proposed new reference method for monitoring PM as $PM_{2.5}$ (40 CFR part 50, Appendix L).

With regard to the secondary standards, the Administrator proposed to revise the current secondary standards by making them identical to the suite of proposed primary standards, in conjunction with the establishment of a regional haze program under section 169A of the Act.

II. Rationale for the Primary Standards

A. Introduction

1. *Overview.* This document presents the Administrator's final decisions regarding the need to revise the current primary ambient air quality standards for PM, and, more specifically, regarding the establishment of new annual and 24-hour $PM_{2.5}$ primary standards and revisions to the form of the current 24-hour PM_{10} primary NAAQS. These decisions are based on a thorough review, in the Criteria Document, of the latest scientific information on known and potential human health effects associated with exposure to PM at levels typically found in the ambient air. These decisions also take into account:

(1) Staff Paper assessments of the most policy-relevant information in the Criteria Document, upon which staff recommendations for new and revised primary standards are based.

(2) CASAC advice and recommendations, as reflected in discussions of drafts of the Criteria Document and Staff Paper at public meetings, in separate written comments, and in the CASAC's closure letters to the Administrator.

(3) Public comments received during the development of these documents, either in connection with CASAC meetings or separately.

(4) Extensive public comments received on the proposed decisions regarding the primary PM standards.

After taking this information and comments into account, and for the reasons discussed below in this unit, the Administrator concludes that revisions to the current primary standards to provide increased public health protection against a variety of health risks are appropriate. More specifically, the Administrator has determined that it is appropriate to establish new annual and 24-hour $PM_{2.5}$ standards, to revise the current 24-hour PM_{10} standard, and to retain the current annual PM_{10} standard. As discussed more fully below in this unit, the rationale for the final decisions regarding the PM primary NAAQS includes consideration of:

(1) Health effects information, and alternative views on the appropriate interpretation and use of the information, as the basis for judgments about the risks to public health presented by population exposures to ambient PM.

(2) Insights gained from a quantitative risk assessment conducted to provide a broader perspective for judgments about protecting public health from the risks associated with PM exposures.

(3) Specific conclusions regarding the need for revisions to the current standards and the elements of PM standards (i.e., indicator, averaging time, form, and level) that, taken together, would be appropriate to protect public health with an adequate margin of safety.

As with virtually any policy-relevant scientific research, there is uncertainty in the characterization of health effects attributable to exposure to ambient PM. As discussed in the proposal, however, there is now a greatly expanded body of health effects information as compared with that available during the last review of the PM standards. Moreover, the recent evidence on PM-related health effects has undergone an unusually high degree of scrutiny and reanalysis over the past several years, beginning with a series of workshops held early in the review process to discuss important new information. A number of opportunities were provided for public comment on successive drafts of the Criteria Document and Staff Paper, as well as for intensive peer review of these documents by CASAC at several public meetings attended by many knowledgeable individuals and representatives of interested organizations. In addition, there have been a number of important scientific conferences, symposia, and colloquia on PM issues, sponsored by the EPA and others, in the U.S. and abroad, during this period. While significant uncertainties exist, the review of the health effects information has been thorough and deliberate. In the judgment of the Administrator, this intensive evaluation of the scientific evidence has provided an adequate basis for regulatory decision making at this time, as well as for the comprehensive research needs document recently developed by EPA, and reviewed by CASAC and others, for improving our future understanding of the relationships between ambient PM exposures and health effects.

The health effects information and human risk assessment were summarized in the proposal and are only briefly outlined below in this unit. Subsequent units provide a more complete discussion of the Administrator's rationale, in light of key issues raised in public comments, for concluding that it is appropriate to revise the current primary standards (Unit II.B. of this preamble) and to revise the specific elements of the standards including indicator (Unit II.C. of this preamble); averaging time, form, and level of new $PM_{2.5}$ standards (Units II.D., II.E., and II.F. of this preamble); and averaging time, form, and level of revised PM_{10} standards (Unit II.G. of this preamble).

2. *Summary of the health effects evidence.* In brief, since the last review of the PM criteria and standards, the most significant new evidence on the health effects of PM is the greatly expanded body of community epidemiological studies. The Criteria Document stated that these recent studies provide ''evidence that serious health effects (mortality, exacerbation of chronic disease, increased hospital admissions, etc.) are associated with exposures to ambient levels of PM found in contemporary U.S. urban airsheds even at concentrations below current U.S. PM standard'' (U.S. EPA, 1996a; p. 13-1). Although a variety of

responses to constituents of ambient PM have been hypothesized to contribute to the reported health effects, the relevant toxicological and controlled human studies published to date have not identified any accepted mechanism(s) that would explain how such relatively low concentrations of ambient PM might cause the health effects reported in the epidemiological literature.

Unit II.A. of the proposal further outlines key information contained in the Criteria Document, Chapters 10-13, and the Staff Paper, Chapter V, on the known and potential health effects associated with airborne PM, alone and in combination with other pollutants that are routinely present in the ambient air. The information highlighted there summarizes:

(1) The nature of the effects that have been reported to be associated with ambient PM, which include premature mortality, aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions and emergency room visits, school absences, work loss days, and restricted activity days), changes in lung function and increased respiratory symptoms, changes to lung tissues and structure, and altered respiratory defense mechanisms.

(2) Sensitive subpopulations that appear to be at greater risk to such effects, specifically individuals with respiratory disease and cardiovascular disease and the elderly (premature mortality and hospitalization), children (increased respiratory symptoms and decreased lung function), and asthmatic children and adults (aggravation of symptoms).

(3) An integrated evaluation of the health effects evidence, with an emphasis on the key issues raised in assessing community epidemiological studies, including alternative interpretations of the evidence, both for individual studies and for the evidence as a whole.

(4) The PM fractions of greatest concern to health.

The summary in the proposal will not be repeated here. EPA emphasizes that the final decisions on these standards take into account the more comprehensive and detailed discussions of the scientific information on these issues contained in the Criteria Document and Staff Paper, which were reviewed by the CASAC and the public.

3. *Key insights from the risk assessment.* The Staff Paper presents the results of a quantitative assessment of health risks for two example cities, including risk estimates for several categories of health effects associated with: existing PM air quality levels, projected PM air quality levels that would occur upon attainment of the current PM_{10} standards, and projected PM air quality levels that would occur upon attainment of alternative $PM_{2.5}$ standards. The risk assessment is intended as an aid to the Administrator in judging which alternative PM NAAQS would reduce risks sufficiently to protect public health with an adequate margin of safety, recognizing that such standards will not be risk-free. The risk assessment is described more fully in the Staff Paper and summarized in the proposal. Related technical reports and updates[7] have been placed in the docket (Abt Associates, 1996a,b; 1997a,b).

EPA emphasizes that it places greater weight on the overall conclusions derived from the studies—that PM air pollution is likely causing or contributing to significant adverse effects at levels below those permitted by the current standards—than on the specific concentration-response functions and quantitative risk estimates derived from them. These quantitative risk estimates include significant uncertainty and, therefore, should not be viewed as demonstrated health impacts. EPA believes, however, that they do represent reasonable estimates as to the possible extent of risk for these effects given the available information. Keeping in mind the important uncertainties inherent in any such analyses, the key insights from the risk assessment that are most pertinent to the current decision include:

(1) Fairly wide ranges of estimates of the incidence of PM-related mortality and morbidity effects and risk reductions associated with attainment of alternative standards were calculated for the two locations analyzed when the effects of key uncertainties and alternative assumptions were considered. Significantly, the combined analysis for these two cities alone found that the risk remaining after attaining the current PM_{10} standards was on the order of hundreds of premature deaths each year, hundreds to thousands of respiratory-related hospital admissions, and tens of thousands of additional respiratory related symptoms in children.

(2) Based on the results from the sensitivity analyses of key uncertainties and the integrated uncertainty analyses, the single most important factor influencing the uncertainty associated with the risk estimates is whether or not a threshold concentration exists below which PM-associated health risks are not likely to occur.

(3) Over the course of a year, the few peak 24-hour $PM_{2.5}$ concentrations appear to contribute a relatively small amount to the total health risk posed by the entire air quality distribution as compared to the aggregated risks associated with the low to mid-range concentrations.

(4) There is greater uncertainty about both the existence and the magnitude of estimated excess mortality and other effects associated with PM exposures as one considers increasingly lower concentrations approaching background levels.

B. Need for Revision of the Current Primary PM Standards

1. *Introduction.* The overarching issue in the present review of the primary NAAQS is whether, in view of the advances in scientific knowledge reflected in the Criteria Document and Staff Paper, the existing PM standards should be revised and, if so, what revised or new standards would be appropriate. The concluding section of the integrative synthesis of health effects information in the Criteria Document, which CASAC characterized as EPA's ''best ever example of a true integrative summary of the state of knowledge about the health effects of airborne PM,'' (Wolff, 1996b) provides the following summary of the science with respect to this issue:

> The evidence for PM-related effects from epidemiological studies is fairly strong, with most studies showing increases in mortality, hospital admissions, respiratory symptoms, and pulmonary function decrements associated with several PM indices. These epidemiological findings cannot be wholly attributed to inappropriate or incorrect statistical methods, misspecification of concentration-effect models, biases in study design or implementation, measurement errors in health endpoint, pollution exposure, weather, or other variables, nor confounding of PM effects with effects of other factors. While the results of the epidemiological studies should be interpreted cautiously, they nonetheless provide ample reason to be concerned that there are detectable health effects attributable

[7] The risk assessment results that appear in the Staff Paper and are summarized in the proposal have been updated to include analyses of the particular forms of standard alternatives contained in the proposal and to correct estimates for one effects category (mortality from long-term exposure) to reflect the actual statistics used in the study upon which they were based (Pope et al., 1995). The corrections, which cumulatively reduce estimates of mortality associated with long-term exposures by 20 to 35%, have no effect on risk estimates for mortality associated with short-term exposures or the estimates for any other effects. Because the key sensitivity analyses that provide additional insights regarding thresholds, copollutants, averaging time and related issues involved the short-term exposure studies, none of these results are affected by changes to the long-term exposure risk estimates.

to PM at levels below the current NAAQS. [U.S. EPA, 1996a, p. 13-92]

Given the nature of the health effects in question, this finding, which is based on a large number of studies that used PM_{10} measurements, as well as studies using other indicators of PM, clearly indicates that revision of the current PM NAAQS is appropriate. Quite apart from the issue of whether PM_{10} should be the sole indicator for the PM NAAQS, the extensive PM epidemiological data base provides evidence of serious health effects (e.g., mortality, exacerbation of chronic disease, increased hospital admissions) in sensitive populations (e.g., the elderly, individuals with cardiopulmonary disease), as well as significant adverse health effects (e.g., increased respiratory symptoms, school absences, and lung function decrements) in children. Moreover, these effects associations are observed in areas or at times when the levels of the current PM_{10} standards are met. Although the increase in relative risk is small for the most serious outcomes, EPA believes it is significant from an overall public health perspective, because of the large number of individuals in sensitive populations that are exposed to ambient PM, as well as the significance of the health effects involved (U.S. EPA, 1996a, p. 1-21). The results of the two-city PM risk assessment reinforce these conclusions regarding the significance of the public health risk—even under a scenario in which the current PM_{10} standards are attained.

While the lack of demonstrated mechanisms that explain the extensive body of epidemiological findings is an important caution, which presents difficulties in providing an integrated assessment of PM health effects research, a number of potential mechanisms have been hypothesized in the recent literature (U.S. EPA, 1996b; p. V-5 to V-8; appendix D). Moreover, qualitative information from laboratory studies of the effects of particle components at high concentrations and dosimetry considerations suggest that the kinds of effects observed in community studies (e.g., respiratory- and cardiovascular-related responses) are at least plausibly related to inhalation of PM.[8] Indeed, as discussed in the Criteria Document and section V.E of the Staff Paper, the consistency of the results of the epidemiological studies from a large number of different locations and the coherent nature of the observed effects[9] are suggestive of a likely causal role of ambient PM in contributing to the reported effects.

2. *Comments on scientific basis for revision.* A majority of the public comments received on the proposal agreed that, based on the available scientific information, the current PM_{10} standards are not of themselves sufficient to protect public health and it would be appropriate to revise them. Included in those calling for revisions to the current standards are many public health professionals, including numerous medical doctors and academic researchers. For example, a group of 27 members of the scientific and medical community recognized as having substantial expertise in conducting research on the health effects of air pollution stated:

> Health studies conducted in the U.S. and around the world have demonstrated that levels of particulate and ozone air pollution below the current U.S. National Air Quality Standards exacerbate serious respiratory disease and contribute to early death. A large body of scientific and medical evidence clearly indicates that the current NAAQS are not sufficiently protective of public health. [Thurston, 1997]

Similar conclusions were reached in a letter signed by more than 1,000 scientists, clinicians, researchers, and other health care professionals (Dickey, 1997). The cosigners to this letter argued that tens of thousands of hospital visits and premature deaths could be prevented with the proposed air quality standard revisions. In fact, these commenters argued that even stronger standards than those proposed by EPA are needed to protect the health of the most vulnerable residents of our communities.

A number of State and local government authorities also submitted comments in support of adopting new air quality standards for fine particulate matter. The commenters concurred with conclusions reached through the EPA's peer review process that the PM standards should be revised to protect public health. A number of these commenters suggested that the standards proposed by EPA should be even stronger, while several other State agencies recommended that EPA adopt $PM_{2.5}$ standards, but at less stringent levels. A number of the comments from states supporting even stronger standards acknowledged the lack of demonstrated mechanism(s) and other uncertainties but stressed the strength of the other evidence in urging EPA to set protective standards.

Many comments were also received from representatives of environmental or community health organizations that supported the adoption of air quality standards for $PM_{2.5}$. These commenters agreed with EPA's finding that a large body of compelling evidence demonstrates that exposure to particulate matter pollution, in general, is associated with premature death, aggravation of heart and lung diseases, increased respiratory illness and reduced lung function. They agreed with EPA that these studies present a consistent and coherent relationship between exposure to PM and both mortality and various measures of morbidity. However, the majority of these commenters argued that EPA's proposed standards for $PM_{2.5}$ were inadequate and recommended adoption of more stringent levels of the 24-hour and/or annual air quality standards for $PM_{2.5}$. Many of these commenters also urged EPA to revise the NAAQS for PM_{10} to be more protective of public health. These commenters based their recommendations on the findings of the studies that were reviewed in the preparation of the Criteria Document and Staff Paper. One commenter used results from five of these studies as the basis for recommending $PM_{2.5}$ standards of 10 $\mu g/m^3$ (annual) and 18 $\mu g/m^3$ (24-hour) (Dockery et al., 1993; Pope et al., 1995; Schwartz et al., 1996; Schwartz et al., 1994; Thurston et al., 1994). The commenters agreed with EPA on the significance of these studies' results and the need to revise the PM standards, while differing with EPA's interpretation of the findings for purposes of developing the proposed PM standards.

Several commenters made reference to the conclusions of a number of international scientific panels regarding the health effects of exposure to airborne particulate matter—the British Expert Panel on Air Quality Standards, the British Committee on the Medical Effects of Air Pollutants, the World Health Organization, the Canadian Ministry of Environment, Lands and Parks, and the Health Council of the Netherlands -- and argued that all these panels found that PM concentrations equivalent to the current U.S. standards for PM_{10} are not protective of human health and made recommendations for greater protection. One commenter noted that the findings of the British Health Panel have resulted in a British

[8] As discussed more fully below in this unit, epidemiological studies alone cannot be used to demonstrate mechanisms of action, but they can provide evidence useful in making inferences with regard to causal relationships (U.S. EPA, 1996b, p. V-9).

[9] As noted in the proposal, the kinds of effects observed in the epidemiological studies are logically related. For example, the association of PM with mortality is mainly linked to respiratory and cardiovascular causes, which is coherent with observed PM associations with respiratory and cardiovascular hospital admissions and respiratory symptoms. Further, similar categories of effects are seen in long- and short-term exposure studies.

proposal to adopt a 24-hour PM_{10} standard of 50 μg/m³, which is one-third the level of the current U.S. NAAQS.

In these comments, some toxicological studies were cited as providing evidence for toxicity of particulate pollution. These commenters disagreed with arguments that PM standards cannot be adopted due to a lack of a sufficient understanding of the biological mechanism of injury. The commenters argued that there is sufficient evidence that particulate pollution is associated with adverse health effects to make it inappropriate to delay the establishment of standards while further studies are undertaken. This group of commenters was also critical of arguments against the establishment of additional PM standards based on the possibility of confounding by other pollutants, and urged that more attention be paid instead to the possible additive or synergistic effects of multiple pollutant exposures.

In general, the EPA agrees with these commenters' arguments regarding the need to revise the PM standards. The scientific studies cited by these commenters were the same studies used in the development of the Criteria Document and the Staff Paper, and the EPA agrees that there is a sufficient body of evidence that the current NAAQS for PM are not adequately protective of the public health. For reasons detailed in Unit II.F. of this preamble and in the Response to Comments, EPA disagrees with aspects of these commenters' views on the level of protection that is appropriate and supported by the available scientific information.

Another body of commenters, including almost all commenters representing businesses and industry associations, many local governmental groups and private citizens, and some States opposed revising the standards. Many of these commenters argued that the available scientific evidence does not provide an adequate basis for revising the current standards. The central arguments made by these commenters can be divided into two categories: (1) General comments on the appropriateness of relying on the epidemiological evidence for making regulatory decisions, and (2) more specific comments challenging EPA's appraisal of the consistency and coherence of the available information, EPA's conclusions regarding causality, and the use of these studies for risk assessment and decisions on whether to revise the standards. While EPA has included comprehensive responses to these comments in the Response to Comments, certain key points are summarized below in this unit.

a. *General comments on the use of epidemiological studies.* The first category of comments was largely derived from ad hoc panels of occupational and other epidemiological experts, consulting groups, and individual consultants. Most of these individuals and groups commented on the use of epidemiology in reaching scientific and policy conclusions primarily from an occupational or hazard assessment perspective, in contrast to the perspective of the review of ambient PM criteria and standards, where the use of community air pollution epidemiological studies are central. Citing accepted criteria used in evaluating epidemiological studies to assess the likelihood of causality (most notably those of Sir Austin Bradford Hill, 1965), these commenters argued that in the absence of a demonstrated biological mechanism, the relative risks of effects in the PM epidemiological studies are too low (less than values variously cited as 1.5 to 2.0) to reach any conclusions regarding causality or to form the basis for regulations. In general, the commenters applied these criteria to a subset of studies evaluated in the Criteria Document, including as few as two long-term exposure studies (EOP Group) (API, 1997), a group of 9 selected studies (Greenland panel) (API, 1997), those studies cited in the proposal (AIHC, 1997), or as many as 23 selected short-term exposure studies examined in a recently published review paper (Gamble and Lewis, 1996).

Based on a careful review of these comments, EPA notes a number of limitations in these commenters' evaluations of the epidemiological studies that they considered, as discussed in detail in the Response to Comments. In summary, EPA notes that these commenters provided scientific advice and conclusions that are in substantial disagreement with the conclusions of the review reflected in the Criteria Document and Staff Paper. EPA stands behind the scientific conclusions reached in these documents regarding the appropriate use of the available community epidemiological studies. These documents were the product of an extended public process that included conducting public workshops involving the leading researchers in the field, drafts of the Criteria Document and Staff Paper providing opportunities for public scrutiny and comment on, and, not least, receiving the advice of an independent panel of air pollution experts, including epidemiologists.

EPA clearly specified the key criteria by which it evaluated the available epidemiological studies in section 12.1.2 of the Criteria Document, with substantial reliance on those specified by Hill (1965). In rejecting results with relative risks less than 1.5 to 2 as meaningful absent demonstrated biological mechanisms, the commenters fail to note that Hill and other expert groups (U.S. DHEW, 1964) have emphasized that no one criterion is definitive by itself, nor is it necessary that all be met in order to support a determination of causality (U.S. EPA, 1996a, p. 12-3).

With respect to biological plausibility, Hill noted that ''this is a feature I am convinced we cannot demand. What is biologically plausible depends upon the biological knowledge of the day'' (Hill, 1965). This statement is clearly pertinent to the toxicological and mechanistic understanding of the effects of PM and associated air pollutants, especially at lower concentrations. It is also important to stress that while the mechanistic evidence published as of the time the Criteria Document closed does not provide quantitative support for the epidemiological results, neither can such limited evidence refute these findings. It is also important to stress that our understanding of biological mechanisms for PM pollution effects is not sufficient to explain the effects observed at much higher concentrations in air pollution episodes, for which causality is generally accepted. Moreover, the toxicological literature has only recently begun to examine animal models (or controlled human studies) that might reflect the sensitive populations in question (the elderly, individuals with chronic respiratory and cardiovascular disease) or that adequately reproduce all of the physico-chemical properties of particles in the ambient atmosphere. In short, the absence of evidence of a particular mechanism is hardly proof that there are no mechanisms that could explain the effects observed so consistently in the epidemiological studies. The absence of biological mechanisms did not deter CASAC from recommending revisions to the PM standards in 1982, 1986, and again in 1996.

While Hill appropriately emphasized the strength of the association as important (e.g., size of the relative risk), he also pointed out that ''We must not be too ready to dismiss a cause-and-effect hypothesis merely on the ground that the observed association appears to be slight. There are many occasions in medicine when this in truth is so'' (Hill, 1965). EPA believes that the effects of air pollution containing PM is such a

case. Unlike the ''textbook'' examples of unlikely significant associations provided by some commenters (e.g., ice cream consumption correlated with heat stroke), the abundant epidemiological literature on combustion particles documents numerous occasions in which single short-term episodes of high air pollution produced unequivocally elevated relative risks. For the week of the well documented 1952 London air pollution episode, for example, the relative risk of mortality for all causes was 2.6, while the relative risk for bronchitis mortality was as high as 9.3 (Ministry of Health, 1954). Hospital admissions also increased by more than a factor of two. British epidemiologists in the 1950s concluded that increased mortality was likely when PM (as mass calibrated British Smoke <4.5 µm in aerodynamic diameter) exceeded 500 $\mu g/m^3$ (Martin and Bradley, 1960). This is only about a factor of 3 higher than that allowed by the current PM standard. Unlike the ''textbook'' and other unlikely statistical associations noted by some commenters, where the only evidence is for low relative risk, clear and convincing links between high-level PM concentrations and mortality and morbidity buttress the findings of similar associations at much lower PM concentrations as suggested in the more recent epidemiological literature.

These commenters also appear to ignore several epidemiological studies conducted at low PM concentrations in U.S. and European cities, including both short- and long-term exposures to PM air pollution, that find statistically significant relative risks of respiratory symptom categories in children in the range of 1.5 to 5 (Schwartz et al., 1994; Pope and Dockery, 1992; Braun-Fahrlander et al., 1992; Dockery et al., 1989; Dockery et al., 1996). Concentrations in these studies extend from moderately above to well below those permitted by the current PM_{10} standards. While, as noted in the proposal, most of the recent epidemiological studies of mortality and hospital admissions report comparatively small relative risks, the findings of relative risks well in excess of the 1.5 to 2 criterion noted by commenters for earlier studies of high PM episodes, as well as the relative risks of 1.5 to 5 reported in more recent studies of less serious, but still important effects categories, lend credibility to EPA's interpretation of the results.

In addition to basing their conclusions primarily on their own assessment of a limited set of studies, this group of commenters reached different conclusions about the consistency of the observed associations because of their assumptions that all model building strategies by all authors are equally valid. Even the most thorough of these treatments (Gamble and Lewis, 1996) shared this flaw, particularly in the discussion of the series of Philadelphia mortality studies and in the discussion of modeling approaches. The authors' treatment of modeling and confounding issues was further limited because they did not include the most recent Philadelphia results (Samet et al., 1996a,b) sponsored by the Health Effects Institute (HEI, 1997). One of the important functions of the Criteria Document is to evaluate the strengths and limitations of various studies. As discussed more fully below in this unit, the Criteria Document found that some of the studies cited by commenters as suggesting a lack of consistency had important limitations. In general, these commenters' analyses suffered by ignoring the much more thorough critical review of these studies and issues contained in the Criteria Document, notably that in section 12.6 on alternative modeling approaches.

EPA also rejects the notion advanced by these commenters that epidemiological studies must use personal exposure monitoring to be considered for regulatory purposes. In particular, commenters ignore the significant strengths of the time-series studies and prospective cohort studies relied on by EPA as compared to cross-sectional epidemiological studies. Time-series studies, such as the daily mortality studies, look at changes in response rate in relation to changes in weather and air pollution over time intervals of a few days. This controls for other factors such as smoking and socioeconomic status, which are little changed during such short intervals. Prospective cohort studies (e.g., Pope et al., 1995; Raizenne et al., 1996), on the other hand, look at changes in health status in a selected cohort of individuals, which allows direct adjustment for smoking status, socioeconomic status, and other subject-specific factors. The commenters also ignore the Criteria Document conclusions on how properly conducted monitoring can provide an adequate index of population exposure to ambient air pollution in such studies that, as detailed below, is more relevant to establishing ambient air quality standards (U.S. EPA 1996a, chapter 7). Although personal monitoring may be practical for some occupational and epidemiological studies, and has been employed in some past studies of air pollution, it is not realistic to require personal monitors in air pollution studies of daily mortality, which require urban scale population data over a period of years. Furthermore, the use of community monitoring-based epidemiological studies as a basis for establishing standards and guidelines has a long history in air pollution, including the British authorities' response to the London episodes and the establishment of the original U.S. NAAQS in 1971. Rejecting the use of the vast array of such studies on this basis alone would also go against the advice of the independent scientific experts on every CASAC panel that has addressed the subject of PM pollution through the years, each of which has recommended general PM standards based primarily on the results of community epidemiological studies (Friedlander, 1982; Lippmann, 1986; Wolff, 1996b). As noted above in this unit, EPA has included a more detailed discussion of its responses to these comments in the Response to Comments.

b. *Specific comments on epidemiologic studies.* The second group of commenters noted above made more specific challenges to EPA's assessment of the epidemiological studies. These comments, although overlapping some of those made by the first group, were generally made by commenters who have taken a more active role in the review of the Criteria Document and Staff Paper. These commenters asserted that the epidemiological evidence on PM is not as consistent and coherent as EPA has claimed, and, in particular, charged that EPA ignored or downplayed a number of studies that the commenters argue contradict the evidence the Agency cited as supporting the consistency and coherence of PM effects. The studies, all of which commenters contend do a better job of addressing one or more key issues, such as confounding pollutants, weather, exposure misclassification, and model specification, than earlier studies, include several that were available during preparation of the Criteria Document, and a number that appeared after the Criteria Document and Staff Paper were completed. Because the status of the later studies differ from that of the earlier ones for purposes of decisions under section 109 of the Act, the two categories are discussed separately below in this unit. Additional responses to comments relating to both sets of studies have been included in the Response to Comments. In addition to the inclusion of specific studies, commenters also raised other issues regarding the limitations of the

epidemiological information and the use of these studies in EPA's two-city risk assessment. Both of these topics are also discussed below in this unit.

(i) *Studies available for inclusion in the criteria review.* With some exceptions, most of the above commenters cited somewhat similar lists of ''negative'' studies that they argue EPA ignored or downplayed in arriving at conclusions on consistency and coherence. Of the most commonly cited studies, the following were available for inclusion in the Criteria Document: daily mortality studies by Styer et al. (1995), Lyon et al. (1995), Li and Roth (1995), Moolgavkar (1995a,b), Wyzga and Lipfert (1995), Lipfert and Wyzga (1995), and Samet et al. (1995, 1996a,b); the long-term exposure mortality study by Abbey et al. (1991); and the re-examination of the Six-City mortality results (Dockery et al., 1993) by Lipfert (1995).

The written record of EPA's evaluations of these studies effectively refutes the claim that the Agency ignored any of these studies and supports the treatment the Agency accorded to each of them. All of the studies available to EPA at the time of CASAC closure on the PM Criteria Document (March 1996) were examined for inclusion in the Criteria Document and Staff Paper, which form the basis for the PM proposal. ''Negative''[10] studies were evaluated in detail along with ''positive'' studies when they were found to have no critical methodological deficiencies, or to point out strengths and limitations. Studies that had more serious problems were generally discussed in less detail, whether positive or negative, than studies with fewer or small deficiencies. The EPA assessments were evaluated by peer reviewers, by CASAC, and by the public.

Most of the short-term exposure studies cited above in this unit are reanalyses and extensions of PM/mortality studies that had been published by other investigators. In general, the Criteria Document concluded that the most comprehensive and thorough reanalyses were those in the series conducted for the HEI, which reanalyzed data sets used in studies from six urban areas in Phase I.A (Samet et al., 1995)[11], with extended analyses for Philadelphia in Phase I.B (Samet et al., 1996a,b). The most important finding in the HEI Phase I.A reanalyses of the six areas is ''the confirmation of the numerical results of the earlier analyses of all six data sets'' (HEI, 1995)[12]. After replicating the original investigators' analyses, Samet et al. (1995) also found similar results analyzing the data using an improved statistical model. The HEI Oversight Committee found

> [I]t is reasonable to conclude that, in these six data sets, daily mortality from all causes combined, and from cardiovascular and respiratory causes in particular, increases as levels of particulate air pollution indexes increase. [HEI, 1995]

It is important to note that these reanalyses by respected independent scientists confirm the reliability and reproducibility of the work of the original investigators, particularly in view of the concerns some commenters have expressed about EPA's reliance on a number of PM studies published by these authors.

The Phase I.A HEI results for Philadelphia also found that it was difficult to separate the effects of PM from those of co-occurring SO_2, in agreement with the Moolgavkar et al.(1995a) analysis. Subsequent HEI work, and several of the other so-called ''negative'' studies cited above in this unit, further examined this issue in terms of confounding or effects modification by one or more co-occurring gaseous pollutants or weather. Contrary to commenters' claims, this issue and these studies received considerable attention in the Criteria Document and Staff Paper, and the overall implications and conclusions from these assessments were summarized in the proposal. In particular, the so-called ''negative'' and other findings of Moolgalvkar et al. (1995a,b) in their Philadelphia and Steubenville studies were discussed in great detail in section 12.6 of the PM Critera Document and compared to those of the original investigators (Schwartz and Dockery, 1992a,b) and other investigators (Li and Roth, 1995; Wyzga and Lipfert, 1995). Further analytical studies of the Philadelphia data set were carried out by HEI (Samet et al., 1996a,b) and have largely resolved many of the uncertainties in the earlier analyses; in EPA's opinion, these studies supersede the results of the original investigators (Schwartz and Dockery, 1992a) and the several earlier reanalyses, including Moolgavkar (1995a), Moolgavkar and Luebeck (1996), Li and Roth (1995), Wyzga and Lipfert (1995), and Samet et al. (1995). Even though TSP is not the best PM indicator for health effects, since it includes a substantial fraction of non-thoracic particles, the extended Criteria Document assessment (U.S. EPA, 1996a, pp. 12-291 to -299; 12-327) of the Phase I.B HEI analyses in Philadelphia (Samet et al., 1996a,b) serves to support the following findings:

(1) The mortality effects estimates for TSP do not depend heavily on statistical methods when appropriate models are used.

(2) Estimated PM effects are not highly sensitive to appropriate methods for adjusting for time trends and for weather.

(3) Air pollution has significant health effects above and beyond those of weather.

(4) Copollutants such as ozone, CO, and NO_2 may be important predictors of mortality, but their effects can be substantially separated from those of TSP and SO_2.

(5) The health effects of TSP in Philadelphia cannot be completely separated from SO_2, which is itself a precursor of fine particles, based solely on the epidemiological analyses in this single city.

The most recent HEI Oversight Committee comments on these studies (HEI, 1997), which were submitted to the docket by HEI, state that:

> Although individual air pollutants (TSP, SO_2, and ozone) are associated with increased daily mortality in these data, the limitations of the Philadelphia data make it impossible to establish that particulate air pollution alone is responsible for the widely observed associations between increased mortality and air pollution in that city. All we can conclude is that it appears to play a role. [HEI, 1997; p.38.]

While recognizing the limitations in the conclusions that can be made based on studies in a single city, the Oversight Committee endorses the approach taken by EPA in evaluating a broader set of epidemiological studies:

> Consistent and repeated observations in locales with different air pollution profiles can provide the most convincing epidemiological evidence to support

[10] The term ''negative'' studies, as used in these comments, should not be construed to mean those in which there is a negative effects estimate (either significant or non-significant) for the nominal cause. As used by these commenters, the term also includes statistically non-significant positive effect estimates. In other words, the commenters define ''positive'' studies as including only those in which the effect estimate is both positive and statistically significant.

[11] Data sets were those used in the original studies by Dockery et al. (1992) for St. Louis and Eastern Tennessee; Pope et al. (1992) for Utah Valley; Schwartz and Dockery (1992a) for Philadelphia; Schwartz (1993) for Birmingham; and a portion of the Santa Clara data from Fairley (1990). The data set from the Moolgavkar et al. (1995a) Philadelphia reanalysis was also included (Samet et al., 1995).

[12] The HEI Board of Directors appointed an eight member Oversight Committee consisting of leading scientists in several disciplines relevant to air pollution epidemiology to oversee key aspects of the project and to prepare HEI's assessment of the results.

generalizing the findings from these models. This has been the approach reported by the EPA in its recent Criteria Document and Staff Paper. [HEI, 1997; p. 38.]

As noted in the proposal, based on this approach, EPA's assessment of numerous mortality studies concludes that when studies are evaluated on an individual basis, the PM-effects associations are valid and, in a number of studies, not seriously confounded by co-pollutants (U.S. EPA, 1996a; p. 13-57); and when a collection of studies from multiple areas with differing concentrations of PM and co-pollutants are examined together, the association with PM_{10} remains reasonably consistent across a wide range of concentrations of these potentially influential pollutants (U.S. EPA, 1996a; p. 12-33; U.S. EPA, 1996b; p. V-55).

In addition to relying on the most comprehensive and best analyses in evaluating the reanalysis in Philadelphia and other areas, the Criteria Document gave less weight to both so-called ''negative'' and ''positive'' studies with methodogical limitations. In particular, EPA agreed with the epidemiological experts on CASAC (Lippmann et al., 1996; Samet, 1995) that the Li and Roth (1995) study approach of using a ''panoply'' of different modeling strategies to produce seemingly conflicting findings provides little useful insight and is superseded by the HEI report. The attempt by Lipfert and Wyzga (1995) to address relative effects of different pollutants was considered inconclusive (Lippmann et al., 1996) and flawed by the use of a metric (elasticity) that ignores the absolute concentrations of the pollutants being compared (see Response to Comments).

Further, the Steubenville studies and reanalyses (Schwartz and Dockery, 1992b; Moolgavkar, 1995b) were discussed in detail to examine methodologies, and the differences in relative risks between the two were regarded as small (U.S. EPA, 1996a, p. 12-280 to 283). Both studies used TSP as the PM indicator variable, and they are augmented by the more recent findings of Schwartz et al. (1996) that examine PM_{10} and its components. The mixed results by Lyon et al. (1995) in Utah Valley are compromised by loss of information related to the methodology (U.S. EPA, 1996a, p. 12-58). As noted above, subsequent reanalyses of the Utah Valley study by HEI (Samet et al., 1995) as well as by Pope and Kalkstein (1996) confirmed the original findings of Pope et al. (1992) using different model specifications. The Salt Lake City study by Styer et al. (1995) was mentioned in the PM Criteria Document, but received little discussion because aspects of the methodological approach limited its statistical power to detect effects. The analysis of Chicago mortality data in the same paper shared these problems, particularly for seasonal analyses; in this larger city, they nonetheless found significant associations on an annual basis between PM_{10} and mortality that are consistent with other studies. In short, the record shows that EPA did not ignore these short-term exposure studies cited by commenters; moreover, EPA's assessment of these studies is consistent with the views of four researchers on the CASAC panel who have extensive involvement in conducting population studies of air pollution (Lippmann et al., 1996).[13]

Similarly, EPA believes that appropriate treatment and weight were given to studies of long-term exposure and mortality. EPA concluded that the lack of associations in the Abbey et al. (1991) prospective cohort study were not inconsistent with two other such studies because the use of days of peak TSP levels as the PM indicator (instead of PM_{10} or $PM_{2.5}$) is inappropriate for California cohorts exposed to both urban smog and fugitive dust episodes, and the overall sample size may have been too small to detect significant effects (U.S. EPA, 1996b; pp. V-17 to -18). The inadequacy of Lipfert's (1995) application of state-wide average sedentary lifestyle data to adjust mortality for the six cities studied by Dockery et al. (1993), in which superior subject-specific body mass index data had already been considered, was also noted and addressed in the Staff Paper (U.S. EPA, 1996b; p. V-16). Again, EPA did not ignore these studies; the rationale for giving them less weight was clearly articulated in the documents reviewed by CASAC and judged appropriate for use in standard setting.

While the proposal presents only a summary discussion of key Criteria Document and Staff Paper findings, EPA believes that discussion is fully consistent with the state of the science. Furthermore, the proposal highlights the nature of alternative viewpoints on the epidemiology in a quotation from the Criteria Document (61 FR 65644, December 13, 1996) and cites explicitly the views of most of the authors noted above in this unit (Moolgavkar et al., 1995b; Moolgavkar and Luebeck, 1996; Li and Roth, 1995; Samet et al., 1996; Wyzga and Lipfert, 1995). The proposal also summarizes EPA conclusions based on all of the literature as assessed in the Criteria Document and Staff Paper with respect to issues raised in these and other studies, including potential confounding by independent risk factors such as weather and other pollutants, choice of statistical models, use of outdoor monitors, and exposure misclassification.

More specifically, in the proposal EPA has not ignored the view advanced by some that the results of individual studies of multiple pollutants, such as the HEI Philadelphia studies, are more suggestive of an ''air pollution'' effect than an effect of PM alone. Indeed, the proposal notes that it is reasonable to expect that other pollutants may play a role in modifying the magnitude of the estimated effects of PM on mortality, either through pollutant interactions or independent effects (61 FR 65645, December 13, 1996). Based on the large body of evidence at hand, however, EPA cannot accept the suggestion that such multi-pollutant studies are in any way ''negative'' with respect to EPA's conclusions that PM, alone or in combination with other pollutants, is associated with adverse effects at levels below those allowed by the current standards. This conclusion is based not only on the consistency of PM effects across areas with widely varying concentrations of potentially confounding copollutants, but also on the extended analyses of the Philadelphia studies in the Criteria Document and Staff Paper.

Because commenters have tended to ignore the latter analyses, it is appropriate to summarize them here briefly. As noted above in this unit, the Criteria Document assessment of the Philadelphia studies finds that PM can reasonably be distinguished from potential effects of all pollutants except SO_2. The Staff Paper builds on this analysis through an integrated assessment that draws on information from atmospheric chemistry, human exposure studies, and respiratory tract penetration results to provide insight as to which of these two pollutants is more likely to be responsible for mortality in the elderly and individuals with cardiopulmonary disease (U.S. EPA 1996b; pp. V-46 to -50). That assessment notes that the inhalable (PM_{10}), including the fine ($PM_{2.5}$), components of TSP are more likely than SO_2 to penetrate and remain indoors where the sensitive population resides most of the time.[14] In addition, these PM

[13] Their March 20, 1996 letter to the Administrator concludes that the HEI analysis of Philadelphia supersedes earlier analyses, specifically Moolgavkar et al. (1995a), Lipfert and Wyzga (1995), and Li and Roth (1995), and points out the limitations of Styer et al. (1995).

[14] In response to comments on this rulemaking, some papers submitted by industry commenters

Continued

components, especially $PM_{2.5}$, penetrate far more effectively to the airways and gas exchange regions of the lung than does SO_2. Furthermore, in Philadelphia, it is possible that SO_2 is a surrogate for fine particulate acid sulfates. For these reasons, even though statistical analyses of the Philadelphia data set cannot fully distinguish between these two highly correlated pollutants, EPA believes that the weight of the available evidence from an integrated assessment more strongly supports the notion that PM is playing an important direct role in the observed mortality effects associations in Philadelphia. Moreover, as noted above in this unit, in some other locations with significant PM-mortality associations, ambient SO_2 levels are too low to confound PM.

(ii) *Recent studies available after completion of criteria review.* As noted above in this unit, other studies cited by some commenters as so-called ''negative'' evidence ignored by EPA were published or otherwise made available only after completion of the PM Criteria Document. EPA agrees that it did not rely on these studies, based on its long-standing practice of basing NAAQS decisions on studies and related information included in the pertinent air quality criteria and available for CASAC review.[15] Although EPA has not relied on such studies in this review and decision process, the Agency nevertheless has conducted a provisional examination of these and other recent studies to assess their general consistency with the much larger body of literature evaluated in the Criteria Document.[16] EPA has placed its examination of recent studies in the rulemaking docket.

Among the most frequently cited new studies relied on by commenters were Davis et al. (1996), Moolgavkar et al. (1997), and Roth and Li (1997). Davis et al. (1996) conducted a reanalysis of the Birmingham mortality data set originally investigated in Schwartz (1993). At the time of the close of the public comment period, the paper based on this manuscript had not been accepted for publication in a peer reviewed journal (Sacks, 1997). Commenters nevertheless highlight the authors' claim that ''when humidity is included among the meteorological variables (it is excluded in the analysis by Schwartz [1993]), we find that the PM_{10} effect is not statistically significant.'' EPA's review found important factual errors in this study. Contrary to Davis et al., Schwartz did include humidity in his 1993 study, and his finding of a hot-and-humid-day effect was reported there. In addition, the PM-related variables used by Davis et al. in their manuscript were not, as the authors claimed, the same as those in Schwartz (1993). Davis et al. also used a different humidity indicator, specific humidity. Reanalysis by one of the co-authors (R. Smith, personal communication, February 8, 1997) showed that when Schwartz's PM metric was used, the estimated PM_{10} effect was of about the same magnitude, and statistically significant at the 0.05 level, even using the characterization of humidity effect proposed by Davis et al. It therefore appears that the Davis et al. PM_{10} result was, in fact, consistent with that of Schwartz, and robust against a very different weather model specification.

Based on its examination of both the content and the publication status of this study, EPA believes the heavy reliance and attention given to it are misguided. In contrast to commenters' assertions, this study does not contradict EPA's conclusions with respect to consistency of the epidemiological evidence and confounding by weather variables; indeed, the consideration of the corrected results would actually support EPA's conclusions. EPA believes this example reinforces the importance of relying on peer reviewed studies and also conducting the kind of critical examination of such studies that takes place in the criteria and standards review process.

Several commenters note that Roth and Li (1997) also reexamined the Birmingham mortality data, as well as hospital admissions data from Schwartz (1994), and produced a number of negative and inconsistent results that depend on temperature effects and choice of statistical model. Preliminary findings from this study were presented by Roth at the May 1996 CASAC meeting. CASAC epidemiologists and statisticians at the meeting pointed out a number of shortcomings, both in the analytical strategy and in details of the models being evaluated.[17] As discussed in more detail in the Response to Comments, the materials from Roth and Li (1997) recently provided to EPA as attachments to public comments show that the deficiencies pointed out at the May 1996 CASAC meeting have not been adequately addressed. EPA concludes that this study does not support commenters' claims.

The paper recently accepted for publication by Moolgavkar et al. (1997) examines hospital admissions and air pollution in Minneapolis and Birmingham and comes to different conclusions than earlier investigators with respect to the role of PM_{10}. While the paper is a useful addition to the literature, the authors clearly do not attempt to replicate the original studies, making the kind of direct comparisons suggested by commenters difficult. The paper finds an air pollution effect in one city that implicates ozone but is unable to separate effects of PM from a group of other pollutants. EPA's provisional examination of this study raises some questions about the methodology, which might usefully be supplemented to further separate pollutants as was done by Samet et al. (1996a,b) in Philadelphia, and about the authors' interpretation of the results in both cities. In any event, EPA does not believe this study negates the PM associations with hospital admissions

make statements that are in substantial agreement with these staff conclusions with respect to the likelihood of SO_2 penetrating to indoor environments and the lesser likelihood of affecting sensitive populations indoors (Lipfert and Wyzga, 1997; Lipfert and Urch, 1997).

[15] Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies that have been assessed in air quality criteria [see e.g., 36 FR 8186 (April 30, 1971) (EPA based original NAAQS for six pollutants on scientific studies discussed in the air quality criteria and limited consideration of comments to those concerning validity of scientific basis); 38 FR 25678, 25679-25680 (September 14, 1973) (EPA revised air quality criteria for sulfur oxides to provide basis for reevaluation of secondary NAAQS)]. This longstanding interpretation was strengthened by new legislative requirements enacted in 1977 (section 109(d)(2) of the Act; section 8(c) of the Environmental Research, Development, and Demonstration Authorization Act of 1978) for CASAC review of air quality criteria and reaffirmed in EPA's decision not to revise the ozone standards in 1993. 58 FR 13008, 13013-13014 (March 9, 1993). Some of the commenters now criticizing EPA for not considering the most recent PM studies strongly supported the Agency's interpretation in the 1993 decision (UARG, 1992).

[16] As discussed in EPA's 1993 decision not to revise the NAAQS for ozone, new studies may sometimes be of such significance that it is appropriate to delay a decision on revision of NAAQS and to supplement the pertinent air quality criteria so the new studies can be taken into account. 58 FR at 13014, March 9, 1993. In the present case, EPA's provisional examination of recent studies suggests that reopening the air quality criteria review would not be warranted even if there were time to do so under the court order governing the schedule for this rulemaking. Accordingly, EPA believes that the appropriate course of action is to consider the newly published studies during the next periodic review cycle.

[17] For example, commenting on the Roth examination of alternative model specifications, Dr. Stolwijk noted ''If you select out of his [Roth's] matrix the things that other people have done, he comes to a different conclusion than when he takes his whole matrix * * *. [Y]ou are going to get a random effect that shows that there is no effect. He [Roth] did this, I think, on purpose in this case. Most epidemiologists, I think, have been trained to limit their observations to something that they can state or would have stated before they started and observe that and base their conclusions on it'' [U.S. EPA 1996(c); May 17, 1996 Transcript, pages 45-46].

reported in a number of other studies cited in the Criteria Document.

Another recent paper by Lipfert and Wyzga (1997) provides analyses suggesting that differential measurement error might account for some or all of the observation by Schwartz et al. (1996) that daily mortality is more strongly associated with fine ($PM_{2.5}$) than with coarse ($PM_{10-2.5}$) PM. EPA staff and CASAC accounted for this possibility, however, and it was factored into both the Staff Paper and CASAC recommendations.[18]

Some commenters have highlighted selected individual papers or summaries from the APHEA[19] project conducted in Europe, and from Roth (1996), calling attention particularly to negative results found in heavily polluted regions of Eastern Europe. EPA notes that a number of the recent APHEA and other studies in Western Europe have shown significant associations between mortality and air pollution including PM, and that a meta-analysis of 12 Western and Central-eastern European studies ''is supportive of a causal association between PM and SO_2 exposure and all-cause mortality'' (Katsouyanni et al., 1997). The Eastern and Western European studies used differing measurement methods for PM, including PM_{10}, gravimetric ''suspended particles,'' and the British Smoke method.[20] The differences in aerometry and the substantial differences in location and strength of primary PM emissions sources in central and eastern Europe as compared to western Europe or the U.S. might well explain the different results in these unique areas. Consequently, integration of these results would involve comprehensive examination of the various PM instruments used, monitor siting in relation to sources, mass calibration procedures and other aspects of these studies.[21] EPA notes that a number of European authorities, who are familiar with this recent literature, have proceeded with recommendations to strengthen their health guidelines, risk assessments, or regulations for PM.[22]

Aside from the recent literature cited by these commenters, there are a number of other recent epidemiological studies that, if considered in today's decision, would tend to support EPA's conclusions about the effects of PM at lower concentrations, assuming their results were accepted following a full review in the criteria and CASAC process. For example, in addition to the APHEA studies, several other recent epidemiologic studies have reported significant positive associations between PM and health effects (Lipsett et al., 1997; Peters et al., 1997; Borja-Aburto et al., 1997; Delfino et al., 1997; Scarlett et al., 1996; Woodruff et al., 1997; Wordley et al., 1977). In addition, a number of recent toxicologic papers have been accepted or appear in proceedings (Costa and Dreher, 1997; Killingsworth et al., 1997; Godleski et al., 1997) that involve exposure to concentrated ambient fine particles or PM constituents and appear to provide supportive evidence as to the plausibility of the effects that have been reported epidemiologically. If considered in this decision, these studies would also provide biological support for the epidemiological observation that certain susceptible groups (notably those with cardiopulmonary disease) are most likely to be affected by PM, again assuming the results were sustained in the full criteria and CASAC review process.

In summary, EPA has conducted a provisional assessment of the more recent scientific literature. Based on this provisional assessment, EPA disagrees with commenters' assertion that full consideration of selected new studies in this decision would materially change the Criteria Document and Staff Paper conclusions on the consistency and coherence of the PM data, or on the need to revise the current standards.

(iii) *Other specific comments on the epidemiological studies.* Aside from their assertion that EPA ignored or downplayed particular studies, this second group of commenters raise additional objections, based on the statistical modeling strategies used and the potential importance of personal exposure misclassification, to EPA's conclusions regarding the consistency of the epidemiological evidence. EPA conclusions on these topics were summarized in the proposal and supported by extensive treatments in the Criteria Document and Staff Paper. With respect to the first issue, commenters argued that sufficient flexibility exists in the analyses of large data sets that it may be possible to obtain almost any result desired through choice of statistical method. Analytical choices include the specific statistical model; methods used to adjust for seasonal variation and the trends in the data; treatment of other variables (e.g., other pollutants, weather, and day of week); ''lag'' structure; and study population.

A more detailed discussion of this issue, which expands on the assessment summarized in the Criteria Document, is included in the Response to Comments. In summary, EPA must reject commenters' contention that legitimate alternative analyses can obtain ''almost any result.'' As outlined above in this unit, EPA's detailed reviews of individual studies have shown that not all methods are equally valid or legitimate. Moreover, strong arguments can be made that the methods and analytical strategies in the studies EPA relied upon are more appropriate approaches than those cited by commenters (e.g., Li and Roth, 1995; Lipfert and Wyzga, 1995; Davis et al., 1996; Roth and Li, 1997). While not all studies have addressed each of the above issues in this unit equally well, the most comprehensive analyses of these issues (e.g., Samet et al., 1995, 1996a,b; Pope and Kalkstein, 1996), as well as the EPA analyses comparing study results for each issue (U.S. EPA, 1996a, pp. 12-261 to 12-305) found that the authors of studies on which EPA

[18] CASAC panelists recommended a discussion of this issue in the Staff Paper. The Staff Paper notes: ''While greater measurement error for the coarse fraction could depress a potential coarse particle effect, this would not explain the results in Topeka relative to other cities. Even considering relative measurement error, these results provide no clear evidence implicating coarse particles in the reported effects.'' (U.S. EPA, 1996b p. V-64). EPA's provisional examination of the Lipfert and Wyzga (1997) paper in the Response to Comments, finds that it is implausible that most of the effect attributed to $PM_{2.5}$ could in fact be due to $PM_{10-2.5}$, since differential measurement error cannot make a weaker effect appear stronger than a stronger one, except under extremely unusual circumstances.

[19] The APHEA (Air Pollution and Health: a European Approach) project was supported by the European Union Environment 1991-1994 Programme to investigate the possible short-term health effects of exposure to low or moderate levels of ambient air pollutants. Eleven European research groups carried out studies in 15 cities (Amsterdam, Athens, Barcelona, Bratislava, Cracow, Helsinki, Koln, Lodz, London, Lyon, Milan, Paris, Poznan, Rotterdam and Wroclaw) in which air pollutant concentration data had been collected for at least 5 years. Initial findings of studies on mortality and hospital admissions were published in a series of papers in Supplement 1 to the Journal of Epidemiology and Community Health in 1996 and a meta-analysis of the mortality data from 12 cities is currently in press (Katsouyanni et al., 1997).

[20] The Roth et al. (1997) study in Prague used a measurement termed ''suspended particles'' that appears to be close to TSP. The relation of this indicator to PM_{10} or $PM_{2.5}$ in this city is not reported. Moreover, this study uses a variant of the problematic methodology in the Roth analyses cited above.

[21] These concerns are consistent with EPA's treatment of a number of European and South American studies that are included in the Criteria Document and contributed to the evaluation of the epidemiology in Chapter 12. Because of differences in aerometry methods and characteristic source classes between North America and other regions of the world, however, the integrative assessment chapter reported results only from studies conducted in the U.S. and Canada (cf. Tables 13-3 to 13-5) in reaching quantitative conclusions for effects estimates.

[22] See, for example, the United Kingdom Air Quality Strategy, 1997; Swiss Federal Commission of Air Hygiene, 1996; World Health Organization Revised Air Quality Guidelines for Europe, In Press).

chiefly relied made appropriate modeling choices. The Criteria Document concludes that: ''[T]he largely consistent specific results, indicative of significant positive associations of ambient PM exposures and human mortality/morbidity effects, are not model specific, nor are they artifactualy derived due to misspecification of any specific model. The robustness of the results of different modeling strategies and approaches increases our confidence in their validity [U.S. EPA, 1996a, p. 13-54].'' While it is true, as evidenced in Li and Roth (1995), that PM-effects data can be randomly manipulated to produce apparently conflicting results, commenters have provided no evidence that different plausible model specifications could lead to markedly different conclusions.

Some commenters have expressed concerns about the reliability of the epidemiological results because some studies showed a lack of correlation in cross-sectional comparisons between outdoor PM measured at central locations and indoor or personal exposures to PM (which includes PM from the outdoor, indoor and personal environments).[23] EPA acknowledged and responded to this issue in chapter 7 of the Criteria Document and the proposal (61 FR 65645, December 13, 1996). The major premise underlying commenters' arguments on this issue is incorrect.[24] The question is not whether central monitoring site measurements contain a signal reflecting actual exposures to total PM from both outdoor and indoor sources at the individual level; the relevant question is whether central monitoring site measurements contain a signal reflecting actual exposures to ambient PM for the subject population, including both ambient PM, while individuals are outdoors, and ambient PM that has infiltrated indoors, while individuals are indoors. The PM standards are intended to protect the public from exposure to ambient PM, not PM generated by indoor or personal sources. There is ample evidence, as discussed in chapter 7 of the Criteria Document, that personal exposure to ambient PM, while outdoors and while in indoor micro-environments, does correlate on a day-to-day basis with concentrations measured at properly sited central monitors (U.S. EPA, 1996a, p. 1-10). EPA has, therefore, concluded that it is reasonable to presume that a reduction in ambient PM concentrations will reduce personal exposure to ambient PM, and that this will protect the public from adverse health outcomes associated with personal exposure to ambient PM.

Commenters have also restated theoretically based concerns on a related issue, namely errors in the measurement of the concentrations of air pollutants, that was summarized in the proposal. In multiple pollutant analyses, measurement error or, more generally, exposure misclassification, could theoretically bias effects estimates of PM or co-pollutants in either direction, introducing further uncertainties in the estimated concentration-response relationships for all pollutants (U.S. EPA, 1996b, pp. V-39 to V-43). Relevant insights on this issue in material appended to public comments (Ozkaynak and Spengler, 1996) have prompted an expanded statistical analysis of the conditions under which such errors could inflate the magnitude of the effects estimates or the significance of PM relative to gaseous pollutants, as has been suggested by Lipfert and Wyzga (1995). This analysis, which is summarized in the Response to Comments, finds that the conditions under which measurement error could inflate the effects estimates or significance of PM relative to other pollutants are restricted to a limited set of statistical relationships. Commenters have not provided evidence that suggest such conditions are likely to occur with respect to the measurement of ambient PM in relation to those for gaseous co-pollutants commonly used in epidemiological studies.[25] Therefore, it appears unlikely that measurement and exposure errors for PM and other pollutants have inflated the estimated effects of PM, even in multivariate analyses. More importantly, the available evidence on the consistency of the PM-effects relationships in multiple urban locations, with widely varying indoor/outdoor conditions and a variety of monitoring approaches, makes it less likely that the observed associations of PM with serious health effects at levels allowed under the current NAAQS are an artifact of errors in measurement of pollution or of exposure (U.S. EPA 1996b, pp. V-39 to V-43).

(iv) *Comments on the PM risk assessment.* As noted in the proposal, uncertainties about measurement errors, exposure misclassification, and the relative effects of copollutants are more important to the quantitative estimates of risk associated with PM than to the existence of valid PM-effects associations at levels found in recent studies. A number of commenters argued that EPA's risk assessment is flawed and incomplete. Chief among the reasons they advanced is that the assessment is based on the same epidemiological studies these commenters argued are inadequate for the reasons summarized and responded to above. Specific comments also addressed the extent to which the risk assessment might overstate risk estimates because it assumes a linear no-threshold relationship and the use of studies that might inflate PM risk due to inadequate consideration of co-pollutants and other potential confounders. The full risk assessment acknowledges these issues and uncertainties, however, and it illustrates the potential influence of such uncertainties in sensitivity analyses (U.S. EPA 1996b; chapter 6, appendix F; Abt Associates, 1996a,b; 1997a,b). For example, Figure 2c in the proposal (61 FR 65653, December 13, 1996)

[23] Paradoxically, some commenters have argued (e.g., Valdberg, 1997) that the PM results are confounded because the weather and other factors that cause daily variations in outdoor pollution will cause similar daily variations in indoor generated air pollution. For this to be true, outdoor ambient pollution concentrations would have to be correlated with personal exposure to indoor generated air pollution such as that from smoking, cleaning, and cooking. This argument is logically inconsistent with the other comments on the lack of any such correlation with personal exposure, and these commenters have offered no scientific evidence to support their claim. In response, EPA has performed and included in the Response to Comments a numerical analysis of the relevant information from the PTEAM exposure study that finds no evidence for such a correspondence in the actual data.

[24] As documented in Chapter 7 of the Criteria Document, time-series community studies observe the effects of varying levels of ambient air pollution; therefore the effects of indoor-generated air pollution would be independent of and in addition to the effects found in these epidemiological studies. Commenters apparently believe EPA is claiming such studies are detecting the effects of daily variations in total PM personal exposure from indoor and outdoor sources. This misunderstanding is evidenced, for example, by Wyzga and Lipfert's (1995) treatment of the difference between ambient monitors and actual personal exposures as ''exposure errors'' and Brown's comment for API that ''if (ambient) PM is causally related to mortality/morbidity, then it is personal PM exposure that must be reduced to have an effect.'' On the contrary, it is personal exposure to ambient PM that must be reduced to address the risk identified in community air pollution studies. Any lack of significant correlation between outdoor PM concentrations and personal exposure to total PM from all sources is irrelevant, except to the extent it may decrease the power of time-series studies to detect the effects of ambient pollution.

[25] The EPA analysis finds that in order for measurement errors in one pollutant variable to significantly bias the estimated effect of another pollutant, three conditions are necessary: (1) The measurement error in the poorly measured pollutant must be very large, roughly at least the same size as the population variability in that pollutant; (2) the poorly measured pollutant must be highly correlated with the other pollutant, either positively or negatively; and (3) the measurement errors for the two pollutants must be highly negatively correlated (Response to Comments, Appendix D). This important factor was not considered in Lipfert and Wyzga (1995) or by commenters.

illustrates the potential influence of what appears to be the most significant uncertainty in current information, whether a population threshold exists below which the effects of PM no longer occur (61 FR 65653, December 13, 1996). EPA notes that a full consideration of the uncertainties, including the analysis summarized above on measurement error, suggests that the epidemiological studies might well have understated the total effects of air pollution; thus, both the direction and the extent of any bias in the risk estimates are less clear than commenters suggest.

EPA believes that, even recognizing the large uncertainties, the key qualitative insights derived from the risk assessment and summarized in Unit II.A.3. of this preamble remain appropriate. While not placing great weight on the specific numerical estimates, EPA believes that the risk analysis confirms the general conclusions drawn primarily from the epidemiological results themselves, that there is ample reason to be concerned that exposure to ambient PM at levels allowed under the current air quality standards presents a serious public health problem.

3. *Key considerations informing the decision.* Having carefully considered the public comments on the above matters, EPA believes the fundamental scientific conclusions on the effects of PM reached in the Criteria Document and Staff Paper, and restated in the introduction to this unit, remain valid. That is, the epidemiological evidence for ambient PM, alone or in combination with other pollutants, shows associations with premature mortality, hospital admissions, respiratory symptoms, and lung function decrements. Despite extensive critical examination in the criteria and standards review, these findings cannot be otherwise explained by analytical, data, or other problems inherent in the conduct of such studies. Although the evidence from toxicological studies available during the criteria review has not revealed demonstrated mechanisms that explain the range of effects reported in epidemiological studies, it does not and cannot refute the observation of such effects in exposed populations. Moreover, the effects observed in the recent epidemiological studies at lower PM concentrations are both coherent with each other and plausible based on the categories of effects observed at much higher concentrations in historic air pollution episodes, laboratory studies of PM effects at high doses, and particle dosimetry studies. The consistency of the results from a large number of locations and the coherent nature of the observed results suggest a likely causal role of ambient PM in contributing to the reported effects (U.S. EPA, 1996a; p. 13-1). Many of the studies showing PM effects were conducted in areas where the current PM_{10} standards are largely met, and both the studies and EPA's risk assessment suggest that the collective magnitude of the effects reflects a significant public health problem.

For these reasons, and having considered public comments on this issue, the Administrator concludes that the review of the criteria and standards provides strong evidence that the current PM_{10} standards do not adequately protect public health, and that revision of the standards is not only appropriate, but necessary.

Aside from that conclusion, the appropriateness of continuing to rely on the use of PM_{10} as the sole indicator for revised PM standards is also relevant here. While the basis for decisions on specific indicators is discussed more fully in Unit II.C. of this preamble, this issue is related to the Administrator's decision on the need to revise the standards. Based on both the staff review (U.S. EPA, 1996b, p. VII-3) and the recommendations of some commenters (e.g., California EPA), there are two alternative approaches for providing additional health protection in revising the standards: Adopt tighter PM_{10} standards and/or recognize the fundamental differences between fine and coarse particles and develop separate standards for the major components of PM_{10}, including fine particles. Conceptually, the first approach would give weight to comments that standards should be based on pollutant indicators for which the most data have been collected, with less consideration of the evidence that suggests that the current standards provide adequate protection against the effects of coarse particles, and that tightening the current PM_{10} standards in an attempt to control fine particles would place unnecessary requirements on coarse particles. Because the PM_{10} network is in place, a more stringent PM_{10} standard would also respond to commenters who have expressed a desire for more immediate implementation of revised standards. The second approach is based on the view that, in the long run, more effective and efficient protection can be provided by separately targeting appropriate levels of controls to fine and coarse PM.

The Staff Paper examined this issue in detail (U.S. EPA 1996b, pp. VII-3 to VII-11), and concluded that the available information was sufficient to develop separate indicators for fine and coarse fractions of PM_{10}, based on the recent health evidence, the fundamental differences between fine- and coarse-fraction particles, and implementation experience with PM_{10}. Further, the staff concluded that:

> [C]onsideration of comparisons between fine and coarse fractions suggests that fine fraction particles are a better surrogate for those particle components linked to mortality and morbidity effects at levels below the current standards. In contrast, coarse fraction particles are more likely linked with certain effects at levels above those allowed by the current PM_{10} standards. In examining alternative approaches to increasing the protection afforded by PM_{10} standards, the staff concludes that reducing the levels of the current PM_{10} standards would not provide the most effective and efficient protection from these health effects. [U.S. EPA 1996b; p. 7-45]

As discussed in Unit II.C. of this preamble, the Administrator believes that it is more appropriate to provide additional protection against the risk posed by PM by adding new standards for the fine fraction of PM_{10}, as opposed to tightening the current PM_{10} standards. Although fewer epidemiological studies have used $PM_{2.5}$ and other fine particle indicators (e.g., sulfates, acids), there are nonetheless significant indications from the scientific evidence - drawn from the physicochemical studies of PM, air quality and exposure information, toxicological studies, and respiratory tract deposition data - that this approach will provide the most effective and efficient protection of public health.

Several commenters have argued that the decision on whether to revise the PM standards should be deferred, particularly with regard to fine particle standards, pending establishment and operation of a national monitoring network to characterize fine PM and a research program to reduce uncertainties in the effects information. These commenters expressed concerns that establishing fine PM standards now might result in needless regulation of PM components that may be unrelated to observed health effects. As discussed more fully in Unit II.F. of this preamble, such commenters recommended, at most, that if fine PM standards were established, they should be set at a level ''equivalent'' to the current PM standards.

EPA strongly disagrees that the decision on revising the standards should be delayed to await the results of new PM monitoring and research programs. Under section 109(d) of the Act, EPA's obligation after reviewing the

existing criteria and standards for PM is to make such revisions in the standards and to promulgate such new standards as are appropriate under section 109(b) of the Act. Based on her review of the criteria and standards for PM, the Administrator has concluded that the current standards are not adequate to protect public health and that revisions are appropriate. In the face of the available evidence, a delay in revising the standards would not only be inconsistent with the statute but -- even under the optimistic assumption that the same extensive monitoring and strategy assessment as now contemplated would occur in the absence of a revised standard -- would add approximately 2 years to the time when significant health benefits can be realized, resulting in potentially significant numbers of additional premature deaths and even larger numbers of children and individuals with air pollution-related illness and symptoms. On the other hand, establishing standards now will set into motion the development of implementation programs and monitoring that can be conducted in parallel with additional scientific research, without undue delays inherent in waiting for the research.

The question of which pollutant components to regulate has been an issue since the inception of the first PM standards. Other ambient pollutants (e.g., NO_2 or CO) are uniquely defined as individual chemicals, whether or not they serve as proxies for a larger class of substances (e.g., ozone as an index of photochemical oxidants). Regulating general PM, as opposed to multiple chemical components of PM, raises the spectre of a host of particulate materials of varying composition, size, and other physicochemical properties, not all of which are likely to produce identical effects.

Both EPA's past and present regulatory experience with PM control programs and its successive reviews of the standards have reaffirmed the wisdom of retaining standards that control particles as a group, rather than eliminating such standards and waiting for scientific research to develop information needed to identify more precise limits for the literally thousands of particle components. Each such decision recognized the possibility that potentially less harmful particles might be included in the mix that was regulated, but concluded that the need to provide protection against serious health effects nonetheless required action under section 109 of the Act. The success of this approach is evident in early U.S. control programs that dramatically reduced ''smoke'' and ''TSP'' in major cities in the 1960's and 1970's and in the continued improvement in air quality through the current PM standards. The major refinements that have been recommended through the course of reviews of PM standards have been to improve the focus of control efforts by defining scientifically based size classes (i.e., moving from TSP to PM_{10} and now, $PM_{2.5}$) that will permit more effective and efficient regulation of those fractions most likely to present significant risks to health and the environment.

As discussed in Unit II.C. of this preamble, the current review has examined the available evidence to determine whether it would tend to support inclusion or exclusion of any physical or chemical classes of PM, for example sulfates, nitrates, or ultra-fine particles. That examination concludes that, while both fine and coarse particles can produce health effects, the fine fraction appears to contain more of the reactive substances potentially linked to the kinds of effects observed in the recent epidemiological studies (U.S. EPA 1996b, section V.F.). However, the available scientific information does not rule out any one of these components as contributing to fine particle effects. Indeed, it is reasonable to anticipate that no single component will prove to be responsible for all of the effects of PM.

EPA recognizes that whether the standards are set for PM_{10} only or also for fine particles, there are uncertainties with respect to the relative risk presented by various components of PM. In this regard, the Administrator places greater weight on the concern that by failing to act now, the PM NAAQS would not control adequately those components of air pollution that are most responsible for serious effects, than on the possibility they might also control some component that is not. EPA believes that moving simultaneously to establish standards based on the best available scientific evidence and to conduct an aggressive monitoring and scientific research program designed to help resolve current uncertainties is a prudent and responsible approach for addressing both the risks and the uncertainties inherent in this important public health issue.

In summary, given the evidence that PM-related health effects appear likely to occur at levels below the current standards, the serious nature and potential magnitude of the public health risks involved, and the need to consider the fine and coarse fractions as distinct classes of particles, the Staff Paper and the CASAC (Wolff, 1996b) concluded that revision of the current standards is clearly appropriate. Moreover, at their May 1996 public meeting (U.S. EPA, 1996c), and in separate written comments (including Lippmann et al., 1996), a majority of CASAC panel members recommended revisions that would strengthen the health protection provided by the current PM standards. Based on the rationale and recommendations contained in the Staff Paper and the advice of CASAC, and taking into account public comments, the Administrator concludes that it is appropriate at this time to revise the current PM standards to increase the public health protection provided against the known and potential effects of PM identified in the air quality criteria.

C. Indicators of PM

In establishing adequately protective, effective, and efficient PM standards, it is necessary to specify the fraction of particles found in the ambient air that should be used as the indicator(s) for the standards. In this regard, EPA concludes that the most recent assessment of scientific information in the Criteria Document, summarized in chapters IV and V of the Staff Paper, continues to support past staff and CASAC recommendations regarding the selection of size-specific indicators for PM standards. More specifically, EPA continues to find that the following conclusions reached in the Staff Paper and in the 1987 review remain valid:

(1) Health risks posed by inhaled particles are influenced both by the penetration and deposition of particles in the various regions of the respiratory tract and by the biological responses to these deposited materials.

(2) The risks of adverse health effects associated with deposition of ambient fine and coarse fraction particles in the thoracic (tracheobronchial and alveolar) regions of the respiratory tract are markedly greater than for deposition in the extrathoracic (head) region. Maximum particle penetration to the thoracic region occurs during oronasal or mouth breathing.

(3) The risks of adverse health effects from extrathoracic deposition of general ambient PM are sufficiently low that particles which deposit only in that region can safely be excluded from the standard indicator.

(4) The size-specific indicator(s) should represent those particles capable of penetrating to the thoracic region, including both the tracheobronchial and alveolar regions.

These conclusions, together with information on the dosimetry of particles in humans, were the basis for the promulgation in 1987 of a new size-specific indicator for the PM NAAQS, PM_{10}, that includes particles with an aerodynamic diameter smaller than or equal to a nominal 10 µm. The recent information on human particle dosimetry contained in the Criteria Document provides no basis for changing 10 µm as the appropriate cut point for particles capable of penetrating to the thoracic regions.

As noted in Unit II.B. of this preamble, however, the Staff Paper concludes that continued use of PM_{10} as the sole indicator for the PM standards would not provide the most effective and efficient protection from the health effects of PM (U.S. EPA, 1996b, pp. VII-4 to VII-11). Based on the recent health effects evidence and the fundamental physical and chemical differences between fine and coarse fraction particles, the Criteria Document and Staff Paper conclude that fine and coarse fractions of PM_{10} should be considered separately (U.S. EPA, 1996a, p. 13-93; 1996b, p. VII-18). Taking into account such information, CASAC found sufficient scientific and technical bases to support establishment of separate standards relating to these two fractions of PM_{10}. Specifically, CASAC advised the Administrator that ''there is a consensus that retaining an annual PM_{10} NAAQS * * * is reasonable at this time'' and that there is ''also a consensus that a new $PM_{2.5}$ NAAQS be established'' (Wolff, 1996b).

Some commenters have noted that it is often difficult to distinguish the effects of either fine or coarse fraction particles from those of PM_{10}; this is to be expected because both fractions are themselves components of PM_{10}, and hence not fully independent. EPA believes that it is more meaningful to examine comparisons between the fine and coarse fraction components. Such comparisons presented in the Staff Paper suggest that fine particles are a better surrogate for those components of PM that are linked to mortality and morbidity effects at levels below the current standards (U.S. EPA, 1996b, p. VII-18). Moreover, a regulatory focus on fine particles would likely also result in controls on gaseous precursors of fine particles (e.g., SO_x, NO_x, VOC), which are all components of the complex mixture of air pollution that has most generally been associated with mortality and morbidity effects. The Staff Paper concludes that, in contrast to fine particles, coarse fraction particles are more clearly linked with certain morbidity effects at levels above those allowed by the current 24-hour standard.

Public comments received on the proposed indicators were overwhelmingly in favor of EPA's proposal to maintain PM_{10} as an indicator for PM, whether as an indicator of coarse particles in conjunction with a fine PM standard, or as the sole PM indicator. This near unanimity shows strong support for retaining general PM standards. While a substantial number of commenters supported EPA's proposal to add an indicator for fine PM, a number of other commenters objected to any standard revisions, including addition of a fine PM indicator. Beyond the general points about the basis for any revisions discussed in Unit II.B. of this preamble, these commenters argued either that the available epidemiological data did not provide a basis for separating fine and coarse fraction particles, or that there were not enough fine particle studies to support selecting standard levels. Most of these commenters also expressed concerns that there were insufficient ambient fine particle data by which to evaluate the relative protection afforded by new standards.

EPA notes that issues relating to the basis for separating PM_{10} fractions were addressed in the Criteria Document and/or Staff Paper assessments, and these perspectives were also available for CASAC consideration in developing its recommendations. The proposal states that the main basis for separating the fine and coarse fractions of PM_{10} is that, because they are fundamentally different PM components with significantly different physico-chemical properties and origins (U.S. EPA 1996b, section V.D), separate standards would permit more effective and efficient regulation of PM. While the difficulty in separating these classes in the epidemiological studies is noted above, the preponderance of the available evidence suggests that strategies to control fine particles will more effectively reduce population exposure to substances associated with health effects in the recent epidemiological studies. Although the number of studies using fine PM indicators is more limited than for PM_{10}, there are more than 20 community studies showing significant associations for a consistent set of mortality and morbidity effects. A substantial subset of these studies (Tables V-12 to V-13; U.S. EPA, 1996b) provides a sufficient quantitative basis for selecting standard levels, without the need to rely on estimates based on $PM_{2.5}/PM_{10}$ ratios.

Having considered the public comments on this issue, the Administrator concurs with staff and CASAC recommendations to control particles of health concern (i.e., PM_{10}) through separate standards for fine and coarse fraction particles. The following units outline the basis for the Administrator's decision on specific indicators for fine and coarse fraction particle standards.

1. *Indicators for the fine fraction of* PM_{10}. The Administrator continues to conclude that it is appropriate to control fine particles as a group, as opposed to singling out particular components or classes of fine particles. The more qualitative scientific literature, evaluated in Chapter 11 of the Criteria Document and summarized in section V.C of the Staff Paper, has reported various health effects associated with high concentrations of a number of fine particle components (e.g., sulfates, nitrates, organics, transition metals), alone or in some cases in combination with gases. Community epidemiolgical studies have found significant associations between fine particles or PM_{10} and health effects in various areas across the U.S. where such fine particle components correlate significantly with particle mass. As noted above in this unit, it is not possible to rule out any one of these components as contributing to fine particle effects.[26] Thus, the Administrator finds that the present data more readily support a standard based on the total mass of fine particles. EPA will conduct additional research, in cooperation with other Federal agencies and in partnership with State and local agencies and the private sector, to better identify which species are of concern for human health, and the sources and relative magnitude of such species.

In specifying a precise size range for a fine particle standard, both the staff and CASAC recommended $PM_{2.5}$ as the indicator of fine particles (Wolff, 1996b). The particle diameter reflecting the mass minimum between the fine and coarse modes typically lies between 1 and 3 µm, and the scientific data support a sampling ''cut point'' to delineate fine particles somewhere in this range. Because of the potential

[26] As discussed above, a number of commenters expressed concerns that various portions of fine particles might not be responsible for any observed effects. One group (PG&E, 1997) recommended that nitrates should be excluded from fine PM mass collected on the basis of their assessment of available effects literature on particulate and gas phase inorganic nitrates. Based on an examination of this information as well as the earlier staff assessment, EPA maintains its conclusion that the available evidence is not sufficient to exclude nitrates or any other class of fine particles that are collected by PM monitors comparable to those used in the recent epidemiological studies.

overlap of fine and coarse particle mass in this intermodal region, EPA recognizes that any specific sampling cut point would result in only an approximation of the actual fine-mode particle mass. Thus, the choice of a specific diameter within this size range is largely a policy judgment. The staff and CASAC recommendations for a 2.5 µm sampling cut point were based on considerations of consistency with the community health studies, the limited potential for intrusion of coarse fraction particles into the fine fraction, and availability of monitoring technology.[27] $PM_{2.5}$ encompasses all of the potential agents of concern in the fine fraction, including most sulfates, acids, fine particle transition metals, organics, and ultrafine particles, and includes most of the aggregate surface area and particle number in the entire distribution of atmospheric particles.

The Administrator concurs with the staff and CASAC recommendations and concludes that $PM_{2.5}$ is the appropriate indicator for fine particle standards. As discussed in Unit VI.B. of this preamble, technical details of how $PM_{2.5}$ is to be measured in the ambient air are specified in the Federal Reference Method (40 CFR part 50, Appendix L).

2. *Indicators for the coarse fraction of* PM_{10}. The Criteria Document and Staff Paper conclude that epidemiological information, together with dosimetry and toxicological information, support the need for a particle indicator that addresses the health effects associated with coarse fraction particles within PM_{10} (i.e., $PM_{10-2.5}$). As noted above, coarse fraction particles can deposit in those sensitive regions of the lung of most concern. Although the role of coarse fraction particles in much of the recent epidemiological results is unclear, limited evidence from studies where coarse fraction particles are the dominant fraction of PM_{10} suggest that significant short-term effects related to coarse fraction particles include aggravation of asthma and increased upper respiratory illness. In addition, qualitative evidence suggests that potential chronic effects may be associated with long-term exposure to high concentrations of coarse fraction particles.

In selecting an indicator for coarse fraction particles, the Administrator took into account the views of several CASAC panel members who suggested using the coarse fraction directly (i.e., $PM_{10-2.5}$) as the indicator. However, the Administrator notes that the existing ambient data base for coarse fraction particles is smaller than that for fine particles, and that the only studies of clear quantitative relevance to effects most likely associated with coarse fraction particles have used undifferentiated PM_{10}. In fact, it was the consensus of CASAC that it is reasonable to consider PM_{10} itself as a surrogate for coarse fraction particles, when used together with $PM_{2.5}$ standards. The monitoring network already in place for PM_{10} is large. Therefore, in conjunction with the decision to have separate standards for $PM_{2.5}$, the Administrator concludes, consistent with CASAC recommendations and public comments, that it is appropriate to retain PM_{10} as the indicator for PM standards intended to protect against the effects most likely associated with coarse fraction particles.

D. Averaging Time of $PM_{2.5}$ Standards

As discussed above in this unit, the Administrator has concluded that $PM_{2.5}$ is an appropriate indicator for standards intended to provide protection from effects associated primarily with fine particles. The recent health effects information includes reported associations with both short-term (from less than 1 day to up to 5 days) and long-term (from a year to several years) measures of PM.

On the basis of this information, summarized in chapter V of the Staff Paper and in the rationale presented in the proposal, the Administrator has considered both short- and long-term $PM_{2.5}$ standards.

1. *Short-term $PM_{2.5}$ standard.* The current 24-hour averaging time is consistent with the majority of community epidemiological studies, which have reported associations of health effects with 24-hour concentrations of various PM indicators such as PM_{10}, fine particles, and TSP. Such health effects, including premature mortality and increased hospital admissions, have generally been reported with same-day, previous day, or longer lagged single-day concentrations, although some studies have reported stronger associations with multiple-day average concentrations. In any case, the Administrator recognizes that a 24-hour $PM_{2.5}$ standard can effectively protect against episodes lasting several days, since attainment of such a standard would provide protection on each day of a multi-day episode, while also protecting sensitive individuals who may experience effects after even a single day of exposure.

Although most reported effects have been associated with daily or longer measures of PM, evidence also suggests that some effects may be associated with PM exposures of shorter durations. For example, controlled human and animal exposures to specific components of fine particles, such as acid aerosols, suggest that bronchoconstriction can occur after exposures of minutes to hours. Some epidemiological studies of exposures to acid aerosols have also found changes in respiratory symptoms in children using averaging times less than 24 hours. However, such reported results do not provide a satisfactory quantitative basis for setting a fine particle standard with an averaging time of less than 24 hours, nor do current gravimetric mass monitoring devices make such shorter durations generally practical at present. Further, the Administrator recognizes that a 24-hour average $PM_{2.5}$ standard which leads to reductions in 24-hour average concentrations is likely to lead as well to reductions in shorter-term average concentrations in most urban atmospheres, thus providing some degree of protection from potential effects associated with shorter duration exposures.

2. *Long-term $PM_{2.5}$ standard.* Community epidemiological studies have reported associations of annual and multi-year average concentrations of PM_{10}, $PM_{2.5}$, sulfates, and TSP with an array of health effects, notably premature mortality, increased respiratory symptoms and illness (e.g., bronchitis and cough in children), and reduced lung function. The relative risks associated with such measures of long-term exposures, although highly uncertain, appear to be larger than those associated with short-term exposures. Based on the available epidemiology, and consistent with the limited relevant toxicological and dosimetric information, the Administrator concludes that significant, and potentially independent, health consequences are likely associated with long-term PM exposures.

[27] The National Mining Association (NMA) and related companies submitted comments favoring ultimate selection of a smaller cutpoint of 1 µm (PM_1) to further reduce coarse particle intrusion. EPA considered this approach in developing the Staff Paper and proposal. PM_1 has not been used in health studies, although in most cases collected mass should be similar to those for cutpoints of 2.1 or 2.5 µm. While a PM_1 indicator could reduce intrusion of coarse particles, it might also omit portions of hygroscopic PM components such as acid sulfates, nitrates, and some organic compounds in higher humidity environments picked up by $PM_{2.5}$ measurements. PM_1 sampling technologies have been developed, but have not been widely used in the field to date; there are some concerns about loss of certain organic materials in available models relative to an instrument with a larger size cut. NMA has also recommended consideration of a methodology that could subtract coarse mass from $PM_{2.5}$ measurements where undue coarse particle intrusion resulted in fine standard violations. EPA will evaluate this recommendation in the context of implementation policies.

The Administrator has considered this evidence, which suggests that some health endpoints reflect the cumulative effects of PM exposures over a number of years. In such cases, an annual standard would provide effective protection against persistent long-term (several years) exposures to PM. Requiring a much longer averaging time would also complicate and unnecessarily delay control strategies and attainment decisions.

The Administrator has also considered the seasonality of emissions of fine particles and their precursors in some areas (e.g., wintertime smoke from residential wood combustion, summertime regional acid sulfate and ozone formation), which suggests that some effects associated with annual average concentrations might be the result of repeated seasonally high exposures. However, different seasons are likely of concern in different parts of the country, and the current evidence does not provide a satisfactory quantitative basis for setting a national fine particle standard in terms of a seasonal averaging time.

In addition, the Administrator recognizes that an annual standard would have the effect of improving air quality broadly across the entire annual distribution of 24-hour $PM_{2.5}$ concentrations, although such a standard would not as effectively limit peak 24-hour concentrations as would a 24-hour standard. The risk assessment summarized above found that because such 24-hour peaks contribute much less to the total health risk over a year than the more numerous low- to mid-range $PM_{2.5}$ levels, an annual standard could also provide effective protection from health effects associated with short-term exposures to $PM_{2.5}$ as well as those associated with long-term exposures (see figure 2; 61 FR 65652-65653, December 13, 1996).

3. *Combined effect of annual and 24-hour standards.* For the reasons outlined in Units II.C.1. and 2. of this preamble, the Administrator concluded in the proposal that a short-term $PM_{2.5}$ standard with a 24-hour averaging time can serve to control short-term ambient $PM_{2.5}$ concentrations, thus providing protection from health effects associated with short-term (from less than 1-day to up to 5-day) exposures to $PM_{2.5}$. Further, a long-term $PM_{2.5}$ standard with an annual averaging time can serve to control both long- and short-term ambient $PM_{2.5}$ concentrations, thus providing protection from health effects associated with long-term (seasonal to several years) and, to some degree, short-term exposures to $PM_{2.5}$.

EPA received comparatively few public comments on these proposed averaging times. Those supporting $PM_{2.5}$ standards also strongly supported adopting both annual and 24-hour averaging times. Many of those opposing $PM_{2.5}$ standards, for the reasons discussed in Unit II.B. of this preamble, provided contingent comments that variously supported both averaging times for $PM_{2.5}$ standards in the event the Administrator disagreed with their overall recommendations. Other opponents of $PM_{2.5}$ standards disagreed with having two standards on administrative grounds, or because some CASAC members did not support both averaging times.

The relationship between standards for the two averaging times is discussed below in this unit. In essence, based on its examination of the effects data and air quality relationships, EPA believes that a single $PM_{2.5}$ standard (24-hour or annual) either would not provide adequate protection against effects of concern for all averaging times, or would be inefficient in the sense that it was more stringent than necessary for at least one averaging time. Contrary to commenters who focused on minority CASAC opinions, EPA notes that a clear majority of CASAC supported both 24-hour and annual standards[28]. After considering public comments on averaging time and the rationale outlined above, the Administrator has concluded that both 24-hour and annual $PM_{2.5}$ standards are appropriate.

The Administrator next considered the potential combined effects of such standards on PM concentration levels and distributions. The existing health effects evidence could, of course, be used to assess the form and level of each standard independently, with short-term exposure health effects evidence being used as the basis for a 24-hour standard and the long-term exposure health effects evidence as the entire basis for an annual standard. Some CASAC panel members apparently used this approach as a basis for their views on appropriate averaging times and standard levels. In particular, a few members focused only on a 24-hour $PM_{2.5}$ standard in light of the relative strength of the short-term exposure studies. On the other hand, two members focused only on an annual standard, recognizing that strategies to meet an annual standard would provide protection against effects of both short- and long-term exposures.

[28] Of the 19 panel members who joined in the consensus for $PM_{2.5}$ standards, 17 (90 percent) recommended a 24-hour standard and 13 (70 percent) recommended an annual standard (Wolff, 1996b).

As noted above in this unit, attempting to provide protection for all of the effects identified in long- and short-term PM exposure studies with a single averaging time would result in either inadequate protection for some effects, or unnecessarily stringent control for others. The Administrator has, instead, emphasized a policy approach that considers the consistency and coherence, as well as the limitations, of the body of evidence as a whole, and recognizes that there are various ways to combine two standards to achieve an appropriate degree of public health protection. Such an approach to standard setting, which integrates the body of health effects evidence and air quality analyses, and considers the combined effect of the standards, has the potential to result in a more effective and efficient suite of standards than an approach that only considers short- and long-term exposure evidence, analyses, and standards independently.

In considering the combined effect of such standards, the Administrator notes that while an annual standard would focus control programs on annual average $PM_{2.5}$ concentrations, it would also result in fewer and lower 24-hour peak concentrations. Alternatively, a 24-hour standard that focuses controls on peak concentrations could also result in lower annual average concentrations. Thus, either standard could be viewed as providing both short- and long-term protection, with the other standard serving to address situations where the daily peaks and annual averages are not consistently correlated.

The Administrator proposed that the suite of $PM_{2.5}$ standards could most effectively and efficiently be defined by treating the annual standard as the generally controlling standard for lowering both short- and long-term $PM_{2.5}$ concentrations. In conjunction with the annual standard, the 24-hour standard would serve to provide protection against days with high peak $PM_{2.5}$ concentrations, localized ''hot spots,'' and risks arising from seasonal emissions that would not be well controlled by a national annual standard.

Relatively few public comments were addressed specifically to the proposal that the annual standard be directed toward controlling both 24-hour and annual levels (thereby basing the annual standard on an evaluation of both the short- and long-term health effects information), with the 24-hour standard being used to address more localized short-term peaks. A number of commenters, notably some among the groups opposing any revised PM

standards, appeared to have ignored this fundamental aspect of the proposal, judging by their assertions that the sole basis for EPA's proposed annual standards was two long-term exposure studies (Dockery et al., 1993; Pope et al. 1995). This is incorrect; as the proposal states, EPA based the proposed annual standard level on a wider range of short- and long-term exposure studies. Other commenters, including some environmental groups, reserved comment on this specific issue, but expressed concerns that the specific levels for both standards were not stringent enough, regardless of which standard is intended to be controlling. Issues regarding specific levels are discussed below in Unit II.F. of this preamble.

Some commenters, however, disagreed with the proposition that EPA's proposed approach would necessarily provide the most effective and efficient standards. In the view of some who opposed $PM_{2.5}$ standards, the likelihood that there are thresholds below which no effects occur means that a 24-hour standard would be more efficient than an annual standard. In this view, the reductions made on days that were below the threshold would provide no protection.[29] Some commenters also noted that while a majority of CASAC members favored both annual and 24-hour standards, more recommended 24-hour standards.

While the available epidemiological studies provide strong evidence suggesting that PM causes or contributes to health effects at levels below the current standards, EPA agrees, as stated previously, that uncertainties increase markedly at lower concentrations. Nevertheless, the level or even existence of population thresholds below which no effects occur cannot be reliably determined by an examination of the results from the available studies. Analyses have placed some limits, however, and EPA has considered hypothetical thresholds in its risk assessment. As noted in Unit II.A. of this preamble, even assuming an example threshold of 18 $\mu g/m^3$, the risk assessment (see Figure 2c; 61 FR 65653, December 13, 1996) finds that most of the annual aggregate risk associated with short-term exposures still results from the large number of days at lower to mid-range values above the mean. Given that neither the Criteria Document nor commenters have provided quantitative evidence regarding the likelihood of a threshold at levels much higher than the above example, EPA believes that the evidence provided in the risk assessment does not support the commenters' position. As noted above, EPA believes that most CASAC opinions on averaging time reflect panelists' judgments on the relative strength of the short-term exposure epidemiological studies, a judgment that EPA shares. Although most CASAC panel members did not offer an opinion on the use of short-term exposure studies in specifying annual standards, two panelists did support this notion. EPA therefore believes this approach is neither inconsistent with the underlying science nor discordant with the advice of CASAC.

Another concern was raised by some air pollution control officials who otherwise supported revised PM standards. These commenters state that, from an implementation perspective, it is often easier to design control strategies for single short-term events than for annual averages. Aside from whether this is a proper consideration in establishing NAAQS, the point in fact highlights one of the important strengths of an annual standard in addressing short-term risks associated with $PM_{2.5}$. As noted by the commenters, risk management for a short-term standard focuses on a characteristic ''design value'' episode responsible for peak concentrations. For PM, such peak values can be associated with single source contributions. Meteorology, relative source contributions, and resulting particle composition for that day may or may not be typical for the area or for the year. Yet the short-term exposure epidemiological results are largely drawn from studies that associated variations in area-wide effects with monitor(s) that gauged the variation in daily levels over the course of up to 8 years. The strength of the associations in these data is demonstrably in the numerous ''typical'' days in the upper to middle portion of the annual distribution, not on the peak days.[30] For these reasons, strategies that focus only on reducing peak days are less likely to achieve reduction of the mix and sources of urban and regional-scale PM pollution most strongly associated with health effects. Although designing control strategies to reduce annual levels may be more difficult than for 24-hour standards, the available short- and long-term epidemiological data suggest it is also likely to result in a greater reduction in area-wide population exposure and risk.

The Administrator concludes that the most effective and efficient approach to establishing $PM_{2.5}$ standards is to treat the annual standard as the generally controlling standard for lowering both short- and long-term $PM_{2.5}$ concentrations, while the 24-hour standard would serve to provide protection against days with high peak $PM_{2.5}$ concentrations, localized ''hot spots,'' and risks arising from seasonal emissions that would not be well controlled by a national annual standard. In reaching this view, the Administrator took into account the public comments and the factors discussed below in this unit.

(1) Based on one of the key observations from the quantitative risk assessment summarized above (see Figures 2a,b,c; 61 FR 65652-65653, December 13, 1996), the Administrator notes that much if not most of the aggregate annual risk associated with short-term exposures results from the large number of days during which the 24-hour average concentrations are in the low- to mid-range, below the peak 24-hour concentrations. As a result, lowering a wide range of ambient 24-hour $PM_{2.5}$ concentrations, as opposed to focusing on control of peak 24-hour concentrations, is the most effective and efficient way to reduce total population risk. Further, there is no evidence suggesting that risks associated with long-term exposures are likely to be disproportionately driven by peak 24-hour concentrations. Thus, an annual standard that controls an area's attainment status is likely to reduce aggregate risks associated with both short- and long-term exposures with more certainty than a 24-hour standard.

(2) The consistency and coherence of the health effects data base are, therefore, more directly related to the more frequently occurring PM exposures reflected in study period mean measures of air quality (e.g., the annual distributions of 24-hour PM concentrations), than to the potentially site-specific and/or otherwise infrequent PM exposures reflected in a limited number of peak 24-hour concentrations. More specifically, judgments about the quantitative consistency of the large number of short-term exposure studies

[29] A related comment criticized the risk assessment conclusion that peak 24-hour concentrations contribute much less to the total risk over a year as inconsistent with the experience in historic air pollution episodes. EPA disagrees. While the historic London episodes were quantitatively different from those assumed in the risk assessment, the record over 14 London winters indicates a continuum of effects down to the lowest levels. It is therefore likely that the cumulative increase in mortality calculated for all the days in the whole 14-year period would not be dominated by the more limited number of episode days.

[30] This point is buttressed by studies that have taken out a limited number of higher PM concentration days with little effect on the effects estimates or significance of the association (e.g., Schwartz et al., 1996; Pope and Dockery, 1992).

reporting associations with 24-hour concentrations arise from comparing the relative risk results per PM increment as derived from analyzing the associations across the entire duration of the studies. These studies typically spanned at least an annual time frame and the reported associations are most strongly influenced by the large number of days toward the middle of the distribution.

(3) An annual average measure of air quality is more stable over time than are 24-hour measures. Thus, a controlling annual standard is likely to result in the development of more consistent risk reduction strategies over time, since an area's attainment status will be less likely to change due solely to year-to-year variations in meteorological conditions that affect the formation of fine particles, than under a controlling 24-hour standard.

Under this policy approach, the annual $PM_{2.5}$ standard would serve in most areas as the target for control programs designed to be effective in lowering the broad distribution of $PM_{2.5}$ concentrations, thus protecting not only against long-term effects but also short-term effects as well. In combination with such an annual standard, the 24-hour $PM_{2.5}$ standard would be set so as to protect against the occurrence of peak 24-hour concentrations, particularly peak concentrations that present localized or seasonal exposures of concern in areas where the highest 24-hour-to-annual mean $PM_{2.5}$ ratios are appreciably above the national average.

E. Form of $PM_{2.5}$ Standards

1. *Annual standard.* As discussed in some detail during the last review of the PM NAAQS (see 49 FR 10408, March 20, 1984; 52 FR 24634, July 1, 1987) and in the December 13, 1996 proposal, the annual arithmetic mean form of the current annual PM_{10} standard (i.e., the annual arithmetic mean averaged over 3 years) is a relatively stable measure of air quality that reflects the total cumulative dose of PM to which an individual or population is exposed. Short-term peaks have an influence on the arithmetic mean that is proportional to their frequency, magnitude, and duration, and, thus, their contribution to cumulative exposure and risk. As a result, the annual arithmetic mean form of an annual standard provides protection across a wide range of the air quality distribution contributing to exposure and risk, in contrast to other forms, such as the geometric mean, that de-emphasize the effects of short-term peak concentrations.

While almost no commenters took specific issue with use of an annual arithmetic mean, a number of commenters disagreed with averaging over 3 years for both the annual and 24-hour standards because of their desire for quick action in the initial implementation of $PM_{2.5}$ controls. The Administrator recognizes the importance of promptly implementing appropriate control programs, but she does not believe that implementation start-up concerns are an adequate basis for adopting a form (e.g., a single year annual average) that would provide less stable risk reduction in the long-run. Therefore, the Administrator continues to concur with the Staff Paper recommendation, supported by CASAC, to use the annual arithmetic mean, averaged over 3 years, as the form for an annual $PM_{2.5}$ standard consistent with the current form of the annual PM_{10} standard. Nevertheless, EPA intends to address the concerns of those who commented that the 3-year form might prevent the public from being informed about the air quality status of their communities. As outlined in Unit II.H. of this preamble, EPA plans to issue revised Pollutant Standard Index criteria for $PM_{2.5}$, to ensure the public is informed promptly about air quality status.

The Staff Paper and some CASAC panel members also recommended that consideration be given to calculating the $PM_{2.5}$ annual arithmetic mean for an area by averaging the annual arithmetic means derived from multiple monitoring sites within a monitoring planning area. In proposing a calculation method for annual arithmetic averages that involves spatial averaging of monitoring data, the Administrator reasoned as follows:

(1) Many of the community-based epidemiological studies examined in this review used spatial averages, when multiple monitoring sites were available, to characterize area-wide PM exposure levels and the associated population health risk. In those studies that used only one monitoring location, the selected site was chosen to represent community-wide exposures, not the highest value likely to be experienced within the community. Thus, spatial averages are most directly related to the epidemiological studies used as the basis for the proposed revisions to the PM NAAQS.

(2) As a part of the overall policy approach discussed in Unit II.D. of this preamble, the annual $PM_{2.5}$ standard would be intended to reduce aggregate population risk from both long- and short-term exposures by lowering the broad distribution of $PM_{2.5}$ concentrations across the community. An annual standard based on spatially averaged concentrations would better reflect area-wide PM exposure levels than would a standard based on concentrations from a single monitor with the highest measured values.

(3) Under this policy approach, the 24-hour $PM_{2.5}$ standard would be intended to work in conjunction with a spatially averaged annual $PM_{2.5}$ standard by providing protection against peak 24-hour concentrations, localized ''hot spots,'' and higher $PM_{2.5}$ concentrations arising from seasonal emissions and meteorology that would not be as well controlled by an annual standard. Accordingly, the 24-hour $PM_{2.5}$ standard should be based on the single population-oriented monitoring site within the monitoring planning area with the highest measured values.

Based on these considerations, the Administrator proposed that the form of an annual $PM_{2.5}$ standard be expressed as the annual arithmetic mean, temporally averaged over 3 years and spatially averaged over all designated monitoring sites,[31] which, in conjunction with a 24-hour $PM_{2.5}$ standard, was intended to provide the most appropriate target for reducing area-wide population exposure to fine particle pollution. Recognizing the complexities that spatial averaging might introduce into risk management programs, in the proposal the Administrator also requested comment on the alternative of basing the annual standard for $PM_{2.5}$ solely on the single population-oriented monitor site within the monitoring planning area with the highest 3-year average annual mean.

The proposed approach to designating sites that are appropriate for spatial averaging was based on criteria and constraints contained in the proposed revision to the monitoring siting and network planning requirements in 40 CFR part 58. In proposing this approach, the Administrator noted concerns regarding the development and implementation of appropriate and effective criteria for the selection of sites and designations of areas for spatial averaging.

A number of commenters who otherwise favored setting $PM_{2.5}$ standards objected to the concept of population-oriented monitors and expressed the view that any monitor regardless of where it was sited should be eligible for comparison to the annual $PM_{2.5}$ standard. They further maintained that the proposed provisions for spatial averaging would fail to provide adequate health protection because

[31] The notice of proposed revisions to 40 CFR part 58 recognized that a single appropriately sited monitor could suffice for an area in place of an average of multiple monitors.

''clean areas'' and ''dirty areas'' would be averaged together. Some commenters expressed concern that the proposed constraints on spatial average would not be sufficient to prevent use of such averaging to avoid pollution abatement. Others may not have fully understood the implications of the specific constraints and siting requirements discussed in the proposed revisions to 40 CFR part 58, which were intended to ensure that the population-oriented monitors used for the annual standard were actually reflective of community-wide exposures and that the spatial averages did not include non-representative monitored values from either ''clean areas'' or ''dirty areas.''[32] In order to clarify the intent that the spatially averaged annual standard protect those in smaller communities, as well as those in larger population centers, the final revisions to 40 CFR part 58 adopt the term ''community-oriented'' monitors.

Other commenters, who supported $PM_{2.5}$ annual standards, endorsed the concept of spatial averaging as being more reflective of the air quality data used in the underlying health studies and because there is general uniformity of fine particle concentrations across an area. Opponents of the $PM_{2.5}$ standards expressed contingent support for spatial averaging in concept, again citing the linkage to the underlying health studies. Indeed, they advocated the extension of spatial averaging to the daily form of the standard, and/or recommended less constrained spatial averaging to allow for averaging across entire metropolitan areas.

The Administrator, of course, shares commenters' concerns that the form of the standards, in conjunction with other components of the standards, must protect public health adequately against risks associated with PM. It was for this reason that EPA proposed a policy approach providing for greatest overall risk reduction for all citizens in the community from exposures to the mix of urban and regional scale PM pollution most strongly associated with health effects. In specifically considering whether to allow for the use of spatial averaging, the Administrator placed great weight on consistency with the underlying body of health effects evidence. The Administrator is mindful that some community studies relied inherently on exposure and effects estimates that reflect comparatively broad spatial scales, as highlighted by those commenters desiring to extend permissible averaging; however, this type of exposure characterization may not be appropriate for all circumstances and might leave some areas without adequate protection.[33]

For these reasons, the 40 CFR part 58 proposal package contained criteria and constraints on spatial averaging. These criteria and constraints were intended to ensure that spatial averaging would not result in inequities in the level of protection provided by the PM standards. The Administrator again recognizes that either a single properly sited community-oriented monitor, or an average of more than one such monitors, are both appropriate indices of area-wide population exposures. Both are consistent with monitoring approaches used in community epidemiological studies upon which the standards are based. On the other hand, comparing the annual $PM_{2.5}$ standard to the maximum concentrations at a site that is not representative of community exposures, as some have suggested, would be inconsistent with the Administrator's goal of using the annual standard to reduce urban and regional scale exposures and risks. Further, the Administrator believes that the criteria and, siting requirements contained in 40 CFR part 58, provide adequate safeguards against inappropriate application of spatial averaging. Therefore, the Administrator continues to believe that an annual $PM_{2.5}$ standard reflective of area-wide exposures, in conjunction with a 24-hour standard designed to provide adequate protection against localized peak or seasonal $PM_{2.5}$ levels, reflects the most appropriate approach for public health against the effects of PM reported in the scientific literature.[34]

The majority of comments from States stressed the need for flexibility in specifying network designs and spatial averaging, given that the nature and sources of particle pollution vary from one area to another. One State agency specifically requested the flexibility to choose whether to use a single community-oriented monitor or a spatial average of several of such monitors, arguing that it is appropriate to provide this flexibility as $PM_{2.5}$ monitoring networks evolve and to address the diversity of local conditions.

As a result of EPA's evaluation of these comments, the requirements of 40 CFR part 50, Appendix K, and 40 CFR part 58 have been revised to clarify that the implementing agencies have the flexibility to compare the annual $PM_{2.5}$ standard either to the measured value at a single representative community-oriented monitoring site, or to the value resulting from an average of community-oriented monitoring sites that meet the revised criteria and constraints enumerated in the 40 CFR part 58 final rule.

In the Administrator's view, the final criteria and siting requirements contained in 40 CFR part 58 and in the new 40 CFR part 50, Appendix N, address the concerns raised by these commenters about the protection afforded by the form of the annual standard. Therefore, the Administrator continues to believe that the form of a $PM_{2.5}$ annual standard should be expressed as an annual arithmetic mean, averaged over 3 years, from single or multiple community-oriented monitors, in accordance with 40 CFR part 50, Appendix N and 40 CFR part 58. In her judgment, an annual standard expressed in this manner and set at an appropriate level, in conjunction with a 24-hour $PM_{2.5}$ standard, will adequately protect public health.

2. *24-hour standard.* The current 24-hour PM_{10} standard is expressed in a ''1-expected-exceedance'' form. That is, the standard is formulated on the basis of the expected number of days per year (averaged over 3 years) on which the level of the standard will be exceeded. The test for determining attainment of the current 24-hour standard is presented in Appendix K to 40 CFR part 50.

As discussed in the proposal, since promulgation of the current 24-hour PM_{10} standard in 1987, a number of concerns have been raised about the 1-

[32] The 40 CFR part 58 proposed rule identified the proposed criteria for monitors to be averaged; namely, monitors must be properly sited to reflect population-orientation, primarily influenced by similar sources, and within +/-20 percent of the average levels and a specific degree of correlation (or meet a ''homogeneity'' constraint). Additional criteria include demonstrations that the monitors to be averaged are influenced primarily by similar sources (e.g., to prevent the placement of monitors upwind in unrepresentative locations), EPA oversight of the monitoring program which includes regular review and approval of the State PM monitoring network design, and other criteria to ensure proper monitor siting. The final rule includes the addition of provisions that the State PM monitoring network design be available for public inspection.

[33] Daily mortality studies generally use urban or metro-areawide effects statistics in conjunction with single or multiple monitors that index day-to-day pollution changes across the area. Ito et al. (1995) found that spatial averages from multiple PM monitors in Chicago were better correlated with daily mortality than were most single monitors, but that single monitors were also associated. A number of morbidity studies (e.g., Schwartz et al., 1994; Neas et al., 1995; Raizenne et al.; 1996) used community scale monitors and effects information from a defined group of subjects from the community, who were more closely represented by the monitor.

[34] Because the 24-hour standard is designed to address localized peaks, it would be inappropriate to extend spatial averaging forms to this standard.

expected-exceedance form. These include, in particular, the year-to-year stability of the number of exceedances, the stability of the attainment status of an area, and the complex data handling conventions specified in 40 CFR part 50, Appendix K, including the procedures for making adjustments for missing data and less-than-every-day monitoring.

In light of these concerns, the Staff Paper and several CASAC panel members (Wolff, 1996b) recommended that consideration be given to adoption of a more stable and robust form for 24-hour standards. In considering this recommendation for the proposal, the Administrator noted that the use of a concentration-based percentile form would have several advantages over the current 1-expected-exceedance form:

(1) Such a concentration-based form would be more directly related to the ambient PM concentrations that are associated with health effects. Given that there is a continuum of effects associated with exposures to varying levels of PM, the extent to which public health is affected by exposure to ambient PM is related to the actual magnitude of the concentration, not just whether the concentration is above a specified level. With an exceedance-based form, days on which the ambient concentration is well above the level of the standard are given equal weight to those days on which the concentration is just above the standard (i.e., each day is counted as one exceedance), even though the public health impact on the 2 days is significantly different. With a concentration-based form, days on which higher concentrations occur would weigh proportionally more than days with lower concentrations for the design value, since the actual concentrations would be used directly in determining whether the standard is attained.

(2) A concentration-based percentile form would also compensate for missing data and less-than-every-day monitoring, thereby reducing or eliminating the need for complex data handling procedures in the 40 CFR part 50, Appendix K test for attainment. As a result, an area's attainment status would be based directly on monitoring data rather than on a calculated value adjusted for missing data or less-than-every-day monitoring.

(3) Further, a concentration-based form, averaged over 3 years, would also have greater stability than the expected exceedance form and, thus, would facilitate the development of more stable implementation programs by the States.

The proposal discussed various specific percentile values for such a form (e.g., 90th to 99th percentiles), taking into account two factors. First, the 24-hour $PM_{2.5}$ standard is intended to supplement the annual $PM_{2.5}$ standard by providing additional protection against extremely high peak days, localized ''hot spots,'' and risks arising from seasonal emissions. Second, given an appropriate level of health protection, the form of the 24-hour $PM_{2.5}$ standard should provide an appropriate degree of increased stability relative to the current form. The Administrator noted in the proposal that a more stable statistic would reduce the impact of a single high exposure event that may be due to unusual meteorological conditions alone, and thus would provide a more stable basis upon which to design effective control programs.

With these purposes in mind, the Administrator observed in the proposal that while a percentile value such as the 90th or 95th would provide substantially increased stability when compared to a more extreme air quality statistic (e.g., the current 1-expected-exceedance form), it would likely not serve as an effective supplement to the annual standard, because it would allow a large number of days with peak $PM_{2.5}$ concentrations above the standard level. For example, in a 365-day data base, the 90th and 95th percentiles would equal the 37th and 19th highest 24-hour concentrations, respectively. On the other hand, a percentile value selected much closer to the tail of the air quality distribution (e.g. a 99th or greater percentile) would not likely provide significantly more health protection or significantly increased stability as compared to a 1-exceedance form. In balancing these issues in the proposal, the Administrator ultimately proposed a 98th percentile value form of the standard.

Some commenters maintained that EPA should retain the current 1-expected-exceedance form for the 24-hour $PM_{2.5}$ standard to limit the number of days per year that the standard is exceeded. These commenters apparently gave little weight to EPA's rationale that a concentration-based form is more directly related to ambient PM concentrations that are associated with health effects because it takes into account the magnitude of PM concentrations, not just whether the concentrations are above a specific level. These commenters also discounted the other advantages of a concentration-based percentile form outlined above in this unit. A number of other commenters supported the concentration-based percentile form for the reasons outlined in the proposal but, as discussed below in this unit, argued for alternative percentile values that were higher or lower than the proposed 98th percentile value.

EPA continues to believe that a concentration-based percentile form is more reflective of the health risk posed by elevated PM concentrations, because it gives proportionally greater weight to days when concentrations are well above the level of the standard than to days when the concentrations are just above the standard. This factor, coupled with the other advantages outlined above in this unit, leads EPA to conclude that a concentration-based percentile form will provide for more effective health protection than a 1-expected-exceedance form.

Some commenters supporting a single exceedance form or a more restrictive concentration-based percentile form (e.g. a 99th percentile) expressed concern that the proposed 98th percentile form could allow too many high concentration excursions, and thus fail to provide adequate protection against seasonal emissions problems or localized peaks. In particular, some commenters expressed concerns that in areas with strongly seasonal emissions, such as western areas with winter inversions, over a three year period an area could experience several excursions in which levels could reach as high as 250 $\mu g/m^3$ and still comply with both the annual and daily standards if the remainder of the days had low levels (e.g., 10 $\mu g/m^3$). Although this combination of events is theoretically possible, EPA believes it is unlikely. Moreover, if such episodic events did occur, the Act provides for emergency State or Federal action to address them.[35] In view of the limits on truely episodic peak concentrations, EPA believes that an appropriately selected 24-hour standard with a concentration-based 98th percentile form can provide a stable and adequately protective supplement to the annual standard in areas with periodic peak concentrations.

Other commenters who were also concerned with monitoring requirements associated with spatial averaging in the annual standard, argued that a 98th percentile form, coupled with the proposed monitoring requirements that would limit

[35] See sections 303, 110(a)(2)(y); 40 CFR part 51. EPA intends to establish a significant harm level for $PM_{2.5}$ and associated guidance so States can develop appropriate emergency episode plans. The significant harm and episode criteria will be included in forthcoming proposed revisions to 40 CFR part 51 and 40 CFR part 58 implementation guidance. In the interim, existing PM_{10} emergency episode plans should be triggered by events of this magnitude.

compliance monitors for the 24-hour standard to population-oriented sites, would not protect people residing in or near localized ''hot spots'' in some areas.[36] The Administrator believes that the siting requirements as proposed and finalized in 40 CFR part 58 for population-oriented sites will provide adequate safeguards for such residential areas.

Other commenters, who otherwise opposed setting $PM_{2.5}$ standards, recommended that alternative lower percentiles (e.g., 95th percentiles) be used, if EPA proceeds to set such standards. As discussed above in this unit, however, EPA continues to hold the view that a 90th to 95th percentile form would not provide an adequate limit against periodic peak values in areas with low annual values and periodic high seasonal or source-oriented peaks.

After carefully assessing the comments received, the Administrator is persuaded that the adoption of a 98th percentile form for the 24-hour $PM_{2.5}$ standard measured at each population-oriented monitoring site in an area would provide an effective supplement to the annual $PM_{2.5}$ standard. This form will provide adequate protection against 24-hour peak $PM_{2.5}$ levels in locations dominated by single point sources, as well as in areas dominated by seasonal emissions. The Administrator also believes that a 98th percentile form, with more frequent sampling and averaged over 3 years, will provide increased stability and robustness as recommended by several members of the CASAC panel. For these reasons, the Administrator has decided to adopt the 98th percentile form for the final $PM_{2.5}$ 24-hour standard. The 24-hour $PM_{2.5}$ standard would be attained when the 3-year average of the 98th percentile of 24-hour concentrations at each populated oriented monitor within an area is less than or equal to the level of the standard. Further details regarding the interpretation of the form, as well as associated calculations and other data handling conventions are specified in the new 40 CFR part 50, Appendix N.

F. Levels for the Annual and 24-Hour $PM_{2.5}$ Standards

As discussed in Unit II.D. of this preamble, the Administrator believes that an annual $PM_{2.5}$ standard can provide the requisite reduction in risk associated with both annual and 24-hour averaging times in most areas of the United States. Under this approach, the 24-hour standard would be intended to provide supplemental protection against extreme peak fine particle levels that may occur in some localized situations or in areas with distinct variations in seasonal fine particle levels. In reaching judgments as to appropriate levels to propose for both the annual and 24-hour $PM_{2.5}$ standards, the Administrator has considered the combined protection afforded by both the annual and 24-hour standards, taking into account the forms discussed in Unit II.E. of this preamble.

With this approach in mind, the Administrator has considered the available health effects evidence and related air quality information presented in the Criteria Document and summarized in chapters IV--VII of the Staff Paper, which provides the basis for decisions on standard levels that would reduce risk sufficiently to protect public health with an adequate margin of safety, recognizing that such standards will not be risk-free. In so doing, the Administrator has considered both the strengths and the limitations of the available evidence and information, as well as alternative interpretations of the scientific evidence advanced by various CASAC panel members (Wolff, 1996b; Lippmann et al., 1996) and public commenters, arising primarily from the inherent uncertainties and limitations in the health effects studies.

Beyond those factors, but clearly related to them, a range of views have been expressed by CASAC panel members and the public as to the appropriate policy response to the available health effects evidence and related air quality information. Toward one end of the spectrum, the view has been expressed that only a very limited policy response is appropriate in light of the many key uncertainties and unanswered questions that, taken together, call into question the fundamental issue of causality in the reported associations between ambient levels of $PM_{2.5}$ and mortality and other serious health effects. Toward the other end, the view has been expressed that the consistency and coherence of the epidemiological evidence should be interpreted as demonstrating causality in the relationships between $PM_{2.5}$ and health endpoints that are clearly adverse, and that uncertainties in the underlying health effects information should be treated, regardless of their nature, as warranting a maximally precautionary policy response. A third view would suggest an alternative policy response, taking into account not only the consistency and coherence of the health effects evidence, but also the recognition of key uncertainties and unanswered questions that increasingly call into question the likelihood of PM-related effects as $PM_{2.5}$ concentrations decrease below the mean values in areas where effects have been observed and/or as such concentrations approach background levels.

Reflecting these divergent views, both of the science itself and of how the science should be used in making policy decisions on proposed standards, the Administrator considered three alternative approaches to selecting appropriate standard levels, as described in the proposal, ultimately deciding to propose standards based on a balanced view of the strengths and uncertainties of the scientific information that reflects the intermediate approach.

Judging by the public comments received, EPA accurately reflected the bases for divergent views. A substantial body of public comments supported revising the PM standards by adding $PM_{2.5}$ standards with levels at least as stringent as those proposed by the Administrator. In general, however, comments on levels for $PM_{2.5}$ standards revealed a strong dichotomy between those who recommended even stronger standards than proposed, and those who counseled against revising the standards at all. As noted above in this unit, many in this latter group made contingent recommendations with respect to the levels and other aspects of $PM_{2.5}$ standards, if the Administrator concluded that any revisions were appropriate.

This latter group of ''contingent'' commenters recommended levels well above those proposed by the Administrator. These commenters placed great weight on factors outlined in Units II.B. and II.C. of this preamble that led them to oppose any revisions to the PM standards, including the uncertainties and limitations in the available health effects studies considered individually, such as the possible existence of effects thresholds and unanswered questions regarding the causal agent(s) responsible for the reported health effects. Further, they emphasized the limited amount of research currently available that has measured $PM_{2.5}$ directly. A substantial group recommended that $PM_{2.5}$ standards be selected so as to be equivalent or close in stringency to the current PM_{10} standards, and cited the opinions of some CASAC PM panel members as support. Some of these commenters provided supplemental analyses of air quality data, arguing that they demonstrate that ''equivalent'' standards would be at $PM_{2.5}$ levels as

[36] The 40 CFR part 58 monitoring rule proposed to limit sites that would be eligible for comparisons to the 24-hour standard to population-oriented monitoring sites.

high as approximately 95 μg/m³ 24-hour average and 27 μg/m³ annual average.

Having evaluated these comments, the Administrator rejects both their underlying rationale and the specific recommendations for $PM_{2.5}$ standard levels that result in similar or only marginally more protection than that afforded by the current PM_{10} standards. Aside from technical problems in the commenters' supporting analyses on the issue of defining ''equivalent'' standards,[37] the Administrator finds this approach inconsistent with her conclusions regarding the adequacy of the current standards and the need to provide additional protection as articulated in Unit II.B. of this preamble. The Administrator believes that, despite well recognized uncertainties, the consistency and coherence of the epidemiological evidence and the seriousness of the health effects require a more protective response than provided by ''equivalence'' or a marginal strengthening of the standards. Moreover, EPA believes that the standard levels should be based on the most recent assessment of the scientific criteria for PM, not on applying uncertain ratios to standard decisions based on much more limited evidence in 1987. The Administrator also rejects the premise of some[38] who suggest that adopting a standard that prompts little or no additional control would cause no delay in risk reduction as compared to conducting monitoring and research now and setting a more stringent standard after the next review. These comments do not consider the realities of implementing air quality standards, which ensure that such an approach would add several years to the risk reduction process. Thus, aside from her obligations under the statute,[39] the Administrator believes that the most prudent and appropriate course is to establish appropriately protective standards now that put into motion monitoring and strategy development programs, while at the same time pursuing an expanded research program to improve implementation and to inform the next periodic review of the criteria and standards.

In sharp contrast to the commenters discussed immediately above, a number of other commenters strongly supported standard levels more stringent than those proposed by EPA. These commenters supported EPA's conclusions regarding the epidemiological studies, but would place much less weight on uncertainties related to the concentration-response relationships for $PM_{2.5}$ as a surrogate for PM and the relative importance of various PM components. Based on their evaluation of the information, and citing the support of some CASAC panel members, these commenters variously recommended 24-hour $PM_{2.5}$ standards as low as 18 to 20 μg/m³ and annual standards of 10 to 12 μg/m³.[40]

EPA notes that setting such standards would result in commensurate reductions in health risks only if, in fact, there is a continuum of health risks down to the lower end of the ranges of air quality observed in the key epidemiological studies, and only if the reported associations are, in fact, causally related to $PM_{2.5}$ at the lowest concentrations measured. Setting standards at low levels where the possibility of effects thresholds is greater, and where there is greater potential that other elements in the air pollution mix (or some subset of particles within the fine fraction) become more responsible for (or modify) the effects being causally attributed to $PM_{2.5}$, might result in regulatory programs that go beyond those that are needed to effectively reduce risks to public health. While placing substantial weight on the results of the key health studies in the higher range of concentrations observed, EPA is persuaded that the inherent scientific uncertainties are too great to support standards based on the lowest concentrations measured in such studies, which approach the maximum range of $PM_{2.5}$ values estimated for short-term background conditions.

Having considered the comments reflecting the two contrasting views summarized above in this unit, the Administrator concludes that the approach she set forth in the proposal is the most appropriate for selecting levels for annual and 24-hour $PM_{2.5}$ standards. This approach focuses primarily on standard levels designed to limit annual $PM_{2.5}$ concentrations to somewhat below those where the body of epidemiological evidence is most consistent and coherent, in recognition of both the strengths and the limitations of the full range of scientific and technical information on the health effects of PM, as well as associated uncertainties, as interpreted by the Criteria Document, Staff Paper, and CASAC. The Administrator believes that this approach appropriately reflects the weight of the evidence as a whole.

In identifying $PM_{2.5}$ standard levels consistent with this overall approach, the Administrator has placed greatest weight on those epidemiological studies reporting associations between health effects and direct measures of fine particles, most notably those recent studies conducted in North America (summarized in Tables V-12 and V-13 of the Staff Paper).[41] Key considerations and study results upon which this approach is based are presented as follows.

As previously discussed, the Administrator has concluded that it is appropriate to select the level of the annual standard so as to protect against the range of effects associated with both short- and long-term exposures to PM,

[37] Nationwide $PM_{2.5}$ estimates have been derived from the current PM air quality data base, but reflect a significant degree of uncertainty due to the highly variable relationship between $PM_{2.5}$ and PM_{10} air quality values across locations and seasons (Fitz-Simons et al., 1996). The American Iron and Steel Institute (AISI) submitted a useful data base (Cooper Associates, 1997) on $PM_{2.5}/PM_{10}$ relationships that examines both these predictions and the issue of equivalence. An EPA examination of this material, which found some problems with the analysis and with commenters' conclusions that appear inconsistent with the Cooper report, is included in the Response to Comments.

[38] Some commenters suggest that CASAC and EPA support for $PM_{2.5}$ standards is based on the need to stimulate additional monitoring and research. While the Administrator agrees that the additional monitoring and research that would accompany establishment of equivalent or marginally tighter $PM_{2.5}$ standards are very important goals, they do not form an adequate rationale for establishing air quality standards.

[39] As stated previously, section 109(d) of the Act requires that, after reviewing the existing criteria and standards for PM, the Administrator make such revisions in the standards and promulgate such new standards as are appropriate under section 109(b) of the Act.

[40] This range of levels for a 24-hour $PM_{2.5}$ standard is close to the lower bound levels recommended by four CASAC panel members (20 μg/m³); no member supported an annual $PM_{2.5}$ standard as low as 10 to 12 μg/m³.

[41] Some confusion is apparent in comments regarding the basis on which the Administrator selected levels for the proposed $PM_{2.5}$ standards, with some commenters suggesting two or at most three studies were used, and others suggesting that EPA relied extensively on uncertain conversion factors to estimate levels for the standards. These comments are in error. To clarify, as stated in the proposal, the Administrator is basing her decision to revise the standards on the full range of PM health effects studies summarized in the Criteria Document and Staff Paper, but in selecting specific levels for $PM_{2.5}$ standards, is relying chiefly on U.S. and Canadian studies, listed in Tables V-12 and V-13 of the Staff Paper, that measured fine PM levels. To ease identification and use of these key studies, the short-term exposure studies and key PM air quality statistics are cited in Koman (1996) and all long-term exposure studies are cited in this preamble. The referenced memorandum (Koman, 1996) has been updated (Koman, 1997) to clarify key aspects of the studies cited and relevant air quality statistics. In accordance with EPA and CASAC views on the relative strength of these studies, greater weight is placed on short-term exposure studies than on long-term exposure studies. Where studies found statistically significant associations with $PM_{2.5}$ components (e.g., sulfates and/or acids, in Thurston et al., 1994; Dockery et al., 1996), the corresponding $PM_{2.5}$ or $PM_{2.1}$ values from the study are cited. No conversions were made from the original measurements used in these studies.

with the 24-hour standard level selected to provide supplemental protection against peak concentrations that might occur over limited areas and/or for limited time periods. In selecting the level for the annual standard, therefore, the Administrator has considered both short- and long-term exposure studies.

In accordance with EPA staff and CASAC views on the relative strengths of the epidemiological studies, the Administrator has placed greater emphasis on the short-term exposure studies in selecting the level of the annual standard. The approach she took to this issue consisted of determining a provisional level based on the short-term exposure studies, and then determining whether the long-term exposure studies are consistent with that level or, instead, suggest the need for a lower level. The effects estimates from the short-term exposure studies (in Table V-12 of the Staff Paper) are based on analyses of daily $PM_{2.5}$ concentrations that occurred over the course of the study period. While effects may occur over the full range of concentrations observed in the studies, consistent with the discussion of this issue in Unit II.D. of this preamble, the strongest evidence for short-term $PM_{2.5}$ effects occurs at concentrations near the long-term (e.g., annual) average. More specifically, the strength of the evidence of effects increases for concentrations that are at or above the long-term (e.g., annual) mean levels reported for these studies.[42] Given the serious nature of the potential effects, the Administrator believes it is both prudent and appropriate to select a level for an annual standard at or below such concentrations. An examination of the long-term means from the combined six city analyses of daily mortality (Schwartz et al., 1996a) and morbidity (Schwartz et al., 1994), together with those from studies in individual cities for which statistically significant PM-effects associations are reported (from Table V-12 in the Staff Paper), finds mean concentrations ranging from about 16 to about 21 μg/m³ (Koman, 1996; 1997). In addition, the mean concentrations in cities where short-term exposure associations are characterized in the Criteria Document as nearly statistically significant (U.S. EPA, 1996a, p. 13-40) range from about 11 μg/m³ to 30 μg/m³. Taken together, and placing greatest weight on those studies that were clearly statistically significant, this evidence suggests that an annual standard level of 15 μg/m³ is appropriate to reduce the risk of effects from short-term exposure to fine particles.

Before reaching a final conclusion, the Administrator also examined this level in light of the effects reported in epidemiological studies of long-term exposures to fine particles (Table V-13 in the Staff Paper), which may reflect the accumulation of daily effects over time as well as potential effects uniquely associated with long-term exposures. Even though subject to additional uncertainties, the long-term exposure studies provide important insights with respect to the overall protection afforded by an annual standard. These studies were examined for general consistency and support for the levels derived from the short-term exposure studies, and to determine whether they provide evidence that a more stringent level is needed.

The most direct comparison with the daily fine particle mortality studies is provided by two long-term prospective cohort studies (Dockery et al., 1993; Pope et al., 1995). The annual mean $PM_{2.5}$ concentration for the multiple cities included in these studies (6 and 50 cities, respectively) was 18 μg/m³ (Dockery et al., 1993), and about 21-22 μg/m³ for the larger Pope et al. (1995) study.[43] The Staff Paper assessment of the concentration-response results from Dockery et al. (1993) concluded that the evidence for increased risk was more apparent at annual concentrations at or above 15 μg/m³ (Table E-3; U.S. EPA; 1996b).[44] EPA notes that the estimated mean values for most of the cities in Pope et al. (1995) are above 15 μg/m³. As noted in the Staff Paper and the Criteria Document, the estimated magnitude of effects in both long-term exposure mortality studies may be related to higher historical concentrations than the affected communities experienced during the time period of the studies; this consideration suggests that a level of 15 μg/m³ would incorporate a margin of safety. An examination of morbidity effects and long-term exposures is provided by the recent ''24 city'' studies, which found that reduced lung function and increased respiratory symptoms in children followed the gradient in annual mean concentrations of fine particles and/or acid-sulfate components of fine particles (Raizenne et al., 1996; Dockery et al., 1996). The results indicate a greater likelihood of effects at annual mean $PM_{2.1}$ levels above about 15 μg/m³ (U.S. EPA, 1996b; Figure V-7). In the judgment of the Administrator, these studies are consistent with a standard level of 15 μg/m³. While they provide some suggestion of risks extending to lower concentrations, they do not provide a sufficient basis for establishing a lower annual standard level.

Taking the epidemiological studies of both short- and long-term exposures together, the Administrator believes the concordance of evidence for PM effects and associated levels provides clear support for an annual $PM_{2.5}$ standard level of 15 μg/m³. This level is below the range of annual data most strongly associated with both short- and long-term exposure effects, and because even small changes in annual means in this concentration range can make significant differences in overall risk reduction and total population exposures, the Administrator believes it will provide an adequate margin of safety against the effects observed in these epidemiological studies. Moreover, the means in areas where $PM_{2.5}$ concentrations were statistically significantly associated with daily mortality (about 16 to 21 μg/m³) reflect a 7 to 9-year average; thus, the use of a 3-year mean will provide additional protection. Although the possibility of effects at lower annual concentrations cannot be excluded, the evidence for that possibility is highly uncertain and, as previously discussed, the likelihood of significant health risk, if any, becomes smaller as concentrations approach the lower end of the range of air quality observed in the key epidemiological studies and/or background levels.

The final annual standard will provide substantial protection against short-term as well as long-term exposures to particles. Nevertheless, for the reasons specified above, a spatially averaged annual standard cannot be expected to offer an adequate margin of safety against the effects of all potential short-term exposures in areas with strong local or seasonal sources. The

[42] As discussed in the proposal and Appendix E of the Staff Paper (U.S. EPA, 1996b, p. E-4), there is generally greatest statistical confidence in observed associations for levels at and above the mean concentration.

[43] Based on a public comment, EPA found that the mean of 18 μg/m³ in Pope et al. (1995) reported in the Criteria Document and elsewhere was actually the mean of median values. Based on typical air quality relationships, the conventional arithmetic mean would be approximately 21 to 22 μg/m³ (Freas, 1997). The lowest median concentration measured in this study (9 μg/m³), which was relied upon by some commenters as a basis for annual standards of 10 μg/m³, is about 11 to 12 μg/m³ as an arithmetic mean.

[44] Based on public comments and a further evaluation of the underlying study, EPA concludes that the comparable assessment of the concentration-response function summarized in Table E-3 for Pope et al. (1995) is not appropriate, because it was based on a supplemental ''ecologic'' comparison for these cities and not on the far more reliable prospective-cohort analysis that was the main focus of the paper.

broad-based community studies considered in this review generally could not evaluate such peak exposure conditions directly. Given the public health purposes of the 24-hour standard, the Administrator believes it should be set at a level that generally supplements the control afforded by an annual standard and proposed an approach based on providing a reasonable degree of protection against the peak levels observed or expected in communities where health effects have been associated with daily levels of fine particles.

For the reasons specified in the previous unit, the Administrator has decided to use a 98th percentile concentration-based form of the standard. As noted in the proposal, the 98th percentile 24-hour $PM_{2.5}$ concentrations in cities with statistically significant or nearly significant short-term fine particle exposure-effects associations ranged from 34 μg/m³ to as high as 90 μg/m³ (Koman, 1996, 1997). Based on an examination of these results, EPA originally proposed a level for the 24-hour standard of 50 μg/m³, and solicited comments on higher and lower alternative levels.

In considering comments on alternative levels for the purpose of making a final decision on the 24-hour standard, the Administrator recognizes the significant uncertainties in identifying the extent of the incremental risk associated with single peak exposures to $PM_{2.5}$ in areas where the annual standard is met. Clearly, the risks associated with the 98th percentile air quality data used in the selecting the proposed level are from the same study cities that experienced long-term levels at varying amounts above that selected for the annual standard. It is unclear what risks might have been associated with such peak levels had the long-term averages in these areas been below that selected for the annual standard. Regardless of this uncertainty, it is clear that reducing the annual concentrations in such areas to that of the annual standard would reduce the risk associated with peak days, whatever the magnitude, as well as that associated with the far more numerous days with concentrations near the annual average. Given these uncertainties and the significant degree of protection afforded by the annual standard, the Administrator is persuaded that it is appropriate to adopt a different approach for selecting the levels of the 24-hour standard than the one proposed.

In making a final decision on an appropriate level for the 24-hour standard, the Administrator considered several key factors: the significant protection afforded against short-term exposures by the annual $PM_{2.5}$ standard; the role of the 24-hour standard in providing supplemental protection against peak exposures not addressed by the annual standard; the air quality and effects information in the studies cited above; the uncertainties in the risks associated with infrequent and isolated peak exposures in areas that meet the annual standard; the range of levels recommended by EPA staff and CASAC panel members; and the extensive public comment on the alternative levels proposed, which ranged between 20 and 65 μg/m³. Because of the approach of establishing the annual standard as the controlling standard, and, in particular, the decision to set the level at the lower end of the annual range, there is no need to consider levels in the lower portion of the 24-hour range below the level proposed. Therefore, the Administrator focused on evaluating the margin of safety associated with levels between 50 and 65 μg/m³.

As has been discussed in previous units, the extent of total risk over the course of a year associated solely with a limited number of peak exposures is uncertain, but it is considerably smaller than that associated with the entire air quality distribution. Further, the risk associated with infrequent peak 24-hour exposures in otherwise clean areas is not well enough understood at this time to provide a basis for selecting the more restrictive levels in the range of 50 to 65 μg/m³. On the other hand, it is clear that any standard level within this range would provide some margin of safety. Taking into account the factors outlined above, the Administrator has concluded that a 24-hour standard at the level of 65 μg/m³ would provide an effective limit in the role as a supplement to the annual standard. This level is at the upper end of the range recommended by staff and most CASAC panel members, and below the levels suggested by some CASAC panel members and by a number of public commenters. Although this level is not risk free, the Administrator believes that it would provide an appropriate degree of additional protection over that provided by the annual $PM_{2.5}$ standard. Accordingly, after weighing these factors in light of the scientific uncertainties, the Administrator believes that a 98th percentile 24-hour $PM_{2.5}$ standard of 65 μg/m³ would provide an adequate margin of safety against infrequent or isolated peak concentrations that could occur in areas that attain the annual standard of 15 μg/m³.

In the Administrator's judgment, the factors discussed above provide ample reason to believe that both annual and 24-hour $PM_{2.5}$ standards are appropriate to protect public health from adverse health effects associated with short- and long-term exposures to ambient fine particles. Further, she believes these factors provide a clear basis for judging that an annual $PM_{2.5}$ standard set at 15 μg/m³, in combination with a 24-hour standard set at 65 μg/m³, will protect public health with an adequate margin of safety.

G. Conclusions Regarding the Current PM_{10} Standards

1. *Averaging time and form.* In conjunction with $PM_{2.5}$ standards, the new function of PM_{10} standard(s) is to protect against potential effects associated with coarse fraction particles in the size range of 2.5 to 10 μm. Coarse fraction particles are plausibly associated with certain effects from both long- and short-term exposures (EPA 1996a,b). Based on qualitative considerations, deposition of coarse fraction particles in the respiratory system could be expected to aggravate effects in individuals with asthma. The Criteria Document and Staff Paper found support for this expectation in limited epidemiological evidence on the effects of coarse fraction particles, suggesting that aggravation of asthma and respiratory infections and symptoms may be associated with daily or episodic increases in PM_{10} that are dominated by coarse fraction particles. The potential build-up of insoluble coarse fraction particles in the lung after long-term exposures to high levels should also be considered.

Based on assessments of the available information in the Criteria Document and Staff Paper, both the staff and CASAC recommended retention of an annual PM_{10} standard. The staff, with CASAC concurrence, recommended retention of the current annual arithmetic mean form of the standard, which is the same form being adopted for the annual $PM_{2.5}$ standard. As noted in the staff assessment, the current annual PM_{10} standard offers substantial protection against the effects of both long- and short-term exposure to coarse fraction particles. Public comment was nearly unanimous in recommending retention of this standard. The Administrator therefore has decided to continue a long-term PM_{10} standard as an annual arithmetic mean, averaged over 3 years.

The staff and CASAC also recommended that consideration be

given to retention of a 24-hour standard to provide additional protection against potential effects of short-term exposures to coarse fraction particles. The staff, with CASAC concurrence, also recommended that if a 24-hour standard is retained, the form of the standard should be revised to provide a more robust target for coarse fraction particle controls. The Administrator originally proposed a 98th percentile form for the 24-hour PM_{10} standard based primarily on the reasons outlined above in this unit regarding the proposed form of the 24-hour $PM_{2.5}$ standard.

The EPA received few comments supporting elimination of the 24-hour PM_{10} standard. The main exceptions were some industries, most notably the mining industry, which as noted above in this unit, argued that the available data provide little evidence for coarse particle effects at current ambient levels. These groups, who generally opposed $PM_{2.5}$ standards, also argued that the daily PM_{10} standard could be eliminated if $PM_{2.5}$ standards were set. Based on the potential aggravation of respiratory symptoms from short-term exposure to coarse fraction particles discussed in the Criteria Document and by numerous commenters, as well as the recommendations of a majority of CASAC panelists who also supported $PM_{2.5}$ standards, the Administrator concludes it is appropriate to retain a 24-hour PM_{10} standard.

In general, comments received on the form of the 24-hour PM_{10} standard paralleled those on the form of the $PM_{2.5}$ standard. Substantial concerns were expressed by environmental groups, some States, and others that the 98th percentile would not provide an adequate limit on the number and magnitude of 24-hour peak PM_{10} excursions. While a number of these commenters suggested keeping the current 1-expected-exceedance form, EPA believes that a concentration- based percentile form offers significant advantages, as outlined above in this unit, for both PM indicators. Some air pollution control officials, who were concerned about the extent to which the 24-hour PM_{10} standard would be relaxed under the proposed form, suggested consideration of a 99th percentile form with increased monitoring as an appropriately protective form. Other commenters, particularly some industry groups and some States, strongly supported concentration-based percentile forms, with some recommending consideration of the 95th percentile form.

The proposal noted that a percentile value selected closer to the ''tail'' of the air quality distribution (e.g., a 99th or greater percentile) would not significantly increase stability as compared to the current form. However, an association of 8 State air pollution agencies commented that a 99th percentile form could provide increased stability if combined with a daily or 1-in-3-day sampling frequency and with greater data capture. In addition, EPA notes that this concentration-based form is inherently more stable than the current exceedance-based form.

Many of these and other commenters were concerned that the uncertainties in the available scientific information on the effects of coarse particles were a reason to be concerned that, assuming the current standard level was kept, a 98th percentile form would represent a significant relaxation in protection relative to the current standards. Unlike the situation for the new $PM_{2.5}$ standards, in the case of the PM_{10} standards, the 24-hour standard has generally been the ''controlling'' standard, making changes to the form of the 24-hour standard potentially more significant to the overall national level of protection afforded. Given the uncertainties in the available scientific evidence with respect to the potential health effects of short-term exposures to coarse fraction particles, the Administrator is persuaded that the somewhat more cautious approach with respect to revising the 24-hour PM_{10} standard recommended by many commenters is appropriate. The only approaches available for increasing the extent of protection for this standard as compared to that of the proposed standard involve modifying the form or reducing the level. For reasons discussed in the following section, the Administrator believes it is not appropriate to revise the level of the standard. In order to provide adequate protection against the potential risk associated with multiple short-term peak exposures to coarse fraction particles, the Administator accepts commenters' recommendations to decrease the frequency of peak values, while still providing for a more stable control target than afforded by the current 1-expected-exceedance form. Therefore, the Administrator concludes that the 99th percentile concentration-based form, averaged over 3 years, and combined with more frequent sampling, would be an appropriate form for a 24-hour PM_{10} standard.

2. *Levels for the annual and 24-hour PM_{10}* standards—a. *Annual PM_{10}* standard. As a result of the more limited information for coarse fraction particles, the Administrator's approach for selecting a level of the standard is directly related to the approach taken in the last review of the PM NAAQS. In that review, evidence from limited quantitative studies was used in conjunction with support from the qualitative literature in selecting the level of the current annual PM_{10} standard. In the current review, the staff assessment of the major quantitative basis for the level of that standard (Ware et al., 1986), together with a more recent related study (Dockery et al., 1989), recommended the same range of levels of concern (40 to 50 $\mu g/m^3$) as in the 1986 staff paper. The staff concludes that it is possible, but not certain, that coarse fraction particles, in combination with fine particles, may have influenced the observed effects at these levels. Based on particle deposition considerations, it is possible that cumulative deposition of coarse fraction particles could be of concern in children, who are more prone to be active outdoors than sensitive adult populations.

Qualitative evidence of other long-term coarse particle effects, most notably from long-term build-up of silica-containing materials, supports the need for a long-term standard, but does not provide evidence of effects below the range of 40 to 50 $\mu g/m^3$ (U.S. EPA, 1996a, p. 13-79). The staff concludes that the qualitative evidence with respect to biological aerosols also supports the need to limit coarse materials, but should not form the major basis for a national standard (U.S. EPA, 1996a, p. 13-79). In addition, staff notes that the nature and distribution of such materials, which vary from endemic fungi (e.g., valley fever) to pollens larger than 10 μm, are not appropriately addressed by traditional air pollution control programs.

Based on its review of the available information, CASAC found ''a consensus that retaining an annual PM_{10} NAAQS at the current level is reasonable at this time'' (Wolff, 1996b). With few exceptions, public comments supported levels at least as stringent as the current annual PM_{10} standard.[45] Taking into account these comments and the above considerations, as more fully detailed in the Staff Paper and the

[45] Some commenters, including some environmental groups and the State of California (Cal EPA, 1997), suggested that the large number of recent studies showing effects at PM_{10} levels below the current standards provides a basis for establishing stricter annual and 24-hour PM_{10} standards, in conjunction with $PM_{2.5}$ standards. As discussed in Units II.B. and C. of this preamble, while these studies could be used either to tighten the PM_{10} standards or to add standards that tighten control of the fine fraction of PM_{10}, the weight of evidence from all of the relevant information more readily supports the development of additional protection for the $PM_{2.5}$ fraction.

CASAC recommendations, the Administrator has decided to retain the current annual PM_{10} standard of 50 μg/m³ to protect against the known and potential effects of long-term exposure to coarse fraction particles.

b. *24-hour PM_{10} standard.* As discussed above in this unit, EPA staff and CASAC also recommended that consideration be given to a 24-hour standard for coarse fraction particles as measured by PM_{10}. Unlike the case for the annual standard, however, the staff found that the original quantitative basis for the level of the current 24-hour PM_{10} standard (150 μg/m³) is no longer appropriate. Instead, the staff found that the main quantitative basis for a short-term standard is provided by the two recent community studies of exposure to fugitive dust (Gordian et al., 1996; Hefflin et al., 1994). Because these studies reported multiple large exceedances of the current 24-hour standard, and because of limitations in the studies themselves, the staff concluded that they provide no basis to lower the level of the standard below 150 μg/m³. Moreover, staff concluded that none of the qualitative literature regarding the potential effects of short-term exposure to coarse particles provides a basis for a lower standard level. Both EPA staff and CASAC recommended that if a 24-hour PM_{10} standard is retained, the level of the standard should be maintained at 150 μg/m³, although with a revised form. Beyond the comments summarized above recommending elimination of the 24-hour standard, no commenters recommended a less stringent level, while some others, as summarized above in this unit, recommended more stringent levels. Most comments favored the current level.

Having considered these factors and the public comments, the Administrator judges that, retention of a 24-hour PM_{10} standard at the level of 150 μ/m³ with a 99th percentile form is appropriate and will provide adequate protection against the known and potential effects of short-term coarse fraction particle exposures that have been identified to date in the scientific literature.

H. Final Decisions on Primary PM Standards

For the reasons discussed above in this unit, and taking into account the information and assessments presented in the Criteria Document and the Staff Paper, the advice and recommendations of CASAC, and public comments received on the proposal, the Administrator is revising the current PM NAAQS by adding new $PM_{2.5}$ standards and by revising the form of the current 24-hour PM_{10} standard. Specifically, the Administrator is making the following revisions:

(1) The suite of PM standards is revised to include an annual primary $PM_{2.5}$ standard and a 24-hour $PM_{2.5}$ standard.

(2) The annual $PM_{2.5}$ standard is met when the 3-year average of the annual arithmetic mean $PM_{2.5}$ concentrations, from single or multiple community-oriented monitors (in accordance with EPA's final rule on monitoring siting guidance, 40 CFR part 58, published in a separate document elsewhere in this issue of the **Federal Register**) is less than or equal to 15 μg/m³, with fractional parts of 0.05 or greater rounding up.

(3) The 24-hour $PM_{2.5}$ standard is met when the 3-year average of the 98th percentile of 24-hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area is less than or equal to 65 μg/m³, with fractional parts of 0.5 or greater rounding up.

(4) The form of the current 24-hour PM_{10} standard is revised to be based on the 3-year average of the 99th percentile of 24-hour PM_{10} concentrations at each monitor within an area.

In addition, the Administrator is retaining the current annual PM_{10} standard at the level of 50 μg/m³, which is met when the 3-year average of the annual arithmetic mean PM_{10} concentrations at each monitor within an area is less than or equal to 50 μg/m³, with fractional parts of 0.5 or greater rounding up.

As discussed below in Units V. and VI. of this preamble, data handling conventions and completeness criteria for the revised standards are being established (40 CFR part 50, Appendix N). The reference method for monitoring PM as PM_{10} for the revised standards has been established (40 CFR part 50, Appendix M). A new reference method is being established for monitoring PM as $PM_{2.5}$ (40 CFR part 50, Appendix L). In a separate document published elsewhere in this issue of the **Federal Register**, EPA is providing opportunity for public comment on supplemental information relating to the new reference method for monitoring PM as $PM_{2.5}$ (40 CFR part 50, Appendix L).

As indicated previously, EPA plans to propose related revisions to the Pollutant Standards Index for PM (40 CFR 58.50) and the significant harm level program (40 CFR 51.66) at a later date.

III. Rationale for the Secondary Standards

The Criteria Document and Staff Paper examined the effects of PM on such aspects of public welfare as visibility, materials damage, and soiling. The following discussion of the rationale for revising the secondary standards for PM focuses on those considerations most influential in the Administrator's decision.

A. Need for Revision of the Current Secondary Standards

1. *Visibility impairment.* This unit of the document presents the Administrator's decision to address the welfare effects of PM on visibility by setting secondary standards identical to the suite of $PM_{2.5}$ primary standards, in conjunction with the establishment of a regional haze program under section 169A of the Act.[46] In the Administrator's judgment, this approach is the most effective way to address visibility impairment given the regional variations in concentrations of non-anthropogenic PM as well as other regional factors that affect visibility, such as humidity. By augmenting the protection provided by secondary standards set identical to the suite of $PM_{2.5}$ primary standards with a regional haze program, the Administrator believes that an appropriate degree of visibility protection can be achieved in the various regions of the country.

In coming to this decision, the Administrator took into account several factors, including: The pertinent scientific and technical information in the Criteria Document and Staff Paper, difficulties inherent in attempting to establish national secondary standards to address visibility impairment, the degree of visibility improvement expected through attainment of secondary standards equivalent to the suite of $PM_{2.5}$ primary standards, the effectiveness of addressing the welfare effects of PM on visibility through the combination of a regional haze program and secondary standards for $PM_{2.5}$ equivalent to the suite of primary standards, and comments received during the public comment period. The Administrator's consideration of each of these factors is discussed below in this unit.

The Administrator first concluded, based on information presented and referenced in the Criteria Document and

[46] Congress adopted section 169A of the Act because of concern that the NAAQS and Prevention of Significant Deterioration programs might not provide adequate visibility protection nationally, particularly for ''areas of great scenic importance.'' See H.R. Rep. No. 95–294,at 203–205 (1977).

Staff Paper, that particulate matter can and does produce adverse effects on visibility in various locations, depending on the PM concentrations involved and other factors discussed below. It has been demonstrated that impairment of visibility is an important effect of PM on public welfare, and that it is experienced throughout the United States, in multi-state regions, urban areas, and remote mandatory Class I Federal areas[47] alike. Visibility is an important welfare effect because it has direct significance to people's enjoyment of daily activities in all parts of the country. Individuals value good visibility for the well-being it provides them directly, both where they live and work, and in places where they enjoy recreational opportunities. Visibility is highly valued in significant natural areas, such as national parks and wilderness areas, because of the special emphasis given to protecting these lands now and for future generations. The Criteria Document cites many studies designed to quantify the benefits associated with improvements in visibility.

The Administrator considered information from the Staff Paper and Criteria Document regarding the effect of the composition of particulate matter on visibility. Visibility conditions are determined by the scattering and absorption of light by particles and gases, from both natural and anthropogenic sources. Visibility can be described in terms of visual range, light extinction, or deciview[48]. The classes of fine particles principally responsible for visibility impairment are sulfates, nitrates, organic matter, elemental carbon (soot), and soil dust. Fine particles are more efficient per unit mass at scattering light than coarse particles. The scattering efficiency of certain classes of fine particles, such as sulfates, nitrates, and some organics, increases as relative humidity rises because these particles can absorb water and grow to sizes comparable to the wavelength of visible light. In addition to limiting the distance that one can see, the scattering and absorption of light caused by air pollution can also degrade the color, clarity, and contrast of scenes.

The Administrator next considered what would be an appropriate level for a secondary standard to address adverse effects of particulate matter on visibility. The determination of a single national level is complicated by regional differences in visibility impairment due to several factors, including background and current levels of PM, composition of particulate matter, and average relative humidity.

The Criteria Document and Staff Paper describe estimated background levels of PM and natural light extinction. In the United States, estimated annual mean background levels of $PM_{2.5}$ are significantly lower in the West than in the East. Based on estimated background fine particle and light extinction levels summarized in Table VIII-2 of the Staff Paper, naturally occurring visual range in the East is approximately 105 to 195 kilometers, whereas in the West it is approximately 190 to 270 kilometers. This significant regional difference in estimated background conditions results from two main factors. First, in the western United States, visibility is more sensitive to an additional 1–2 $\mu g/m^3$ of $PM_{2.5}$ in the atmosphere than in the eastern United States. Secondly, light scattering is increased for certain particles (e.g., sulfates, nitrates, and some organics) due to higher average relative humidity in the East.

The combination of naturally occurring and manmade emissions also leads to significant differences in current visibility conditions between the eastern United States, 23–39 kilometers average visual range, and western United States, 55–150 kilometers average visual range. Table VIII-4 of the Staff Paper indicates that the current level of annual average light extinction in several western locations, such as the Colorado Plateau, is about equal to the level of background light extinction, i.e., the level generally regarded as representing the absence of anthropogenic emissions in North America, in the East. This regional difference is due to higher background particle concentrations in the East, a composition of fine particles in the East that, in association with higher eastern humidity levels, is more efficient at light scattering, and significantly lower concentrations of anthropogenic PM in remote western locations as compared with remote eastern sites.

Because of these regional differences, it is the Administrator's judgment that a national secondary standard intended to maintain or improve visibility conditions on the Colorado Plateau or other parts of the West would have to be set at or even below natural background levels in the East, which would effectively require elimination of all eastern anthropogenic emissions. Conversely, a national secondary standard that would achieve an appropriate degree of visibility improvement in the East would permit further degradation in the West. Due to this regional variability in visibility conditions created by differing background fine particle levels, fine particle composition, and humidity effects, the Administrator finds that addressing visibility solely through setting more stringent national secondary standards would not be an appropriate means to protect the public welfare from adverse impacts of PM on visibility in all parts of the country.[49] Aside from the problem of regional variability, the Administrator has also determined that the Agency currently lacks sufficient information to establish a level for a national secondary standard that would represent a threshold above which visibility conditions would always be adverse and below which visibility conditions would always be acceptable. Because visibility varies not only with PM concentration, but also with PM composition and humidity levels, attaining even a low concentration of fine particles might or might not provide adequate protection, depending on these factors.

The Administrator next assessed potential visibility improvements[50] that would result from attainment of the new primary standards for $PM_{2.5}$. The spatially averaged form of the annual standard is well suited to the protection of visibility, which involves effects of PM throughout an extended viewing distance across an urban area. Indeed, as

[47] There are 156 mandatory Class I Federal areas protected by the visibility provisions in sections 169A and 169B of the Act. These areas are defined in section 162 of the Act as those national parks exceeding 6,000 acres, wilderness areas and memorial parks exceeding 5,000 acres, and all international parks which were in existence on August 7, 1977.

[48] Visual range can be defined as the maximum distance at which one can identify a black object against the horizon sky. It is typically described in miles or kilometers. Light extinction is the sum of light scattering and absorption by particles and gases in the atmosphere. It is typically expressed in terms of inverse megameters (Mm^{-1}), with larger values representing poorer visibility. The deciview metric describes perceived visual changes in a linear fashion over its entire range, analogous to the decibel scale for sound. A deciview of 0 represents pristine conditions. Under many scenic conditions, a change of 1 deciview is considered perceptible by the average person.

[49] Congress adopted a visibility protection program in section 169A of the Act because it recognized the impracticability of revising the NAAQS to protect visibility in all areas of the country: ''It would be impracticable to require a major city such as New York or Los Angeles to meet the same visibility standards as the Grand Canyon and Yellowstone Park.'' See H.R. Rep. No. 95–294 at 205. (1977)

[50] Estimates of annual average visibility improvements assume that, on a percentage basis, the reduction for each fine particle component is equal to the % reduction in the mass of fine particles, and that the overall light extinction efficiency of the fine particle pollutant mix does not change. Further, for the estimates presented here, the reductions in fine mass at monitored locations are assumed to reflect the spatial average concentrations through the viewing distance. (Damberg and Polkowsky, 1996.)

the generally controlling standard focused on reducing urban and regional scale fine particle levels, most of the visibility protection provided by the $PM_{2.5}$ primary standards would be derived from the annual standard. In many cities having annual mean $PM_{2.5}$ concentrations exceeding 17 μg/m³, improvements in annual average visibility resulting from attainment of the new annual $PM_{2.5}$ primary standard are expected to be perceptible (i.e., to exceed 1 deciview). Based on annual mean $PM_{2.5}$ data reported in Table 12-2 of the Criteria Document and Table V-12 in the Staff Paper, many cities in the Northeast, Midwest, and Southeast, as well as Los Angeles, would be expected to see perceptible improvement in visibility if the annual $PM_{2.5}$ primary standard is attained.

In Washington, DC, for example, where the IMPROVE network[51] shows annual mean $PM_{2.5}$ concentrations at about 19 μg/m³ during 1992–1995, approximate annual average visibility would be expected to improve from 21 km visual range (29 deciview) to 27 km (27 deciview). Annual average visibility in Philadelphia, where annual $PM_{2.5}$ levels have been recently measured at 17 μg/m³, would be expected to change from about 24 to 27 km, an improvement of about 1 deciview. In Los Angeles, where recent data shows annual mean $PM_{2.5}$ concentrations at approximately 30 μg/m³, visibility would be expected to improve from about 19 to 34 km (30 to 24 deciview) if the new annual primary $PM_{2.5}$ standard is attained.

It is important to note that some urban areas, many in the eastern United States, would be expected to have annual mean $PM_{2.5}$ concentrations reduced below the primary standard level of 15 μg/m³ when implementation of regional control strategies for PM and other air quality programs, such as those addressing acid rain and mobile sources, are taken into account together. On the other hand, some urban areas with annual $PM_{2.5}$ levels at or below the 15 μg/m³ level would be expected to see little, if any, improvement in annual average visibility. This may be particularly true of certain western urban areas that are dominated by coarse rather than fine particles.

The Administrator also considered the potential effect on urban visibility if the 24-hour 98th percentile $PM_{2.5}$ standard of 65 m³ is attained. In areas with violations caused by localized hot spots, the 24-hour standard might have little effect other than on visible source emissions. In other areas, for example, with seasonally high woodsmoke, a more areawide improvement is possible. In such urban areas, attainment of the 24-hour standard would be expected to reduce, to some degree, the number and intensity of ''bad visibility'' days, i.e., the 20% of days having the greatest impairment over the course of a year. For example, maximum 24-hour $PM_{2.5}$ concentrations have been recorded in recent years at over 140 μg/m³ at several California locations. If the level and frequency of peak PM concentrations are reduced, improvements would be expected in those days where visibility is worst, even in urban areas having annual averages below the annual $PM_{2.5}$ primary standard.

Having concluded that attainment of the annual and 24-hour $PM_{2.5}$ primary standards would lead to visibility improvements in many eastern and some western urban areas, the Administrator also considered potential improvements to visibility on a regional scale. In the rural East, attainment of the $PM_{2.5}$ primary standards could result in regional visibility improvement, e.g., in certain mandatory Class I Federal areas such as Shenandoah and Great Smoky Mountains National Park, if regional control strategies are adopted and carried out in order to reduce the impact of long-range transport of fine particles such as sulfates. Fine particle emission reductions achieved by other air quality programs, such as those to reduce acid rain or mobile source emissions, are also expected to improve Eastern regional visibility conditions (U.S. EPA, 1993). In the West, strategies to attain the primary $PM_{2.5}$ standards are less likely to significantly improve visibility on a regional basis. However, areas downwind from large urban areas, such as Southern California, would likely see some improvement in annual average visibility.

Based on the foregoing, the Administrator concludes that attainment of $PM_{2.5}$ secondary standards set at the level of the primary standards for $PM_{2.5}$ would be expected to result in visibility improvements in the eastern United States at both urban and regional scales, but little or no change in the western United States except in and near certain urban areas. Additionally, the Administrator determined that attainment of secondary standards equivalent to the suite of $PM_{2.5}$ primary standards for particulate matter would address some but not all of the effects of particulate matter on visibility. The extent to which these effects would be addressed is expected to vary regionally.

The Administrator then considered the potential effectiveness of a regional haze program to address the remaining effects of particulate matter on visibility (i.e., those that would not be addressed through attainment of secondary standards identical to the suite of $PM_{2.5}$ primary standards). A program to address the widespread, regionally uniform type of haze caused by a multitude of sources is required by sections 169A and 169B of the Act. In 1977, Congress established as a national goal ''the prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Class I Federal areas which impairment results from manmade air pollution'', section 169A(a)(1) of the Act. The EPA is required by section 169A(a)(4) of the Act to promulgate regulations to ensure that ''reasonable progress'' is achieved toward meeting the national goal. EPA originally deferred establishment of a program to address regional haze in 1980 due to the need for greater scientific and technical knowledge, but the current Criteria Document and Staff Paper cite information supporting the Administrator's conclusion that the scientific state of understanding and analytical tools are now adequate to develop such a program. Because regional emission reductions are needed to make visibility improvements in mandatory Class I Federal areas, the structure and requirements of sections 169A and 169B of the Act, provide for visibility protection programs that can be more responsive to the factors contributing to regional differences in visibility than can programs addressing a nationally applicable secondary NAAQS. The visibility goal is more protective than a secondary NAAQS since the goal addresses any man-made impairment rather than just impairment at levels determined to be adverse.

Thus, an important factor considered in this review is whether a regional haze program, in conjunction with secondary standards set identical to the suite of $PM_{2.5}$ primary standards, would provide appropriate protection for visibility in non-Class I areas. The Administrator continues to believe that the two programs and associated control strategies should provide such protection due to the regional approaches needed to manage emissions of pollutants that impair visibility in many of these areas. Regional strategies implemented to attain the NAAQS, meet other air program goals, and make reasonable progress toward the national visibility goal in mandatory Class I Federal areas are expected to improve

[51] IMPROVE (Interagency Monitoring of PROtected Visual Environments) is a visibility monitoring network managed cooperatively by EPA, Federal land management agencies, and State representatives. An analysis of IMPROVE data for 1992–1995 is found in Sisler et al. (1996).

visibility in many urban and non-Class I areas as well. The following recommendation from the 1993 report of the National Research Council, *Protecting Visibility in National Parks and Wilderness Areas*, addresses this point:

> Efforts to improve visibility in Class I areas also would benefit visibility outside these areas. Because most visibility impairment is regional in scale, the same haze that degrades visibility within or looking out from a national park also degrades visibility outside it. Class I areas cannot be regarded as potential islands of clean air in a polluted sea.

Before making a final decisions on the secondary standards, the Administrator also considered a number of public comments that addressed this aspect of the proposal. Some commenters suggested setting secondary standards for $PM_{2.5}$ more stringent than the proposed primary standards for the purpose of addressing visibility impairment and other environmental effects. For the reasons discussed above in this unit, however, the Administrator has concluded that this may not be an effective and would not be an appropriate means of protecting against visibility impairment in all parts of the country. Other commenters raised the possibility of establishing a nationally applicable secondary standard defined as a ''floor,'' or increment, above regionally specific background levels of $PM_{2.5}$ or associated visibility. Although this idea is of interest and may warrant further study, the Administrator determined that it was not appropriate to pursue such an approach at this time for two principal reasons. First, the Agency does not currently have adequate scientific information to establish a specific floor or increment level that would protect against adverse effects nationally, nor is it clear as a conceptual matter whether further information would support selection of a single, uniform increment as providing an appropriate degree of protection in all areas of the country. Second, there are serious, unresolved questions about whether such an approach is consistent with the statutory language and purposes of section 109 of the Act.

Other commenters argued that national secondary standards equivalent to the proposed $PM_{2.5}$ primary standards are not necessary or not supported by the Administrator's findings. As noted earlier, however, it is clear that coarse and fine particles can cause adverse effects on visibility and significant quantitative data exist to demonstrate that visibility impairment occurs at small concentrations of $PM_{2.5}$. Substantial efforts have been put forth to assess the effects of PM on visibility. For example, the Grand Canyon Visibility Transport Commission[52] spent several years and significant effort studying the effects of pollution on 16 mandatory Class I Federal areas on the Colorado plateau and has made recommendations to the Administrator for actions to improve visibility in these areas (GCVTC, 1996). All of the mandatory Class I Federal areas studied by the GCVTC with monitoring data have annual mean $PM_{2.5}$ concentrations below 5 $\mu g/m^3$ (Sisler, 1996) while also documenting anthropogenic visibility impairment. The Southern Appalachian Mountain Initiative[53] is currently assessing air pollution impacts on visibility, terrestrial resources, and aquatic resources in the southeastern U.S. in order to recommend measures to remedy existing and prevent future adverse effects on these air quality related values. The IMPROVE network shows that all of the mandatory Class I Federal areas in the SAMI region have annual mean $PM_{2.5}$ concentrations for 1992–95 between 11.0–13.5 $\mu g/m^3$ (Sisler, 1996). The inclusion in section 169A of the Act of a national visibility goal of no manmade impairment also places significant value on reducing PM concentrations and resulting visibility impairment to low levels.[54] The differences between the fine particle levels associated with visibility impairment in eastern and western mandatory Class I Federal areas provide further impetus to act under the provisions of sections 169A and 169B enabling the Administrator to establish a regionally-tailored visibility program to address impairment of visibility in mandatory Class I Federal areas. For these reasons, the Administrator has concluded that a national regional haze program allowing for regional approaches to addressing fine particle pollution, combined with a nationally applicable level of protection achieved through secondary $PM_{2.5}$ standards set equal to the suite of primary standards, would be more effective in addressing regional variations in the adverse effects of $PM_{2.5}$ on visibility than establishing national secondary standards for particulate matter that are lower than the suite of $PM_{2.5}$ primary standards. The Administrator emphasizes that in order to appropriately address the regional differences in adverse effects of particulate matter on visibility, it is essential to establish secondary standards for $PM_{2.5}$ equivalent to the primary standards and an effective new regional haze program. A regional haze program will be particularly important in those areas of the country that do not exceed any of the primary standards for $PM_{2.5}$, yet still experience significant visibility impairment due to particulate matter. The EPA will propose a regional haze regulation in the near future.

In addition to providing a more regionally tailored approach than establishing a more stringent national secondary standard, an effective regional haze program will also fulfill the Administrator's regulatory responsibility under sections 169A and 169B of the Act to address both reasonably attributable impairment and regional haze impairment in mandatory Class I Federal areas. Indeed, regional haze has been shown to be the principal cause of visibility impairment in mandatory Class I Federal areas today. Thus, the promulgation of a regional haze program in conjunction with secondary standards for $PM_{2.5}$ equivalent to the suite of primary standards will serve as an appropriate approach for addressing adverse effects of visibility that vary regionally, and it will also establish a comprehensive program for making reasonable progress toward the national visibility goal in mandatory Class I Federal areas by addressing visibility impairment in the form of both source-specific impacts and regional haze. Further, the regional haze rulemaking will fulfill the Administrator's responsibilities to address the visibility protection recommendations of the Grand Canyon Visibility Transport Commission, pursuant to section 169B(e) of the Act.

The Administrator recognizes that people living in certain urban areas may place a high value on unique scenic resources in or near these areas, and as a result might experience visibility problems attributable to sources that would not necessarily be addressed by the combined effects of a regional haze program and secondary standards identical to the suite of primary standards for $PM_{2.5}$. Commenters from

[52] EPA established the Grand Canyon Visibility Transport Commission (GCVTC) in 1991 under section 169B of the Act. Section 169B(d) requires visibility transport commissions to assess the ''adverse impacts on visibility from potential or projected growth in emissions'' and to recommend to EPA measures to remedy such adverse impacts. The Commission issued its final report in June 1996.

[53] The Southern Appalachian Mountain Initiative is a voluntary effort begun in 1993. Participants include eight southeastern States, Federal land managers, EPA, and representatives from industry and environmental groups. A final report has not been issued to date.

[54] Indeed, Congress recognized when it adopted section 169A that the ''visibility problem is caused primarily by emission into the atmosphere of sulfur dioxide, oxides of nitrogen and particulate matter, especially fine particulate matter, from inadequately controlled sources.'' H.R. Rep. No. 95–294 at 204 (1977).

certain western cities and States raised this issue. In the Administrator's judgment, State or local regulatory approaches, such as past action in Colorado to establish a local visibility standard for the City of Denver, would be more appropriate and effective in addressing these special situations because of the localized and unique characteristics of the problems involved. Visibility in an urban area located near a mandatory Class I Federal area can also be improved through State implementation of the current visibility regulations, by which emission limitations can be imposed on a source or group of sources found to be contributing to ''reasonably attributable'' impairment in the mandatory Class I Federal area. EPA also intends to pursue opportunities to obtain information on urban and non-Class I area visibility through examination of available fine particle monitoring data. Current or planned monitoring networks and initiatives, such as monitoring and chemical analysis of $PM_{2.5}$ in urban and background sites, efforts to better characterize real-time environmental conditions in major populations centers, and new automated airport visibility monitoring networks should provide data needed to evaluate trends in these areas. This information should help to better characterize the nature and spatial extent of urban and non-Class I visibility problems and thus serve to inform future decisions on NAAQS revisions or other appropriate measures.

Based on all of the considerations discussed, the Administrator has decided to establish secondary standards identical to the suite of $PM_{2.5}$ primary standards, in conjunction with a regional haze program under sections 169A and 169B of the Act, as the most appropriate and effective means of addressing the welfare effects associated with visibility impairment. Together, the two programs and associated control strategies should provide appropriate protection against the effects of PM on visibility and enable all regions of the country to make reasonable progress toward the national visibility goal.

2. *Materials damage and soiling effects.* Annual and 24-hour secondary standards for materials damage and soiling effects of PM were established in 1987 at levels equal in all respects to the primary standards. As discussed in the Criteria Document and Staff Paper, particles affect materials by promoting and accelerating the corrosion of metals, by degrading paints, and by deteriorating building materials such as concrete and limestone. Soiling is found to reduce the aesthetic quality of buildings and objects of historical or social interest. Past studies have found that residential properties in highly polluted areas typically have lower values than those in less polluted areas. Thus, at high enough concentrations, particles become a nuisance and result in increased cost and decreased enjoyment of the environment.

In the proposal, EPA proposed to establish secondary standards for PM_{10} and $PM_{2.5}$ identical to the suite of proposed primary standards. Several comments recommended setting secondary standards at levels more stringent than the proposed primary standards in order to address various welfare effects of PM, including soiling and materials damage, acid deposition, and visibility. Some commenters specifically suggested changing the form or level of the proposed 24-hour, 98th percentile PM standards to better protect against elevated PM episodes and associated soiling, materials damage, and visibility effects.

After reviewing the extent of relevant studies and other information provided since the 1987 review of the PM standards, the Administrator concurs with staff and CASAC conclusions that the available data do not provide a sufficient basis for establishing a separate secondary standard based on soiling or materials damage alone. In the Administrator's judgment, however, setting secondary standards identical to the suite of $PM_{2.5}$ and PM_{10} primary standards would provide increased protection against the effects of fine particles and retain an appropriate degree of control on coarse particles. Accordingly, the Administrator establishes the secondary standards for $PM_{2.5}$ identical to the suite of primary standards to protect against materials damage and soiling effects of PM.

B. Decision on the Secondary Standards

The Administrator establishes secondary standards identical to the suite of primary standards. In the Administrator's judgment, the establishment of these standards, in conjunction with implementation of a regional haze program, will provide appropriate protection against the welfare effects associated with particle pollution.

IV. Other Issues

Commenters have raised a number of legal and procedural issues that are discussed in this unit. These include:

(1) Whether EPA must give consideration to costs and similar factors in setting NAAQS.

(2) Whether EPA erred in its selection of a methodology for determining the level of a NAAQS that protects public health with an adequate margin of safety.

(3) Whether EPA committed a procedural error by not entering into the rulemaking docket underlying data from certain epidemiological studies.

(4) Whether the 1990 amendments to the Act preclude EPA from revising the PM NAAQS to establish a new $PM_{2.5}$ indicator.

Responses to other legal and procedural issues are included in the Response-to-Comments Document.

A. Consideration of Costs

For more than a quarter of a century, EPA has interpreted section 109 of the Act as precluding consideration of the economic costs or technical feasibility of implementing NAAQS in setting them. As indicated in the proposal, a number of judicial decisions have confirmed this interpretation. *Natural Resources Defense Council* v. *Administrator*, 902 F.2d 962, 972–973 (D.C. Cir. 1990)(PM NAAQS)(''PM_{10}''), vacated, in part, dismissed, 921 F.2d 326 (D.C. Cir.), certs. dismissed, 498 U.S. 1075, and cert. denied, 498 U.S. 1082 (1991); *Natural Resources Defense Council* v. *EPA*, 824 F.2d 1146, 1157–1159 (D.C. Cir. 1987)(en banc)(CAA section 112 standards for vinyl chloride)(''Vinyl Chloride''); *American Petroleum Institute* v. *Costle*, 665 F.2d 1176, 1185–1186 (D.C. Cir. 1981)(ozone NAAQS)(''Ozone''), cert. denied, 455 U.S. 1034 (1982); *Lead Industries Ass'n* v. *EPA*, 647 F.2d 1130, 1148–1151 (D.C. Cir.)(lead NAAQS)(Lead Industries), cert. denied, 449 U.S. 1042 (1980).

Some commenters have argued that costs and similar factors should, nonetheless, be considered, both in this rulemaking and in the rulemaking on proposed revisions to the NAAQS for ozone. Although most of the commenters' arguments are inconsistent with the judicial decisions cited in this unit, several commenters have argued that those decisions are not dispositive. For reasons discussed in this unit and in the Response-to-Comments Document, EPA disagrees with these comments and maintains its longstanding interpretation of the Act as precluding consideration of costs and similar factors in setting NAAQS.

1. *Background.* Given the nature of the points raised, a brief review of the issue seems useful before addressing the comments. The requirement that EPA establish national ambient air quality standards for certain pollutants, to be implemented by the States, was enacted in 1970 as part of a set of comprehensive amendments that established the basic framework for

Federal, State, and local air pollution control. When EPA promulgated the original NAAQS in 1971, its first Administrator, William D. Ruckelshaus, concluded that costs and similar factors could not be considered in that decision.[55] This conclusion was not challenged in litigation on the original NAAQS. It has been confirmed since then, however, by every judicial decision that has considered the issue.

As discussed in this unit, EPA's interpretation rests primarily on the language, structure, and legislative history of the statutory scheme adopted in 1970. It is also supported by the judicial decisions cited in this unit, as well as by legislative developments since 1970 that reaffirm Congress' original approach to the issue.

Without cataloguing all relevant aspects of the 1970 amendments and their legislative history, several basic points should be noted. Under section 109(b) of the Act, NAAQS are to be ''based on'' the air quality criteria issued under section 108 of the Act. Under section 108(a)(2) of the Act, the kind of information EPA is required to include in criteria documents is limited to information about health and welfare effects ''which may be expected from the presence of [a] pollutant in the ambient air * * * .'' There is no mention of the costs or difficulty of implementing the NAAQS, nor of ''effects'' that might result from implementing the NAAQS (as opposed to effects of pollution in the air).[56] By contrast, Congress explicitly provided for consideration of costs and similar factors in decisions under other sections of the Act.[57] Moreover, States were permitted to consider economic and technological feasibility in developing plans to implement the NAAQS to the extent such consideration did not interfere with meeting statutory deadlines for attainment of the standards.[58] Finally, the legislative history indicated that Congress had considered the issue and had deliberately chosen to mandate NAAQS that would protect health regardless of concerns about feasibility.[59]

The first judicial decision on the issue came in the Lead Industries case. An industry petitioner argued that EPA should have considered economic and technological feasibility in allowing a ''margin of safety'' in setting primary standards for lead. Based on a detailed review of the language, structure, and legislative history of the statutory scheme, the U.S. Court of Appeals for the District of Columbia Circuit concluded that:

> This argument is totally without merit. [The petitioner] is unable to point to anything in either the language of the Act or its legislative history that offers any support for its claim * * * . To the contrary, the statute and its legislative history make clear that economic considerations play no part in the promulgation of ambient air quality standards under section 109.

647 F.2d at 1148.

The Court cited a number of reasons for this conclusion. *Id.* at 1148–1150. Among other things, it noted the contrast between section 109(b) of the Act and other provisions in which Congress had explicitly provided for consideration of economic and technological feasibility, as well as the requirement that NAAQS be based on air quality criteria defined without reference to such factors. *Id.* at 1148–1149 and n.37. The Court also noted that, in developing plans to implement NAAQS, States may consider economic and technological feasibility only to the extent that this does not interfere with meeting the statutory deadlines for attainment of the standards; and that EPA may not consider such factors at all in deciding whether to approve State implementation plans. *Id.* at 1149 n.37 (citing *Union Electric Co.* v. *EPA*, 427 U.S. 246, 257–258, 266 (1976)).[60]

As to the legislative history of the 1970 amendments, the Court observed that:

> [T]he absence of any provision requiring consideration of these factors was no accident; it was the result of a deliberate decision by Congress to subordinate such concerns to the achievement of health goals.

Id. at 1149. Citing several leading Supreme Court decisions, as well as the Senate report quoted in this unit, the Court noted that Congress had intended a drastic change in approach toward the control of air pollution in the 1970 amendments and was well aware that sections 108–110 of the Act imposed requirements of a ''technology-forcing'' character. *Id.*[61]

The Court also noted that Congress had already acted, in further amendments adopted in 1977, to relieve some of the burdens imposed by the 1970 amendments. *Id.* at 1150 n.38. Observing that Congress had, however, declined to amend section 109(b) of the Act to provide for consideration of costs and similar factors as requested by industrial interests, *Id.* n.39, the Court concluded:

> A policy choice such as this is one which only Congress, not the courts and not EPA, can make. Indeed, the debates on the [1970 amendments] indicate that Congress was quite conscious of this fact * * * .
>
> * * * [I]f there is a problem with the economic or technological feasibility of the lead standards, [the petitioner], or any other party affected by the standards, must take its case to Congress, the only institution with the authority to remedy the problem.

Id. at 1150.

After the decision in Lead Industries, Supreme Court review was sought on the question whether costs and similar factors could be considered in setting NAAQS, among other issues. The Supreme Court declined to review the decision. *Lead Industries Ass'n* v. *EPA*, 449 U.S. 1042 (1980). The subsequent decisions in Ozone, Vinyl Chloride, and PM_{10}, cited in this unit, strongly reaffirmed the interpretation adopted in Lead Industries.[62] Supreme Court

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[55] 36 FR 8186, April 30, 1971. EPA has maintained this interpretation consistently since then.

[56] That consideration of such factors was not intended in NAAQS decisions is also supported by section 109(a)(1) of the Act. For pollutants for which air quality criteria had been issued prior to the 1970 amendments, that provision required EPA to propose NAAQS within 30 days after enactment and to take final action 90 days later. The criteria issued previously did not include information on costs and similar factors, and it would have been difficult if not impossible for EPA to supplement them in time to include meaningful consideration of such factors in NAAQS proposed 30 days after enactment.

[57] See, e.g., sections 110(e)(1), 111(a)(1), 231(b) of the 1970 Act; see also, e.g., sections 113(d)(4)(C)(ii), 125(a)(3), 202(a)(3)(C), 317 of the 1977 Act.

[58] *Union Electric Co.* v. *EPA*, 427 U.S. 246, 257–58 (1976).

[59] The Senate report on the 1970 amendments stated: ''In the Committee discussions, considerable concern was expressed regarding the use of the concept of technical feasibility as the basis of ambient air standards. The Committee determined that (1) the health of people is more important than the question of whether the early achievement of ambient air quality standards protective of health is technically feasible; and, (2) the growth of pollution load in many areas, even with application of available technology, would still be deleterious to public health.''

''Therefore, the Committee determined that existing sources of pollutants either should meet the standard of the law or be closed down * * * .''

S. Rep. No. 91–1196, at 2–3 (1970).

[60] These limitations would, of course, make little sense if such factors could be considered in setting the NAAQS themselves.

[61] Such requirements ''are expressly designed to force regulated sources to develop pollution control devices that might at the time appear to be economically or technologically infeasible.''' *Id.* (quoting *Union Electric Co.* v. *EPA*, 427 U.S. at 257).

[62] In the PM_{10} case, for example, the Court considered an argument that EPA should have considered potential health consequences of unemployment that might result from revision of the primary NAAQS for PM:

> ''This claim is entirely without merit. In three previous cases, this court has emphatically stated that § 109 does not permit EPA to consider such costs in promulgating national ambient air quality standards * * * . It is only *health effects relating to pollutants in the air* that EPA may consider * * * . Consideration of costs associated with alleged health risks from unemployment would be flatly inconsistent with the statute, legislative history and case law on this point.''

902 F.2d at 973 (emphasis in original; citations omitted).

review of the Ozone and PM_{10} decisions was sought but denied. *American Petroleum Institute* v. *Gorsuch,* 455 U.S. 1034 (1984); *American Iron and Steel Institute* v. *EPA*, 498 U.S. 1082 (1991).

The Lead Industries opinion focused largely, though not exclusively, on the 1970 amendments and their legislative history. Perhaps as a result, it did not canvass all the factors that, in fact, supported its conclusions at the time. For example, when Congress enacted major amendments to the Act in 1977, it was clearly aware that some areas of the country had experienced difficulty in attempting to attain some of the NAAQS.[63] It was also aware that there might be no health-effects thresholds for the pollutants involved, and that significant uncertainties are inherent in setting health-based standards under the Act.[64] In response, Congress made significant changes in the provisions for implementation of the NAAQS, including changes intended to ease the burdens of attainment. It also amended sections 108 and 109 of the Act in several ways; for example, by requiring periodic review and, if appropriate, revision of air quality criteria and NAAQS and by establishing a special scientific advisory committee (CASAC) to advise EPA on such reviews. Notably, Congress recognized that implementation of NAAQS could cause ''adverse public health, welfare, social, economic, or energy effects'' and charged CASAC with advising EPA on such matters.[65] Yet it made no changes in section 109(b) or section 108(a)(2) of the Act; that is, in the substantive criteria for setting or revising NAAQS. In other words, Congress chose to address economic and other difficulties associated with attainment of the NAAQS by adjusting the scheme for their implementation, rather than by changing the instructions for setting them.[66]

Congress enacted major amendments to the Act again in 1990, well after the Lead Industries and Ozone decisions that interpreted section 109 of the Act as precluding consideration of costs in NAAQS decisions.[67] In doing so, Congress was clearly aware of intervening developments such as EPA's decision to revise the PM NAAQS in 1987—the result of an elaborate review in which the Administrator strongly underscored the scientific uncertainties involved[68]—and the Vinyl Chloride case drawing a sharp distinction between sections 109 and 112 of the Act with regard to consideration of costs and similar factors.[69] Indeed, the legislative history of the 1990 amendments reflects Congress' understanding that primary NAAQS were to be based on protection of health ''without regard to the economic or technical feasibility of attainment.''[70] Again, however, Congress chose to respond to severe, widespread, and persistent problems with attaining the NAAQS by adjusting the scheme for their implementation rather than by changing the basis for setting them. See, e.g., sections 181–192 of the Act.

2. *Public comments.* As noted previously, a number of commenters have argued that costs and similar factors should be considered in EPA's final decisions on revision of both the particulate and ozone NAAQS. Aside from arguments that are simply inconsistent with the judicial decisions cited in this unit, some of the commenters argue that those decisions are not dispositive for a variety of reasons. One commenter submitted a particularly comprehensive version of this argument; the following discussion focuses primarily on points raised by that commenter, among others.[71]

As a general matter, the commenter acknowledges that Congress intended to preclude consideration of economic costs and similar factors in setting NAAQS. The commenter argues, however, that this is so only when the scientific basis for NAAQS is ''clear and compelling'' or ''unambiguous.'' From that premise, the commenter advances three key assertions:

a. Where non-threshold pollutants are involved and the health evidence is ambiguous, section 109 of the Act must be interpreted to allow consideration of all relevant factors, including the practical consequences of EPA's decisions.

b. To the extent the judicial decisions cited in this unit are read as precluding this, they rest on a faulty analysis that pre-dates and cannot survive scrutiny under *Chevron, U.S.A.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984).[72]

c. Because EPA has discretion to consider costs and similar factors where the health evidence is ambiguous, it must do so in light of Executive Order 12866 (58 FR 51735, October 4, 1993), and two recent statutes, the Unfunded

[63] See, e.g., H.R. Rep. No. 95-294, at 207–217 (l977).

[64] See, e.g., *Id.* at 110–112; *Id.* at 43-51.

[65] Section 109(d)(2)(C)(iv) of the Act. Some commenters have argued that this provision requires EPA to consider such effects in setting NAAQS. From the language and structure of section 109(d) of the Act, however, it is clear that CASAC's responsibility to advise on these factors is separate from its responsibility to review and recommend revision of air quality criteria and NAAQS, and that the advice pertains to the implementation of NAAQS rather than to setting them. The legislative history confirms this view, indicating that the advice was intended for the benefit of the States and Congress. See H.R. Rep. No. 95-294, at 183 (1977).

[66] The 1977 amendments also required EPA to prepare economic impact assessments for specified actions but limited the requirement to non-health-based standards, excluding decisions under sections 109 and 112 of the Act. Section 317; H.R. Rep. No. 95-294, at 51–52 (1977). In this and other respects, Congress continued the approach it took in the l970 amendments, making careful choices as to when consideration of costs and similar factors would be required and giving paramount priority to protection of health. See 123 Cong. Rec. H8993 (daily ed. Aug. 4, 1977) (Clean Air Conference Report (1977); Statement of Intent; Clarification of Select Provisions), reprinted in 3 Senate Committee on Environment and Public Works, 95th Cong., A Legislative History of the Clean Air Act Amendments of 1977, at 319 (1978).

[67] In the interim, the National Commission on Air Quality had also submitted its report to Congress as required by a provision of the 1977 amendments. Among other things, the Commission recommended that the statutory approach of requiring NAAQS to be set at levels necessary to protect public health, without consideration of economic factors, be continued without change. National Commission on Air Quality, To Breathe Clean Air 55 (1981).

[68] As the Administrator indicated in EPA's proposal to revise the PM standards:

''[T]hat review has revealed a highly limited data base—particularly where quantitative studies are concerned—and a wide range of views among qualified professionals about the exact pollution levels at which health effects are likely to occur. The setting of an 'adequate margin of safety' below these levels calls for a further judgment—in an area for which the scientific data base is even more sparse and uncertain * * * .''

''* * * [L]ong and expert review of public health issues has to date revealed no scientific method of assessing exactly what level of standards public health requires. The scientific review indicates substantial uncertainties concerning the health risks associated with lower levels of particulate matter.'' (49 FR 10408, 10409, March 20, l984)

[69] Congress was clearly aware of the 1987 decision to revise the PM NAAQS, which among other things involved changing the indicator for particulate matter from ''total suspended particulate'' to PM_{10}, because it enacted special nonattainment provisions, as well as provisions for PSD increments, applicable to PM_{10}. Sections 188–190 of the Act; section 166(f) of the Act. It was clearly aware of the Vinyl Chloride decision because it amended section 112 of the Act in response to that decision, essentially creating a new scheme for setting emission standards for hazardous pollutants.

[70] H.R. Rep. No. 101–490, pt. 1, at 145 (1990). See also S. Rep. No. 101–228, at 5 (1989).

[71] Additional responses to points raised by this commenter and others are included, as appropriate, in the Response-to-Comments Document.

[72] Several other commenters argue that the cited decisions are not dispositive because they held only that EPA is not required to consider costs and similar factors in setting NAAQS. As discussed in this unit in connection with Chevron, however, the decisions clearly concluded that Congress intended to preclude consideration of such factors, and that EPA is not free to alter that congressional choice. Although these conclusions are technically dicta, nothing in the Court's opinions suggests that it would have interpreted section 109 of the Act differently had EPA claimed authority to consider costs and similar factors in NAAQS decisions. Indeed, the tone of the opinions argues to the contrary. See, e.g., PM_{10}, 902 F.2d at 973. Cf. *Ethyl Corp.* v. *EPA,* 51 F.3d 1053 (D.C. Cir. 1995).

Mandate Reform Act of 1995, 2 U.S.C. 1501–1571 (UMRA), and the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. 104–121, 110 Stat. 857 (SBREFA), which in part amended the Regulatory Flexibility Act, 5 U.S.C. 601–808.

EPA believes all three assertions are clearly incorrect. Regarding the first point, it should be evident, both from previous NAAQS decisions and from the court opinions upholding them, that the scientific basis for NAAQS decisions has never pointed clearly and unambiguously to a single ''right answer.''[73] This is inherent in the statutory scheme for the establishment and revision of NAAQS, which in effect requires them to be based on the ''latest scientific knowledge'' on potential health and welfare effects of the pollutant in question. See sections 109(b) and 108(a)(2) of the Act. Although advances in science increase our understanding of such effects, they also raise new questions. For this reason, the key studies for any given decision on revision of a NAAQS are, almost by definition, ''at the very 'frontiers of scientific knowledge.'''[73] That is, studies that call into question the adequacy of a standard are always those that go beyond previous studies—by reporting new kinds of effects, for example, or effects at lower concentrations than those at which effects have been reported previously.

As with pioneering work in other fields, such studies may have a variety of strengths and limitations.[8][75] As a result, the validity and implications of such studies may be both uncertain and highly controversial. Given the precautionary nature of section 109 of the Act,[76] however, it is precisely these kinds of studies that the Administrator must grapple with when advances in science suggest that revision of a NAAQS is appropriate.

As a result, the EPA staff typically recommends for consideration, and the Administrator may propose for comment, a range of alternatives based on what the commenter would call ''ambiguous'' science. In this respect, the current reviews of the NAAQS for ozone and particulate matter are not unusual and do not differ, for example, from the review that led to adoption of the PM_{10} NAAQS in 1987.[77] Indeed, the NAAQS that were upheld in the Lead Industries, Ozone, and PM_{10} decisions were all based on highly controversial health evidence; the Lead Industries decision took note of congressional statements recognizing that there may be no thresholds for criteria pollutants; and the Ozone and PM_{10} decisions noted the Administrator's findings that clear thresholds could not be identified for ozone and particulate matter, respectively.[78] Thus, the present decisions on revision of the NAAQS for ozone and particulate matter cannot be distinguished from those past decisions in terms of the nature of the health evidence or pollutants involved.[78]

Regarding the second of the commenter's key assertions, EPA determines it is clear that the judicial decisions cited in this unit were correctly decided and continue to be good law under Chevron. In Chevron, the Supreme Court essentially reaffirmed the principle that courts must defer to reasonable agency interpretations of the statutes they administer where Congress has delegated authority to them to elucidate particular statutory provisions. Where the intent of Congress on an issue is clear, however, it must be given effect by the agency and the courts. See 467 U.S. at 842–45. Thus, the first question on review of an agency's interpretation under Chevron is ''whether Congress has directly spoken to the precise question at issue.'' If the court determines that it has not, the remaining question for the court is ''whether the agency's answer is based on a permissible construction of the statute.'' 467 U.S. at 842–843 (footnote omitted). In determining whether Congress ''had an intention on the precise question at issue,'' a court employs ''traditional tools of statutory construction.'' *Id.* at 843 n.9.[80]

In essence, the commenter's argument here is that the Lead Industries decision did not address whether Congress had ''spoken directly'' to the precise issue posed by the commenter; that is, whether section 109 of the Act must be interpreted differently for NAAQS decisions involving non-threshold pollutants and ''ambiguous'' health evidence. The Lead Industries opinion, which pre-dated Chevron, did not pose the question in those terms. Its focus, however, was clearly on what Congress intended to be the basis for NAAQS decisions, in a context the Court understood to involve considerable uncertainty and debate about the health evidence, as well as the possibility that there was no threshold for health effects of the pollutant.[81] In short, the health evidence was hardly ''unambiguous,'' yet the Court interpreted section 109 of this Act as precluding consideration of costs and similar factors even in allowing a margin of safety. Nothing in the Lead Industries decision or in the subsequent cases suggests in any way that section 109 of the Act should be interpreted differently based on the nature of the pollutants or health evidence involved, and the Court's findings on congressional intent admit of no exceptions:

> * * * [T]he statute and its legislative history make clear that economic considerations play no part in the promulgation of ambient air quality standards under Section 109.

647 F.2d at 1148.

Alternatively, the commenter argues that the Lead Industries case decided the issue incorrectly in light of the principles announced subsequently in Chevron. In this context, the commenter essentially argues that the Lead Industries decision rested on two factors that are no longer probative:

(1) That there was no indication that Congress meant to allow consideration of costs in NAAQS decisions, and

(2) That Congress specifically provided for such consideration in other sections of the Act but not in section 109.

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[73] See, e.g., Lead Industries, 647 F.2d at 1146–1147, 1153–1156, 1160–1161, 1167 n.106. In enacting the 1970 amendments, Congress was aware that there were gaps in the scientific information available then as a basis for establishing the original NAAQS. See, e.g., S. Rep. No. 91-1196, at 9–11 (1970). If anything, Congress had an even greater understanding of the point when it enacted the 1977 amendments without changing the substantive criteria for setting NAAQS. See H.R. Rep. No. 95-294, at 43–51, 181–182 (1977).

[74] Lead Industries, 647 F.2d at 1147 (quoting *Ethyl Corp.* v. *EPA*, 541 F.2d 1, 24–27 (D.C. Cir.) (en banc), cert. denied, 426 U.S. 941 (1976)).

[75] They may have methodological flaws, for example, but nonetheless report effects that are of serious medical significance; or they may be of impeccable quality but involve effects of uncertain significance. Others may involve results that are striking but hard to explain in terms of previous knowledge, or results that seem plausible and important but are not yet replicated by other studies.

[76] See, e.g., Lead Industries, 647 F.2d at 1155–1156; H.R. Rep. No. 94-295, at 43–51 (1977).

[77] As previously discussed, the Administrator strongly emphasized the uncertainties involved in that review. As a result of the uncertainties, he proposed ''relatively broad'' ranges for comment, though he focused on lower levels within the ranges as providing greater margins of safety against the health risks involved. See 49 FR 10408, 10409, March 20, l984.

[78] See, e.g., Lead Industries, 647 F.2d at 1152–53 and n. 43, 1159–60; Ozone, 665 F.2d at 1185, 1187; PM_{10}, 902 F.2d at 969–71, 972.

[79] Indeed, the present decisions on the NAAQS for PM and ozone are based on some of the best scientific information the Agency has ever been able to rely on in NAAQS decision-making. In particular, the science underlying these decisions is much more extensive and of much better quality than the science underlying the existing NAAQS for PM and ozone.

[80] In practice, analysis of this question is sometimes referred to as a ''Chevron step one'' analysis.

[81] See, e.g., 647 F.2d at 1148–51, 1152–53 and n.43, 1160–61.

On the first point, the commenter argues that EPA is free under Chevron to consider costs and similar factors (by reinterpreting section 109 of the Act) unless there is evidence that Congress intended to restrict its discretion. As to the second point, the commenter argues that similar reasoning was rejected in Vinyl Chloride.

In Vinyl Chloride, however, an en banc decision that post-dated Chevron, the Court essentially underscored the point that such issues cannot be decided mechanically but must turn, instead, on more analytical attention to relevant indicia of congressional intent. See, e.g., 824 F.2d at 1157 n.4; *Id.* at 1157–1163. With reference to NAAQS decisions in particular, the Court concluded that there were concrete indications of congressional intent to preclude consideration of costs and similar factors; for example, the fact that section 108 of the Act ''enumerate[s] specific factors to consider and pointedly exclude[s] feasibility.'' 824 F.2d at 1159. In a later case, moreover, the same Court held that EPA could not consider certain factors, in decisions under section 211(f)(4) of the Act, for reasons exactly parallel to those that the commenter criticizes in Lead Industries. See *Ethyl Corp.* v. *EPA*, 51 F.3d 1053, 1057–1063 (D.C. Cir. 1995).

Beyond this, the commenter's characterization of the Lead Industries decision ignores or discounts much of the key evidence cited by the Court, including the language, structure, and legislative history of the statutory scheme established in 1970, for its conclusion that Congress intended to preclude consideration of costs and similar factors in NAAQS decisions.[82] As indicated in this unit, the Vinyl Chloride and PM_{10} cases, both of which post-dated Chevron, reached the same conclusion.

Moreover, this series of decisions went far beyond mere deference to an agency interpretation. As indicated in the Vinyl Chloride case, the Lead Industries court found ''clear evidence'' of Congressional intent, which was to limit the factors EPA may consider under section 109 of the Act. 824 F.2d 1159. Consistent with Chevron, these findings were based on traditional tools of statutory construction. See *Id.* at 1157–1159; Lead Industries, 647 F.2d at 1148–1151. In terms of the analytical framework later established by Chevron, these were Chevron step one findings, meaning that the statute spoke directly to the issue and that the courts, as well as the agency, must give effect to Congress' intent as so ascertained. See 467 U.S. at 842–843.[83] Thus, absent a more recent legislative enactment overriding that intent, EPA has no discretion to alter its longstanding interpretation that consideration of costs and similar factors is precluded in NAAQS decisions under section 109 of the Act.[84]

As to the commenter's third key assertion, Executive Order 12866, UMRA sections 202 and 205, and the Regulatory Flexibility Act (RFA), as amended by SBREFA, do not conflict with this interpretation or require a different result. Basically, the commenter argues that the Executive Order, UMRA, and the RFA (as amended by SBREFA) require agencies to use cost (or similar factors) as a decisional criterion in making regulatory decisions, and that this modifies the Clean Air Act's directive that EPA is precluded from considering costs when setting a NAAQS. The commenter's argument is flawed on a number of grounds. First, UMRA and the RFA (as amended by SBREFA) do not conflict with section 109 of the Act because they do not apply to this decision, as discussed in Unit VIII. of this preamble. Second, the Executive Order and both statutes are quite clear that they do not override the substantive provisions in an authorizing statute. Third, the commenter's premise that UMRA and the RFA (as amended by SBREFA) establish substantive decisional criteria that agencies are required to follow is wrong.

As a matter of law, the Executive Order cannot (and does not purport to) override the Clean Air Act. The Executive Order does not conflict with section 109 of the Act because the requirement that agencies ''select approaches that maximize net benefits'' does not apply if a ''statute requires another regulatory approach.'' Executive Order 12866, section (1)(a), (58 FR 51735, October 4, 1993). More generally, the Executive Order provides that agencies are to adhere to its regulatory principles only ''to the extent permitted by law.'' *Id.*, section (1)(b).

UMRA sections 202 and 205 do not apply to this decision, as discussed in Unit VIII. of this preamble. Even when they do apply to a regulatory action, they do not establish decisional criteria that an agency must follow, much less override decisional criteria established in the statute authorizing the regulatory action. UMRA does not require an agency to select any particular alternative. Rather, an agency can select an alternative that is not the least costly, most cost-effective or least burdensome if the agency explains why. Section 205(b)(1) of UMRA. Such an explanation is not required if the least costly, most cost-effective or least burdensome alternative would have been ''inconsistent with law,'' section 205(b)(2) of UMRA, and the only alternatives that an agency should consider are ones that ''achieve[] the objectives of the rule,'' section 205(a) of UMRA. The UMRA Conference Report confirms that UMRA does not override the authorizing statute. ''This section [202] does not require the preparation of any estimate or analysis if the agency is prohibited by law from considering the estimate or analysis in adopting the rule.'' 141 Cong. Rec. H3063 (daily ed. March 13, 1995).

The RFA (as amended by SBREFA) also does not apply to this decision, as

[82] See 647 F.2d at 1148–51. By contrast, the commenter's argument that Congress actually intended EPA to consider such factors relies heavily on statements made in subsequent legislative history, most of which were made in floor debate, that sought to justify controversial amendments to establish a different program than the NAAQS and did not involve any proposed changes in section 109 of the Act or related provisions; and statements in early judicial decisions involving programs under other statutory provisions. In context, EPA determines these and other statements cited by the commenter are consistent with and do not alter the conclusion that Congress intended to preclude consideration of costs and similar factors under section 109 of the Act.

[83] The commenter argues that the post-Chevron cases accepted the Lead Industries analysis uncritically rather than re-examining it under Chevron. Clearly, this elevates form over substance. It is true that neither case referred to Chevron in discussing the point at issue. In Vinyl Chloride, however, the Court retraced the steps in the Lead Industries analysis in some detail, characterized some of the key evidence reviewed in that analysis in terms going beyond mere rote repetition (e.g., ''a far clearer statement than anything in the present case that Congress considered the alternatives''), and used Chevron-like language in discussing the significance of that evidence; that is, that it demonstrated congressional intention on the point at issue. E.g., 824 F.2d at 1159. Given that the Vinyl Chloride case was decided three years after Chevron, that it was an en banc decision of the D.C. Circuit involving interpretation of statutory language very similar to that in Lead Industries, and that the Court cited Chevron twice in analyzing the language and history of section 112 of the Act, it seems highly unlikely that the Court was unmindful of Chevron principles in concluding that Congress intended to preclude consideration of costs under section 109 of the Act but not under section 112 of the Act.

In the PM_{10} decision, the Court confirmed the sharp distinction it had drawn, based on such evidence of congressional intent, between sections 109 and 112 of the Act in Vinyl Chloride. 902 F.2d at 972–973. Although discussion of the point was brief and did not mention Chevron, the industry petitioner raising the point had cited Chevron in arguing that the Lead Industries interpretation was not binding, and that EPA's decision on the PM_{10} standards should be reversed on the ground that it rested on a legal position that EPA unjustifiably believed was mandated by Congress. Reply Brief of the American Iron and Steel Institute at 11 and n.10, *Natural Resources Defense Council* v. *Administrator*, 902 F.2d 962 (D.C. Cir. 1990) (Nos. 87-1438 et al.). Thus, Chevron issues were properly before the Court and were brought squarely to its attention.

[84] See also 52 FR 24854, July 1, 1987.

discussed in Unit VIII. of this preamble. As is the case with UMRA, even when the RFA (as amended by SBREFA) does apply to a regulatory action, it does not establish decisional criteria that an agency must follow, much less override the underlying substantive statute. When the RFA was adopted in 1980, Congress made clear that it did not alter the substantive standards contained in authorizing statutes: ''The requirements of section 603 and 604 of this title [to prepare initial and final regulatory flexibility analyses] do not alter in any manner standards otherwise applicable by law to agency action.'' Section 606 of the RFA. The legislative history further explains that section 606 ''succinctly states that this bill does not alter the substantive standard contained in underlying statutes which defines the agency's mandate.''[85] When Congress passed SBREFA in 1996 and amended parts of the RFA, it did not amend section 606.

Even when a regulatory decision is subject to sections 603 and 604 of the RFA and an agency is therefore required to analyze alternatives that minimize significant economic impacts on small entities, the RFA (as amended by SBREFA) does not establish decisional criteria that an agency is required to follow. Both section 603 and 604 of the RFA provide that the alternatives an agency should consider are to be ''consistent with the stated objectives of applicable statutes.'' Section 603(c) and 604(a)(5) of the RFA. Furthermore, although the RFA (as amended by SBREFA) requires agencies to consider alternatives that minimize impacts on small entities subject to the rules' requirements and to explain their choice of regulatory alternatives, it does not require agencies to select such alternatives. For these reasons, the RFA (as amended by SBREFA) does not conflict with or override the Clean Air Act's preclusion of considering costs and similar factors in setting NAAQS.

3. *Conclusion*. In summary, EPA determines that the judicial decisions cited in this unit are both correct and dispositive on the question of considering costs in setting NAAQS, and that the Agency is not free to reinterpret the Act on that question.

B. Margin of Safety

Several commenters questioned the approach used by the Administrator in specifying PM standards that protect public health with an adequate margin of safety. Rather than the integrative approach applied by the Administrator, these commenters maintained that EPA must employ a two-step process. One line of argument was that the Administrator must first determine a ''safe level'' and then apply a margin of safety taking into account costs and societal impacts. It was argued that this was the only approach that would enable the Administrator to reach a reasoned decision on a standard level that protects public health against unacceptable risk of harm, such that any remaining risk was ''acceptable.'' In effect, these commenters adopted the two-step methodology endorsed by Vinyl Chloride, 824 F.2d 1146, for setting hazardous air pollutant standards under section 112 of the Act. Another commenter also maintained that the Administrator must apply a two-step process but from a different perspective. It was argued that EPA should first identify the lowest observed effect level and then apply a margin of safety to address uncertainties and to protect the most sensitive individuals within the at-risk population(s). This commenter also maintained that the use of risk assessment in establishing a NAAQS was a departure from past practice, and that this departure was not adequately explained.

In recognition of the complexities facing the Administrator in determining a standard that protects public health with an adequate margin of safety, the courts have declined to impose any specific requirements on the Administrator's methodological approach. Thus, in Lead Industries the court held that the selection of any particular approach to providing an adequate margin of safety ''is a policy choice of the type Congress specifically left to the Administrator's judgment. This court must allow him the discretion to determine which approach will best fulfill the goals of the Act.'' 647 F.2d at 1161–1162. As a result, the Administrator is not limited to any single approach to determining an adequate margin of safety and, in the exercise of her judgment, may choose an integrative approach, a two-step approach, or perhaps some other approach, depending on the particular circumstances confronting her in a given NAAQS review.

With respect to the approaches advanced in comment, the PM_{10} case made clear that the two-step process endorsed in Vinyl Chloride was necessary because of the need under section 112 of the Act to ''sever determinations that must be based solely on health considerations from those that may include economic and technical considerations.'' 902 F.2d at 973. Because the Administrator may not consider cost and technological feasibility under section 109 of the Act, however, the Court concluded that ''the rationale for parsing the Administrator's determination into two steps is inapposite.'' *Id*.

The claim that EPA must follow a two-step process of first identifying the lowest observed effects level and then applying a margin of safety has also been rejected by the courts. In Lead Industries, the Court specifically held that the Administrator need not apply a margin of safety at the end of the analytical process but may take into account margin of safety considerations throughout the process as long as such considerations are fully explained and supported by the record. 647 F.2d 1161–1162. Accord, PM_{10}, 902 F.2d at 973–974.

Because such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, the types of health information available, and the kind and degree of uncertainties that must be addressed will vary from one pollutant to another, the most appropriate approach to establishing a NAAQS with an adequate margin of safety may be different for each standard under review. Thus, no generalized paradigm such as that imbedded in EPA's cancer risk policy can substitute for the Administrator's careful and reasoned assessment of all relevant health factors in reaching such a judgment. As noted in this unit, both Congress and the courts have left to the Administrator's discretion the choice of analytical approaches and tools, including risk assessments, rather than prescribing a particular formula for reaching such determinations.[86] Because of the inherent uncertainties that the Administrator must address in margin of safety determinations, they are largely judgmental in nature, particularly with respect to non-threshold pollutants, and may not be amenable to quantification in terms of what risk is ''acceptable'' or any other metric. In view of these considerations, the task of the Administrator is to select an approach that best takes into account the nature of the health effects and other information assessed in the air quality criteria for the pollutant in question and to apply appropriate and reasoned analysis to ensure that scientific

[85] 126 Cong. Rec. 21452, 21455 (1980) (Description of Major Issues and Section-By-Section Analysis of Substitute for S. 299).

[86] Contrary to one of the comments received, EPA's use of risk assessment in this rulemaking is by no means a departure from past practice. The EPA first considered and began applying risk assessment methods in the late 1970's (44 FR 8210, 8211, February 8, 1979).

uncertainties are taken into account in an appropriate manner.

In this instance, the Administrator has clearly articulated the factors she has considered, the judgments she has had to make in the face of uncertain and incomplete information, and alternative views as to how such information should be interpreted, in reaching her decision on standard specifications that will protect public health with an adequate margin of safety. See Unit II. of this preamble. Her conclusions on these matters are fully supported by the record.

C. Data Availability

Several commenters questioned EPA's ability to rely on studies demonstrating an association between PM and excess mortality without obtaining and disclosing the raw ''data'' underlying these studies for public review and comment. In particular, a number of commenters cited Dockery, D.W., et al. 1993 and Pope, C.A. III, et al., 1995, as studies upon which EPA relied without obtaining and disclosing the underlying raw data. One commenter also cited J. Schwartz et al., 1996 in the same context.[87] According to the commenters, without the underlying data used in these studies, the reliability of these studies cannot be assessed accurately. These commenters requested that EPA obtain the relevant data and make it available for public review. In light of the court-ordered requirement that EPA publish its rule by July 19, 1997, the commenters argued that EPA must retain the current PM_{10} NAAQS pending additional review of the raw data and the studies at issue. One commenter, the American Petroleum Institute (API) requested that EPA remove the studies from the docket, unless the underlying data was also included in the docket.[88]

A few commenters argued that section 307(d) of the Act requires that EPA obtain the raw data underlying these studies and that a failure to do so contradicts the plain language of section 307(d)(3) of the Act, which requires EPA to place in the docket any ''factual data on which the proposed rule is based.'' Other commenters argued that under section 307(d)(8) of the Act, a failure to obtain and disclose the underlying raw data used in the studies would constitute an error ''so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made.'' *Id.* According to one commenter, without the raw data and an opportunity for an analysis of it, ''EPA has no legal alternative other than to conclude that no new air quality standard would be appropriate within the meaning of CAA section 109(a)(1)(B).'' Finally, a number of commenters have argued that recent caselaw under the Clean Air Act and other statutes makes clear that EPA has a legal obligation to obtain and disclose the data used in these studies.[89]

In developing the proposed revisions to the PM NAAQS, the Administrator relied on the scientific studies cited in the rulemaking record, rather than on the raw data underlying them.[90] In this case, the raw data consists of responses to health questionnaires based on information supplied by individual citizens, or computer tabulations of this information, which remains confidential, and air quality and monitoring data, most of which is now publicly available. EPA does not generally undertake evaluations of raw, unanalyzed scientific data as part of its public health standard setting process. Only in extreme cases—for example where there are credible allegations of fraud, abuse or misconduct—would a review of raw data be warranted. It would be impractical and unnecessary for EPA to review underlying data for every study upon which it relies as support for every proposed rule or standard. If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment. In addition, such data are often the property of scientific investigators and are often not readily available because of the proprietary interests of the investigators or because of arrangements made to maintain confidentiality regarding personal health status and lifestyle information of individuals included in such data. Without provisions of confidentiality, the possibility of conducting such studies could be severely compromised.[91]

In this case, the merits of the studies considered and used in developing the $PM_{2.5}$ standard have been discussed and debated extensively over the past several years, both as part of the EPA review of the pertinent science and in a number of other public forums. The studies at issue were critically evaluated

[87] Contrary to this commenter's assertion, both the health and air quality data used in the 1996 Schwartz study are available to interested parties. EPA's Office of Research and Development maintains a copy of the air pollution database used in the Schwartz study and it has previously been made available in response to Freedom of Information Act requests from interested parties, such as the American Iron and Steel Institute (AISI). The Harvard School of Public Health has also made this data available to several collaborators and to the Health Effects Institute. With regard to the health data underlying the Schwartz study, that mortality data was compiled by the National Center for Health Statistics (NCHS) and can be purchased from the NCHS by interested parties. Thus, there is no real data availability concern with regard to the 1996 Schwartz study. However, even were this not the case, for the reasons discussed more fully in this unit and elsewhere in the preamble, EPA believes it would be entitled to rely upon this study and other studies, including the Dockery and Pope studies, regardless of the availability of the underlying health data.

[88] API's letter stated that ''API petitions EPA to identify all studies that rely, in any way, on data not available for public review as part of the rulemaking process and remove those studies from the record.'' To the extent this letter constitutes a ''petition'' for EPA action, EPA hereby denies the ''petition'' for the reasons stated in this unit and elsewhere in this preamble.

[89] One commenter argued that the failure to obtain and disclose the underlying data was a violation of the Administrative Procedure Act (APA). The NAAQS rulemaking is promulgated under section 307(d) of the Act; the APA generally does not apply to such rulemakings. See section 307(d)(1) of the Act.

[90] It is important to note that while EPA did use the Dockery and Pope studies to confirm its conclusions regarding the health effects of fine particulate air pollution and thus as support for its decision to revise the PM standard, these studies do not provide the sole (or even primary) basis for EPA's decision regarding $PM_{2.5}$, despite the assertions of numerous commenters. The proposed standards are based on a consideration of a large body of epidemiological studies, a clear majority of which suggest PM is strongly linked to mortality and other serious health effects at concentrations permitted under the current standards. Although the specific levels of the $PM_{2.5}$ standards are based on a more limited number of studies that actually measured fine particles and/or components of fine particles, the Dockery and Pope studies were not used in initially selecting the annual fine particle standard level, which was principally based on examination of other daily mortality and respiratory effects studies (Koman, 1996, 1997) that found significant associations between fine PM and effects in cities with annual average $PM_{2.5}$ concentrations of about 16 to 21 μg/m3. Only then were the long-term Dockery and Pope studies examined and used to help corroborate this result; in the opinion of the Administrator, neither study alone (or together) provided sufficient evidence to support more stringent levels below those identified from the daily studies. Thus, removal of the Dockery and Pope studies would not affect the conclusions about the significance of the risks and therefore, while these long-term studies tend to strengthen the need for fine particle control and provide important insights into the nature of PM effects, removal of these two studies from consideration would not have changed the selected standard level.

[91] Some commenters noted that with regard to the health data underlying the 1993 Dockery and 1995 Pope studies, since EPA provided partial funding for these studies, EPA has access to this data and cannot shield itself from the duty to obtain this data by claiming that it is not in its possession. Although a legal argument potentially exists that EPA may obtain access to such data, this legal argument has not been tested in the courts. More importantly, EPA's ability to rely on studies without reviewing the raw data should not depend on whether some Agency of the Federal government funded the science.

by the Agency's Office of Research and Development (ORD) and by the EPA's independent Clean Air Scientific Advisory Committee (CASAC), in a multi-year process for assessment of the science at issue. As with other studies on which EPA relied, particular attention was given to the strengths and limitations of the Dockery, Schwartz and Pope studies during this process, which involved numerous opportunities for public participation and extensive input from interested parties. The results of these studies are not only consistent with each other, but they are also consistent with the results of other studies demonstrating significant associations between long-term exposure to fine particle indicators and mortality. See U.S. EPA, 1996b, p. V–62. The CASAC concluded that EPA's assessments of the pertinent science properly characterized both the current state of knowledge and the range of policy options for revising the standards.

In fact, many peer reviewed studies have reported associations between PM and premature death; the Dockery, Schwartz and Pope studies are among the most recent studies to corroborate this association. In the early 1990s, several studies were published showing associations at levels below the current PM standards. Some critics began raising questions about the extent to which the results could be reproduced and the unavailability of underlying data. In response, an independent group of investigators under the auspices of the Health Effects Institute (HEI), a highly respected research organization jointly funded by EPA and several motor vehicle manufacturers, undertook a reanalysis of several such studies. The original investigators of several studies, including studies conducted at Harvard University, Brigham Young University, and the San Francisco Bay Area Air Quality Management District provided their raw air quality data sets to the HEI investigation team for reanalysis. HEI's reanalysis produced numerical results from the data sets for all six cities that closely agree with and, in general, confirm the results of the original investigators. Thus, as noted in Unit II. of this preamble, these reanalyses by respected independent scientists confirmed the reliability and reproduceability of prior work of the original investigators, including work by Dockery et al. (1992), Pope et al. (1992), Schwartz and Dockery (1992a), and Schwartz (1993).

Thus, the 1993 Dockery and 1995 Pope studies build upon previous studies done by a number of different researchers and have been subject to an extensive peer review process by EPA's ORD, CASAC and HEI. They also underwent a peer review process at the time of their publication in reputable scientific journals. Given the consistency and coherence of the scientific evidence and the scrutiny the studies have received in peer review and in the extensive scientific review process described in this unit, EPA does not agree that review of the underlying data for these studies is also necessary. Considering the various reviews described in this unit and the fact that EPA has received no specific and substantiated reason, such as plausible allegations of fraud or scientific abuse, to doubt the overall validity of their conclusions, EPA agrees with CASAC that revision of the standard is appropriate, based on these and other studies.

In spite of EPA and CASAC's conclusion that it is appropriate to rely on the Pope, Dockery and other studies to establish a $PM_{2.5}$ NAAQS, EPA also believes in public disclosure and supports efforts to seek appropriate release of data underlying the studies in question. On January 31, 1997, EPA wrote to the principal scientific investigators at the Harvard School of Public Health and at Brigham Young University and urged them to make the data associated with their studies available to interested parties. Studies conducted by these investigators relied on data compiled as part of the Harvard Six-Cities Study and data compiled by the American Cancer Society (ACS) as part of the Cancer Prevention Study II.

The studies in question combined health data on individuals with air pollution data. The air pollution data are publicly available. The health data consist of personal and confidential information, e.g. age, sex, weight, eduction level, smoking history, occupational exposures, medical history. These data are not publicly available. In compiling these data, researchers have promised study participants that private, personal information would be kept confidential under signed assurances of confidentiality. Data-sharing arrangements with outside parties must, therefore, accommodate interests both in making data accessible and in protecting the confidentiality of the information contained within them.

Both the Harvard School of Public Health and the American Cancer Society have made such arrangements. Both have processes which allow ouside scientists, in collaboration with Harvard and ACS researchers, to access their databases for the conduct of legitimate scientific research. Scientists from all over the world have applied for and have been granted such access and numerous studies have been conducted and published using the databases.

Because of increased interest resulting from EPA's rulemaking on PM standards and at the request of the Harvard School of Public Health, HEI is taking additional steps to provide a forum for outside researchers to access health data associated with the Harvard-Six Cities Study and perhaps others. HEI has convened an expert panel of esteemed scientists to access underlying data and to conduct additional reanalyses. This arrangement appears to provide a constructive venue for testing legitimate scientific hypotheses while protecting the confidentiality of the underlying data.

Nevertheless, as noted previously, EPA has full confidence in the scientific integrity of the Dockery, Schwartz, and Pope studies and their suitability for use in the Agency's rulemaking on PM, without undertaking a separate or additional review and analysis of the underlying raw data. The decision to propose revisions of the current PM standards was based on careful assessment of the scientific and technical information presented in the PM Criteria Document and Staff Paper. The decision was also consistent with the consensus of CASAC that ''although an understanding of health effects of PM is far from complete, the Staff Paper, when revised, will provide an adequate summary of our present understanding of the scientific basis for making regulatory decisions concerning PM standards.'' The extensive PM epidemiological data base provides evidence that serious adverse health effects, e.g., mortality, exacerbation of chronic disease, increased hospital admissions, respiratory symptoms, and pulmonary function decrements, in sensitive subpopulations, e.g., the elderly, individuals with cardiopulmonary disease and children, are attributable to PM at levels below the current standards. The increase in risk is significant from an overall public health perspective because of the large number of individuals in sensitive subpopulations that are exposed to ambient PM and the significance of the health effects. These considerations, as well as others discussed in the proposal and Staff Paper, such as the need to consider fine and coarse particles as distinct classes, led both the Administrator and CASAC to conclude that revision of the current standards is clearly appropriate. This conclusion remains unchanged despite the fact that EPA is without the actual raw and

unanalyzed health data underlying the studies.

A number of commenters cited section 307(d) of the Act in support of their position that EPA is required to obtain and disclose the underlying raw data. Under section 307(d)(3) of the Act, EPA is required to issue a notice of proposed rulemaking in the **Federal Register** that is accompanied by a ''statement of basis and purpose'' that includes ''a summary'' of:

(A) The factual data on which the proposed rule is based.

(B) The methodology used in obtaining the data and in analyzing the data.

Thus, it is clear from the language of section 307(d) of the Act that where EPA relies on any ''data'' as support in its rulemakings under the Clean Air Act, it has an obligation to include such data or information in the rulemaking docket that is open to the public. Where EPA fails to do so and the error is ''so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made,'' a reviewing court may overturn the rule.

In this case, as noted previously, EPA did not rely upon the raw health data supporting the Dockery and Pope studies; it relied instead upon the studies themselves. These studies may properly be considered ''data.'' The EPA has never had the raw health data in its possession; thus EPA has neither reviewed it nor had an opportunity to place it in the docket. The EPA did rely on the studies and these studies are included in the docket and are available for public review. Because EPA neither reviewed nor relied upon the raw data, there is no obligation to obtain it or to make it available.

Some commenters argued that the language of section 307(d) of the Act, which refers to the ''factual data'' and which also discusses the ''methodology used in obtaining and analyzing the data'' distinguishes between raw data and studies. In the view of these and other commenters, the plain language of section 307(d) of the Act requires that EPA obtain and disclose the raw data used in the Dockery and Pope studies. According to these commenters, without such raw ''data,'' EPA cannot legally promulgate its rule.

The EPA disagrees with this narrow interpretation of the word ''data'' and of section 307(d) of the Act. Data can take many forms, including studies, reports, tabulations, graphs and summaries, as well as more raw forms, such as questionnaire responses, test results and even actual physical specimens. The ''factual data'' called for by section 307(d) of the Act may clearly include peer-reviewed scientific studies. Nor does section 307(d) of the Act prohibit EPA from relying on a study for standard setting without obtaining the raw, underlying data supporting a study. Indeed, as noted in the legislative history to section 307(d) of the Act,

> * * * [t]he [House Commerce] Committee recognizes that the factual support needed for a rule may vary greatly according to the subject being addressed and that rules on some subjects, such as procedures, may not require any factual basis at all. There is no intention to increase the amount of 'factual' support now required to support 'policy judgments where no factual certainties exist or where facts alone do not provide the answer,' Industrial Union Department, *AFL-CIO* v. *Hodgson*, 499 F.2d 467, 476 (D.C. Cir. 1974). Nor is there any intent to diminish the Administrator's authority to adopt precautionary regulations based on a showing of risk * * * .

H.R. Rep. No. 95-294, at 323 (1977) (footnote omitted). As this legislative history makes clear, the language in section 307(d) of the Act is not intended to require EPA to change the amount of ''factual support'' that EPA must assemble in order to promulgate a rule and EPA may adopt ''precautionary'' regulations ''where no factual certainties exist.'' Given this clarification in the legislative history, it is evident that EPA is entitled under section 307(d) of the Act to rely on studies rather than raw data in developing its Clean Air Act rules, despite the arguably ambiguous use of the term ''data.''[92]

Moreover, EPA has relied on studies in the past (including studies using the undisclosed Six Cities data) without obtaining or disclosing the underlying raw data, and EPA's reliance on such studies to set Clean Air Act standards has been upheld in court. In *NRDC* v. *EPA*, 902 F. 2d 962 (D.C. Cir. 1990), the D.C. Circuit declined to delay its review of the PM_{10} NAAQS rulemaking due to concerns raised by the American Iron and Steel Institute about the integrity of the Six Cities data base. 902 F.2d at 974. In that case, EPA had relied upon an earlier Dockery study based on the Six Cities data base. Although the National Institutes of Health (NIH) undertook a review of the allegations regarding the Six Cities database, the court nevertheless upheld EPA's reliance on that Dockery study without waiting for the results of the NIH review. NIH eventually concluded that the allegations were without merit. According to the court in the NRDC case:

> AISI claims that the EPA relied *too much* on the Six Cities Study, which is comprised of the Dockery study and the Ware study * * * . We do not agree that the Administrator's selection of the twenty-four hour standard lacks the necessary reasoned analysis and supportive evidence * * * . After carefully reviewing the record, we find EPA's selection of the twenty four hour standard reasonable in light of the divergent results in the studies and the agency's mandate to provide an adequate margin of safety. Studies contained in the record provided evidence of adverse health effects at levels below 250 µg/m3.

902 F.2d at 969 (footnotes omitted; *emphasis in original*). The court also stated that:

> In setting a standard under section 109 of the Act, the Administrator must ''take into account all the relevant studies revealed in the record'' and ''make an informed judgment based on available evidence.'' *American Petroleum Institute* v. *Costle*, 665 F.2d at 1187. The record shows that the Administrator did so. The Administrator relied on studies which showed adverse effects at and below the 250 µg/m3 level. AISI essentially asks this court to give different weight to the studies than did the Administrator. We must decline. It is simply not the court's role to ''second-guess the scientific judgments of the EPA. * * * [T]he Administrator did not act arbitrarily in drawing conclusions from the uncertain and conflicting data. The Administrator may reasonably apply his expertise to draw conclusions from ''imperfect data,'' Ethyl Corp., 541 F.2d at 28, as he did here.

Id. at 971.

As this language makes plain, the term ''data'' may include a study relied upon by EPA. It should be equally plain that EPA may properly rely on such a study in setting a standard despite the fact that such ''data'' may be ''imperfect,'' ''conflicting,'' and ''uncertain.'' There are numerous other cases in which EPA has relied on studies in setting standards under the Clean Air Act. See, e.g., *Engine Manufacturers Association* v. *EPA*, 88 F. 3d 1075, 1099 (D.C. Cir. 1996)(upholding EPA's use of the 1993 Dockery study for setting mobile source standards); *API* v. *Costle*, 665 F.2d 1176, 1185 (D.C. Cir. 1981)(Administrator's conclusion that normal body functions

[92] EPA also does not agree that because the language of section 307(d) of the Act mentions ''factual data'' as well as ''the methodology used in obtaining and analyzing the data,'' EPA cannot rely on a study alone. In this case, the study is the ''factual data'' and EPA's methodology used in obtaining and analyzing the ''factual data'' is the method that EPA used to review and rely upon the studies. This methodology is discussed extensively in the staff paper and summarized in some detail elsewhere in this preamble. In fact, as is clear from the overall structure of section 307(d) of the Act, as well as the legislative history cited in this unit, section 307(d) of the Act merely requires that EPA summarize and disclose the information and methodology that it relied upon in developing its rule. It leaves unchanged the ''level'' of support that an agency must bring to bear in drafting a proposed rule.

are disrupted by ozone is ''supported by the studies'').

A number of commenters cited *Endangered Species Committee* v. *Babbitt,* 852 F. Supp. 32 (D.D.C. 1994) (hereafter ''Gnatcatcher'') in support of the proposition that EPA must obtain and disclose the raw data underlying the Dockery and Pope studies. Relying on cases such as *Connecticut Light and Power Co.* v. *NRC,* 673 F.2d 525 (D.C. Cir. 1982), *Portland Cement* v. *Ruckelshaus,* 486 F.2d 375 (D.C. Cir. 1973), and *United States* v. *Nova Scotia Food Processing Corp,* 568 F.2d 240 (2nd Cir. 1977), these commenters suggest that ''a body of legal decisions is emerging whereby federal courts are increasingly dubious of final regulatory decisions that are being made absent public scrutiny of the data underlying and purportedly supporting such decisions.'' According to these commenters, based on Gnatcatcher and other cases, failure by EPA to obtain and place in the docket the raw unanalyzed data used in the Dockery and Pope studies constitutes serious procedural error under the Clean Air Act.

Under Connecticut Light and Power, agencies must make available technical studies and data that have been relied upon during the rulemaking process in order for the public to have an adequate opportunity for notice and comment. There is no question that EPA has done this with regard to the Dockery and Pope studies, which are included in the rulemaking docket. The Portland Cement case makes clear that where an agency actually relies on factual data it cannot ''promulgate rules on the basis of inadequate data, or on data that, [to a] critical degree, is known only to the agency.'' 486 F.2d at 393. See also, Nova Scotia, 568 F.2d 240, at 251 (where all of the research was collected by the agency, and none of it was disclosed ''as the material upon which the proposed rule would be fashioned,'' error resulted); *CMA* v. *EPA,* 870 F.2d 177, 200 (5th Cir. 1989) (''fairness requires that the agency afford interested parties an opportunity to challenge the underlying factual data relied on by the agency'').

However, in this case, EPA did not rely on, nor did it ever have or review, the underlying data used in the Dockery and Pope studies. Instead, it relied upon the studies themselves. Thus, the cases cited in this unit are inapposite. They stand only for the proposition that where an agency actually reviews and relies on ''data,'' which may be raw data, a study or a variety of other forms of information, it must make these data available. They do not and cannot stand for the proposition that an agency may not rely on a study alone and must always obtain the raw and unanalyzed data underlying a study. Indeed, as one D.C. Circuit case noted: ''Portland Cement and Nova Scotia simply cannot be twisted so as to require notices of proposed or interim rules to contain elaborate reproductions of underlying studies.'' *Petry* v. *Block,* 737 F.2d 1193, 1198 (D.C. Cir. 1984). Requiring EPA to obtain, analyze and disclose the data underlying the Pope and Dockery studies, which EPA neither reviewed nor relied upon, would be to require EPA to attempt such an ''elaborate reproduction.'' Such a step is not required under the law and would make it extremely difficult, if not impossible, for EPA to regulate in complex, technical areas ''at the frontiers of science.'' *Baltimore Gas and Electric Co.* v. *NRC,* 462 U.S. 87 (1983).

The district court's decision in the Gnatcatcher case is similarly inapposite. That case concerned a scientific study regarding the range of the California Gnatcatcher, a small insectivorous songbird. As the Gnatcatcher opinion itself notes, ''courts have generally allowed agencies to rely on scientific reports.'' Gnatcatcher, 852 F.Supp. at 37. Thus, the question at issue in Gnatcatcher was whether specific circumstances exist in which an agency may not be entitled to rely on studies alone. In the Gnatcatcher case, a single author had published two directly contradictory studies on the same issue, while relying on the same data. In light of this clear contradiction, commenters in that rulemaking argued that without the underlying data it was impossible to determine whether the conclusions in either study were correct. The district court noted that:

> The Secretary had before him a report by an author who, two years before had analyzed the same data and come to an opposite conclusion. It is the disputed nature of this report that distinguishes this from other cases where a scientific report alone has been considered sufficient for ESA purposes.

Id. Thus, according to the court: ''While courts have generally allowed agencies to rely on scientific reports * * * this is not sufficient in this case because the report itself is under serious question.'' *Id.*

The EPA's current reliance on the Dockery and Pope studies bears no resemblance to the circumstances present in the Gnatcatcher decision. As noted previously, these studies have been subject to extensive peer review and scrutiny, and neither researcher has published a contradictory study on the same issue, much less using the same data base. The EPA is not aware of, nor have any of the commenters raised any particular issues relating to either gross error, fraud or scientific abuse arising from the data. Indeed, as noted previously, the prior work of these particular researchers has been subject to extensive independent scrutiny and reanalysis, which has confirmed, rather than called into question, the underlying validity of their conclusions and the integrity of their research methods. Reading Gnatcatcher to suggest that EPA cannot rely on such a study, where the study and its methods have been subject to extensive peer review, would place the district court's rationale in Gnatcatcher in conflict with applicable D.C. Circuit precedent that makes evident the right of agencies to rely on studies alone. See, e.g., *Engine Manufacturers Association* v. *EPA,* 88 F.3d 1075, 1099 (D.C. Cir 1996); *API* v. *Costle,* 665 F.2d 1176, 1185 (D.C. Cir. 1981), ''studies discussed in the Criteria Document constitute a rational basis for the finding that adverse health effects occur at ozone levels of 0.15-0.25 ppm for sensitive individuals''; see also, *NRDC* v. *Thomas,* 805 F.2d 410, 418 (D.C. Cir. 1986)(EPA use of a summary of confidential data that was not disclosed provides ''a reasoned explanation for moving from a 4.0 to 5.0 long term NOx standard'').

In addition, to require EPA to obtain and analyze the data prior to revising the standard would also contradict the ''common sense notion that Congress, in providing for notice and comment under the APA, could not have intended to subject the agencies—and the public on whose behalf they regulate—to [a] sort of interminable back and forth.'' *International Fabricare Institute* v. *EPA,* 972 F.2d 384, 399 (D.C. Cir. 1992). In the view of some commenters, EPA has no choice but to either postpone its decision for a year or more awaiting a review of data or choose to retain the current standard. Yet were EPA to adopt such an approach, these commenters would undoubtedly insist that EPA be required to include an analysis of the data in the docket; further questions would likely be raised regarding the re-analysis and once again EPA might find itself unable to promulgate its rule pending review of further hypothetical questions. This type of unending inquiry is not required under the law. As the D.C. Circuit has noted:

> * * * [D]isagreement among the experts is inevitable when the issues involved are at the ''very frontiers of scientific knowledge,'' and such disagreement does not prevent us from finding that the Administrator's decisions are adequately supported by the evidence in the record * * * . It is not our function to resolve disagreement among the experts or to judge

the merits of competing expert views * * * . Cf. *Hercules, Inc.* v. *EPA*, 598 F.2d 91,115 (D.C. Cir. 1978) (''[c]hoice among scientific test data is precisely the type of judgment that must be made by EPA, not this court'').

Lead Industries Association v. *EPA*, 647 F.2d 1130, 1160 (D.C. Cir. 1980).

Neither Gnatcatcher, nor any other case can fairly be read to suggest that EPA has an obligation to respond to all possible questions that might be raised regarding its scientific conclusions or that where EPA relies on a study, it must engage in a multi-phased and possibly unending re-examination of the data supporting such a study until all commenters are satisfied in full with the details of the underlying science. Even assuming that EPA could obtain the confidential Six Cities data through litigation, a substantial delay of many months, if not years, would likely result, in order for both EPA and industry to reanalyze the data. In the meantime, some tens of thousands of premature deaths could result. Neither the Clean Air Act nor relevant case law requires or permits such a result.

Indeed, the suggestion that EPA cannot and should not rely upon the Pope, Dockery, and Schwartz studies, unless and until interested parties have had an opportunity to examine and reanalyze the underlying raw data, is extraordinary. Given the precautionary nature of section 109 of the Act and the need to allow an adequate margin of safety, see Lead Industries, 647 F.2d at 1154, 1155, there are limits on EPA's discretion to disregard even studies that are clearly flawed, if they are nonetheless ''useful'' in indicating the kind and extent of health effects that may result from the presence of a pollutant in the ambient air. See sections 109(b)(1) and 108(a)(2) of the Act.

A few commenters cited *Kennecott* v. *EPA*, 684 F.2d 1007 (D.C. Cir. 1982) and argued that under sections 307(d)(8) and 307(d)(9)(D) of the Act, a failure by EPA to obtain and include in the docket the data underlying the Pope and Dockery studies would constitute an ''error'' that is ''so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such error[] had not been made.''[93] EPA disagrees. Peer reviewed studies conducted by outside parties were not at issue in Kennecott. Kennecott involved a dispute over financial analyses that EPA itself had previously conducted and used in earlier rulemakings. The court determined that the financial analyses at issue must have provided at least part of the factual basis for EPA's rule, and EPA referenced these analyses in the preamble to the final rule without placing them in the docket until one week before promulgation. The factual circumstances in Kennecott are substantially different than the current situation and thus, Kennecott cannot fairly be read to establish the applicable legal standard with regard to EPA's reliance on peer reviewed studies for use in setting the NAAQS.

In this case, EPA—well before proposal—has placed the information that it relied upon in the docket. This information is in the form of studies. These studies have been subject to extensive scrutiny and peer review. To date no specific allegation has been made that the studies are clearly in error or that the data underlying them are the subject of fraud, scientific misconduct, or gross error going to the basic validity of the studies.[94] Instead, various commenters have merely stated their view that were the raw data behind these studies available, they would be able to better verify and assess the results reached in the studies.

As one commenter noted, ''In the absence of data on which EPA's proposal is based, [key scientific] issues remain shrouded in uncertainty and skepticism. The disclosure of the data would allow for robust scientific analysis and discussion of these issues.'' A similarly hypothetical concern is raised by another commenter who stated that ''seeing the data would clarify substantial questions of methodology'' and ''had the Harvard data been available, a far broader evaluation of the defects of the Harvard Studies would have been possible with the same expenditure of time and money.'' Yet, despite having spent ''in the neighborhood of a million dollars to duplicate and reanalyze the Harvard data set'' this commenter was unable to allege any particular defect in the methodology or results of these studies and noted instead that ''the track record to date suggests that the claimed associations to $PM_{2.5}$ and health effects would not have held up under such a broader evaluation.''

EPA is not required to await the results of such an inquiry before proceeding to regulate to protect human health and the environment. The concerns raised by the commenters regarding these studies remain hypothetical; the comments themselves raise no allegations of fraud, scientific misconduct or gross error that calls into question the fundamental validity of the studies. Given this fact, EPA does not agree with the commenters that reliance on these studies and/or a failure to place the underlying data in the docket constitutes an error, much less an error that is ''so serious and related to matters of such central relevance that there is a substantial likelihood that the rule would have been significantly changed.'' EPA is entitled to rely upon these studies and it has satisfied its obligation to provide the ''factual data'' upon which the proposed rule is based by placing these studies in the docket.

In fact, the concerns raised by the commenters ultimately boil down to a disagreement with EPA over the level of scientific certainty necessary to adopt the NAAQS revisions. In setting standards under the Clean Air Act, EPA is not required to resolve all scientific issues to the complete satisfaction of every interested party. As noted by the D.C. Circuit in *Lead Industries Association* v. *EPA*, 647 F.2d 1130, 1160 (D.C. Cir. 1980):

> To be sure, the Administrator's conclusions were not unchallenged; both LIA and the Administrator are able to point to an impressive array of experts supporting each of their respective positions. However, disagreement among the experts is inevitable when the issues involved are at the ''very frontiers of scientific knowledge,'' and such disagreement does not preclude us from finding that the Administrator's decisions are adequately supported by the evidence in the record. It may be that LIA expects this court to conclude that LIA's experts are right, and the experts whose testimony supports EPA are wrong. If so, LIA has seriously misconceived our role * * * . It is not our function to resolve disagreement among the experts or to judge the merits of competing expert views * * * . Cf. *Hercules, Inc.*, v. *EPA*, 598 F.2d 91, 115 (D.C. Cir. 1978) (''[c]hoice among scientific test data is precisely the type of judgment that must be made by EPA, not this court'').

[93] One commenter argued that EPA's failure to place the ''data'' in the docket was not an ''error'' but a ''refusal to comply with the clear language of the law that should be reviewed by the courts under section 307(d)(9)(C), rather than 307(d)(9)(D).'' As noted previously, EPA does not agree with this interpretation of section 307(d)(3) of the Act. Under applicable caselaw, the term ''data'' may include information in many forms, including studies that EPA has placed in the docket. See *Endangered Species Committee* v. *Babbitt*, 852 F. Supp. 32, 37 (D.D.C., 1994) (''data can come in many forms: it can be a scientific report, it can be graphs and tabulations * * * it can be raw numbers'').

[94] A number of commenters did argue these studies do not form a sufficient basis for EPA's decision to revise the NAAQS and that attempts to replicate these studies have not been universally successful. These same commenters also listed a number of hypothetical questions and issues that might be resolved through a review of the underlying data and suggested that before EPA may properly rely on these studies to revise the NAAQS, a variety of confounders (such as smoking) should also be ruled out by reviewing the data. As set forth more fully in Unit II. of this preamble, neither EPA nor CASAC agrees that any of these factors precludes reliance on the studies in question.

647 F.2d at 1160 (footnotes omitted).

The EPA's rationale for proposing to add a fine particle standard was detailed in the preamble to the proposed rule, most notably at 61 FR 65654–65662, December 13, 1996. This decision is based on the extensive review of the science and policy issues contained in the PM Criteria Document and Staff Paper; the CASAC concluded, after extensive review, that both of these documents were appropriate for use in decision making on standards. These documents contain a full discussion of both what is known about PM and the information gaps and uncertainties. Considering the full weight of the scientific evidence, including the uncertainties, the CASAC recommended that the Administrator adopt fine particle standards and a number of panel members based their support for a $PM_{2.5}$ standard on the following reasoning:

> [T]here is strong consistency and coherence of information indicating that high concentrations of urban air pollution adversely affect human health, there are already NAAQS that deal with all of the major components of that pollution except $PM_{2.5}$, and there are strong reasons to believe that $PM_{2.5}$ is at least as important as $PM_{10-2.5}$ in producing adverse health effects.

Wolff, 1996.

Given the consistency and coherence of the evidence that premature mortality and sickness occur in large numbers of Americans at concentrations permitted by the current standards, it would be irresponsible to delay action that would put more appropriate air quality goals into place based on the most recent scientific information. After a review of the comments submitted, the Agency's conclusion that it is appropriate to rely on the existing studies remains unchanged.

D. 1990 Amendments

Contrary to the view expressed in some public comments, the provisions of subpart 4 of Part D of Title I of the Act, enacted in 1990, do not preclude EPA from adopting $PM_{2.5}$ as an additional indicator for PM and establishing standards for $PM_{2.5}$. The provisions of subpart 4 of Part D of Title I of the Act simply do not limit EPA's clear authority under section 109 of the Act to revise the PM standards.

The basic contention is that because the provisions of subpart 4 of Part D of Title I of the Act refer to PM_{10}, they prohibit EPA from regulating any other type of PM, for example, by revising the existing NAAQS for PM by adopting an ambient air quality standard for $PM_{2.5}$. These provisions, however, do not lead to such a conclusion. Moreover, this view ignores provisions indicating that Congress believed that EPA could revise any existing NAAQS or adopt a new NAAQS.

At the outset, it should be noted that Congress expressly authorized EPA to revise any ambient air quality standard and to adopt a new NAAQS in section 109 of the Act. That section, which requires EPA to review and revise, as appropriate, each NAAQS every five years, contains no language expressly or implicitly prohibiting EPA from revising a NAAQS or adopting a new NAAQS. If Congress had intended to preclude EPA from reviewing and revising a NAAQS or adopting a new NAAQS, which are part of EPA's fundamental functions, Congress would have specifically done so. Clearly, Congress knew how to preclude EPA from exercising otherwise existing regulatory authority and did so in other instances. See section 202(b)(1)(C) of the Act (expressly precluding EPA from modifying certain motor vehicle standards prior to model year 2004); section 112(b)(2) of the Act (preventing EPA from adding to the list of hazardous air pollutants any air pollutants that are listed under section 108(a) of the Act unless they meet the specific exceptions of section 112(b)(2) of the Act); section 249(e)(3), (f) and section 250(b) (limiting EPA's authority regarding certain clean-fuel vehicle programs). No such language was included either in section 109 of the Act or elsewhere in the Act and no such implication may properly be based on the provisions of subpart 4 of Part D of Title I of the Act.

Second, other provisions of the Act expressly contemplate EPA's ability to promulgate a new or revised NAAQS, and provide no indication that such ability is limited to standards other than those whose implementation is the subject of subparts 2, 3 and 4 of Part D of Title I of the Act. For example, section 110(a)(2)(H)(i) of the Act provides that SIPs are to provide for revisions ''from time to time as may be necessary to take account of revisions of such national primary or secondary ambient air quality standard * * * .'' Section 107(d)(1)(A) of the Act provides a process for designating areas as attainment, nonattainment, or unclassifiable ''after promulgation of a new or revised standard for any pollutant under section 109 * * * .'' Section 172(e) of the Act addresses modifications of national primary ambient air quality standards. Finally, section 172(a)(1) of the Act expressly contemplates that EPA may revise a standard in effect at the time of enactment of the 1990 Clean Air Act Amendments. Section 172(a)(1)(A) of the Act provides EPA with authority to classify nonattainment areas on or after the designation of an area as nonattainment with respect to ''any revised standard, including a revision of any standard in effect on the date of the enactment of the Clean Air Act Amendments of 1990.'' Plainly, Congress had no intention of prohibiting EPA from revising any of the ambient standards in effect at the time of the enactment of the 1990 amendments.

Third, the provisions of subpart 4 of Part D of Title I of the Act do not support the contention that they somehow preclude EPA from exercising its authority to adopt a revised PM NAAQS based on a metric other than PM_{10}. The fact that Congress laid out an implementation program for the PM standard existing at the time of the 1990 amendments in no way suggests that Congress intended to preclude EPA from exercising the authority it provided EPA to revise the NAAQS when the health data on which EPA bases such decisions warranted a change in the standard.

The fact that Congress drafted subpart 4 of Part D of Title I of the Act in 1990 to specify the implementation regime for the PM standard then in effect, a PM_{10} standard, in terms that explicitly refer to PM_{10} in no way suggests that Congress meant to preclude EPA from adopting a PM standard based on another metric if scientific information supported such a change. Obviously, PM_{10} was the standard in existence in 1990 and Congress drafted subpart 4 of Part D of Title I of the Act, the purpose of which was to delineate an implementation regime for that standard, in terms of that standard. There is simply no language in subpart 4 of Part D of Title I of the Act that limits EPA's ability to establish a different PM standard if such a standard were warranted under section 109 of the Act or indicates any implicit intent on the part of Congress to limit EPA's authority under section 109 of the Act in such a way. Subpart 4 of Part D of Title I of the Act simply does not speak to the question of whether EPA may establish a PM standard based on a different metric. In addition, section 107(d)(4) of the Act, the only provision outside of subpart 4 of Part D of Title I of the Act invoked as a basis for the view that the Act prohibits EPA from adopting a $PM_{2.5}$ standard, does not support that view. That provision simply preserved pre-existing designations for ''total suspended particulates,'' the PM metric utilized prior to PM_{10}, for certain purposes. It provides no suggestion that Congress intended to prohibit EPA from adopting

a metric other than PM_{10}. Indeed, if anything, it indicates that Congress was fully aware that EPA had previously changed the PM metric used in the PM NAAQS and confirms the view that Congress would have explicitly barred EPA from changing the metric had it intended to do so.

Finally, for the reasons stated in this unit, EPA's analysis of its ability to implement a $PM_{2.5}$ standard under the provisions of subpart 1 of Part D of Title I does not support the view that Congress prohibited EPA from promulgating such a standard. Congress clearly specified an approach to the implementation of the PM_{10} standard in the provisions of subpart 4 of Part D of Title I of the Act. The EPA believes that the clear and express linkage of that approach to the PM_{10} standard indicates that a different PM standard should be implemented under the general principles of subpart 1 of Part D of Title I of the Act. That Congress directed specifically how EPA and the States should implement the PM_{10} standard does not carry with it the implication that Congress intended to prohibit EPA from exercising its otherwise clear and express authority to adopt a PM standard based on a different metric in order to carry out one of its fundamental missions, the establishment of ambient air quality standards to protect public health with an adequate margin of safety. It is entirely reasonable and logical for Congress to, on the one hand, specify an implementation regime for the PM standard in effect at the time of enactment of the 1990 amendments, but, on the other hand, leave EPA free to exercise the authority provided it by Congress in section 109 of the Act to adopt a new or revised standard when EPA determined that such a standard was needed to protect public health with an adequate margin of safety. Congress explicitly required EPA to review and revise as appropriate the NAAQS every five years. If Congress did not intend for EPA to revise the NAAQS when warranted, it would not have required EPA to review and revise them. If Congress had intended to prohibit EPA from exercising such a fundamental authority it would have clearly specified, as it did in other instances, that EPA could not do so.

V. Revisions to 40 CFR Part 50, Appendix K—Intrepretation of the PM NAAQS

Because the revocation of the existing PM_{10} standards will become effective at a later date (as discussed in Unit VII. of this preamble), EPA is retaining 40 CFR part 50, Appendix K, although it is being published today in revised format to conform with the format of the other appendices in this part. A new Appendix N to 40 CFR part 50 explains the computations necessary for determining when the primary and secondary $PM_{2.5}$ and PM_{10} standards being adopted today are met. The discussion in this unit sometimes refers to the contents of the new Appendix N as revisions to Appendix K, so as to highlight how the new Appendix N differs from the current Appendix K.

Key elements of the new 40 CFR part 50, Appendix N, particularly as they differ from those of Appendix K, are outlined in this unit.

A. $PM_{2.5}$ Computations and Data Handling Conventions

As discussed in Unit II.E. of this preamble, the form of the annual $PM_{2.5}$ standard is a spatially averaged annual mean averaged over 3 years, and the form of the 24-hour $PM_{2.5}$ standard is a 98th percentile concentration averaged over 3 years.

With regard to the annual $PM_{2.5}$ standard, the EPA proposed a form expressed as the annual arithmetic mean, averaged over 3 years and spatially averaged over all designated monitoring sites to represent population exposures. As discussed in Unit II.E.1. of this preamble, the form of the annual $PM_{2.5}$ standard has been clarified to make explicit that implementing agencies have the flexibility to base comparison of the standard level with measured values from either a single community-oriented site or an average of measured values from such monitors within the constraints enumerated in 40 CFR part 58. The new Appendix N of 40 CFR part 50 reflects this clarification. The spatial average, if used, is to be carried out using data from monitoring sites designated in a State PM Monitoring Network Description in accordance with the provisions of 40 CFR part 58.

Also, the EPA proposed that, for spatial averaging, the requirements for 3 years of data for comparison with the standard be fulfilled by the spatial averaging network as a whole, not by individual monitors within the network. The EPA received comments regarding the application of the 75 percent data completeness requirement to spatial averaging. The commenters stated that the inclusion or exclusion of a site not meeting the data completeness requirements from a spatial average, based on the level of the single site average, would bias the spatial average for that year. The EPA has responded to the comment by demonstrating in Example 1 in 40 CFR part 50, Appendix N the application of the data completeness criterion that is consistent with a spatially averaged network. Specifically, the application of the data completeness requirement has been altered in the example if a particular site has quarters in a year that do not meet the minimum data completeness requirement. Instead of comparing a site's annual average to the level of the standard to decide whether or not to keep the site in the calculations, the annual average for all the sites (the spatial average) is compared to the level of the standard. If the spatial average is above the level of the standard, the site is kept in the calculations. If it is below, the site is omitted from the calculations.

The EPA also proposed that averaging over calendar quarters be retained for the annual average form of the standard. Although several commenters stated that the step of calculating quarterly averages to obtain the annual average was unnecessary, the EPA maintains that quarterly averages are important to ensure representative sampling in areas with extreme seasonal variation.

Regarding the 75 percent data completeness requirement, the proposal stated that a given year meets data completeness requirements when at least 75 percent of the scheduled sampling days for each quarter have valid data, and high values measured in incomplete quarters shall not be ignored but shall be included if their value causes the annual calculation to be above the level of the standard. Some commenters felt that this treatment was unfair in that measured data below the standard in incomplete quarters are not retained. In addition, the commenters felt that this could create a bias where a single sample could inflate an annual average to a level above the standard. The EPA agrees and has incorporated in 40 CFR part 50, Appendix N the following provisions.

(1) A statement has been added that less than complete data may be used in certain cases subject to the approval of the appropriate Regional Administrator in accordance with EPA guidance for dealing with less than complete data. This statement was considered necessary for those situations where measured data and air quality analyses would indicate that the area met or did not meet the standard although it did not exactly meet the data completeness requirements.

(2) A provision has been added that a minimal amount of data is needed before the requirement to retain high values in an incomplete quarter comes into effect for the annual standards. Sites with at least 11 samples but less than 75 percent data completeness in a quarter will have to include high values

if they result in calculated values which are above the level of the standard. This provision is based upon the change in sampling frequency set forth in the revisions to 40 CFR part 58 which effectively doubles the minimum sampling frequency from 1-in-6 day sampling to 1-in-3 day sampling. The data completeness requirement for the annual form of the standard under the original 1-in-6 day sampling schedule is equivalent to a minimum of 37.5 percent under the new sampling schedule of 1-in-3 days. This is equivalent to a minimum of 11 samples in each quarter. Therefore, a minimum of 11 samples in a quarter should be sufficient for an annual average above the level of the standard to be used under the new sampling schedule.

(3) In sharp contrast, this minimum requirement was considered unnecessary for the 24-hour form of the standard when the 98th percentile is above the level of the standard. That is, for a site with a 98th percentile above the level of the standard that does not meet the 75 percent data completeness requirement, the 98th percentile would be equivalent to the maximum or second maximum daily concentration in that year. While adding more data samples up to the minimum data completeness requirement of 75 percent could help to ensure that the second maximum value (rather than the maximum value) corresponds to the 98th percentile, this difference is not considered significant enough to require some minimal number of data samples when dealing with the form of the 24-hour standard.

With regard to the 24-hour $PM_{2.5}$ standard, the proposed revision to 40 CFR part 50, Appendix K defined the 98th percentile as the daily value out of a year of monitoring data below which 98 percent of all values in the group fall. The calculation of the percentile form has been revised to reflect general comments that the form of the standard and its calculation should be simplified. The EPA maintains that the revised calculation is consistent with the definition of the percentile being that number below which a certain percent of the data fall.

Regarding the expression of the annual standard to the nearest 0.1 $\mu g/m^3$ and the 24-hour standard to the nearest 1 $\mu g/m^3$, virtually no commenters disagreed with the EPA's proposed approach. The few that did, however, took issue with the overall stringency of the standards, not the rationale discussed in the proposal. The EPA maintains its position that instrument sensitivity and the number of measured values used in calculating the values to be compared to the standard, as discussed at length in the proposal, point to keeping the expressions of the standards stated in this unit.

B. PM_{10} Computations and Data Handling Conventions

As discussed in Unit II.G. of this preamble, the EPA proposed retaining the current annual arithmetic mean, averaged over 3 years, as the form of the annual PM_{10} standard, and changing the form of the 24-hour PM_{10} standard to a 98th percentile value form, averaged over 3 years. As discussed in Unit II.G. of this preamble, the form of the daily PM_{10} standard has been revised to a 99th percentile instead of the 98th percentile, and the related calculations have been revised accordingly. The same revision described above in Unit V.A. of this preamble to simplify the formula used to calculate the percentile form of the 24-hour $PM_{2.5}$ standard also applies to the PM_{10} 99th percentile calculation.

The revisions made to the annual and 24-hour $PM_{2.5}$ standards regarding the 75 percent data completeness requirement also apply to the annual and 24-hour PM_{10} standards. Appendix N of 40 CFR part 50 reflects this change.

As with the $PM_{2.5}$ standards, the EPA maintains its position that instrument sensitivity and the number of measured values used in calculating the values to be compared to the standard, as discussed in detail in the proposal, point to keeping the expressions of the standards to the nearest 1 $\mu g/m^3$ for the annual standard and to the nearest 10 $\mu g/m^3$ for the 24-hour standard.

C. Changes That Apply to Both $PM_{2.5}$ and PM_{10} Computations

In the proposal, the EPA stated that revisions to 40 CFR part 50, Appendix K would not address the treatment of exceptional events data, which are considered part of the standards implementation process. Since several commenters mentioned the handling of these events in conjunction with the proposed revisions to Appendix K, the EPA has addressed this concern in Appendix N of 40 CFR part 50, which states that whether to exclude, retain, or make adjustments to data affected by uncontrollable or natural events is subject to the approval of the appropriate Regional Administrator.

Comments were also received expressing the desire of some areas to conduct seasonal sampling, reducing the frequency of monitoring during a period of expected low concentrations to save resources. The proposed revision to 40 CFR part 50, Appendix K did not prohibit this course of action, and referred matters of sampling frequency to 40 CFR 58.13. For clarification, 40 CFR part 50, Appendix N adds that exceptions to specified sampling frequencies, such as a reduced frequency during a season of expected low concentrations, shall be subject to the approval of the appropriate Regional Administrator.

VI. Reference Methods for the Determination of Particulate Matter as PM_{10} and $PM_{2.5}$ in the Atmosphere

A. Revisions to 40 CFR Part 50, Appendix J—Reference Method for PM_{10}

Because the revocation of the existing PM_{10} standards will become effective at a later date (as discussed in Unit VII. of this preamble), EPA is retaining Appendix J in its current form. A new Appendix M to 40 CFR part 50 establishes the reference method for measuring PM_{10} in the ambient air for the revised PM_{10} standards. The discussion in this unit sometimes refers to the contents of the new Appendix M as revisions to Appendix J, so as to highlight how the new Appendix M differs from the current Appendix J. As discussed below, the only revision to the Reference Method for PM_{10} relates to the calculation of the volume of air sampled.

During the course of this standards review, EPA has received a number of comments regarding the appropriateness of the current practice of adjusting measured PM_{10} concentrations to reflect standard conditions of temperature and pressure (25° C and 760 mm Hg, respectively), as required by 40 CFR part 50, Appendix J. The practice was originally adopted to provide a standard basis for comparing all pollutants measured in terms of mass per unit volume (e.g., $\mu g/m^3$). As EPA has reviewed the ambient standards for gaseous pollutants, however, technical changes have been made to express them on a pollutant volume/air volume basis (i.e., ppm) that is insensitive to differences in altitude and temperature. Such an approach is not applicable to particulate pollutants. The question arises whether continuing the past practice of making temperature and pressure adjustments for PM is appropriate or necessary.

Information in the Criteria Document on the health and welfare effects of PM provides no clear basis for making such adjustments. Recent health effects studies have been conducted in cool and warm climates, and in cities at high altitude, e.g., Denver, as well as near sea level, e.g., Philadelphia (U.S. EPA, 1996a). These studies provide no evidence that risk associated with PM exposures is affected by variations in

altitude. Accordingly, any effect that would be accounted for by temperature and pressure adjustments would be below the detection limits of epidemiological studies. While extremes of altitude might be expected to increase the delivered dose of PM in those not acclimatized to such locations, the dosimetric studies summarized in the Criteria Document provide no clear support for any quantitative adjustment to standard conditions. With respect to welfare effects, visibility is directly related to the actual mass of fine particles in the atmosphere. Adjustment of PM concentrations collected at higher altitudes to standard conditions would therefore lead to an overstatement of the effect of PM on visibility in such locations. Similarly, there is no evidence in the Criteria Document suggesting that effects on materials damage and soiling are dependent on altitude.

Based on this assessment, EPA proposed to delete the requirement to adjust PM_{10} concentrations to standard conditions of temperature and pressure from 40 CFR part 50, Appendix J for the revised standards and to make corresponding revisions in 40 CFR 50.3. Comments received on this issue were divided. A number of commentors supported EPA's proposal for the reasons set forth above. A few States opposed the change because the lack of adjustment for very cold temperature in areas near sea level could make the standard more stringent. Some commentors were concerned that the proposed change would relax protection afforded for areas at high altitude. A few commentors expressed concern that ''sojourners'' who visit high altitude area would have higher ventilation rates and receive reduced protection as compared to local residents whose ventilation patterns were more adapted to these conditions.

The EPA does not believe that the localized comparisons regarding increased or decreased stringency of standards relative to the proposed change are an appropriate rationale for keeping the current adjustment for temperature and pressure. The issue is whether the available scientific evidence on the health and welfare effects of PM provides a basis for continuing with the traditional adjustments. The comments with respect to sojourners at altitude are relevant, but this issue was considered in reaching the proposed decision. Furthermore, commentors provided neither laboratory nor epidemiologic evidence that would support their theoretical concerns regarding increased annual or 24-hour PM effects at altitudes typical of mountainous urban areas in the United States.

Based on its assessment of the available evidence and public comments, EPA concludes that a continuation of the practice of adjusting PM_{10} concentrations to standard conditions of temperature and pressure is not warranted or appropriate. Accordingly, this requirement is not included in 40 CFR part 50, Appendix M and corresponding revisions are made in 40 CFR 50.3. In addition, EPA is also incorporating the proposed minor modifications to 40 CFR part 50, Appendix J in Appendix M.

B. 40 CFR Part 50, Appendix L - New Reference Method for $PM_{2.5}$

1. *Introduction.* A new reference method for the measurement of fine particles (as $PM_{2.5}$) in the ambient air has been developed for the primary purpose of determining attainment of the new $PM_{2.5}$ standards. The method is described in the new 40 CFR part 50, Appendix L, and joins the other reference methods (or measurement principles) specified for other criteria pollutants in other appendices to 40 CFR part 50.

In developing the proposed new reference method for $PM_{2.5}$, EPA staff consulted with a number of individuals and groups in the monitoring community, including instrument manufacturers, academics, consultants, and experts in State and local agencies. The approach and key specifications were submitted to the CASAC Technical Subcommittee for Fine Particle Monitoring, which held a public meeting to discuss the proposed new reference method for $PM_{2.5}$ and related monitoring issues on March 1, 1996. Comments on the proposed method were provided orally and in writing by interested parties. The Technical Subcommittee indicated their overall satisfaction with the method in a letter (Price, 1996) forwarded by CASAC to the Administrator.

On December 13, 1996, EPA proposed the new 40 CFR part 50, Appendix L at 61 FR 65676 for public comment. The proposal described in detail the approach taken and the design specifications and performance requirements for the new $PM_{2.5}$ sampler. On January 14, 1997, EPA held a public hearing on the proposed new 40 CFR part 50, Appendix L and associated 40 CFR parts 53 and 58 requirements.

2. *Basic reference method approach.* In addition to the primary purpose of the new $PM_{2.5}$ reference method (determining attainment of the standards), EPA considered a variety of possible secondary goals and objectives that the $PM_{2.5}$ reference method might also fulfill. Subsequently, various alternative $PM_{2.5}$ measurement techniques were evaluated. From this analysis, EPA proposed to base its $PM_{2.5}$ reference method on a conventional type sampler that collects 24-hour integrated $PM_{2.5}$ samples on a 47 mm Teflon filter that is subsequently moisture and temperature conditioned and analyzed gravimetrically. The sampler is a low volume sampler that operates at a flow rate of 1 cubic meter per hour, for a total sample volume of 24 m^3 for the specified 24-hour sample collection period. The sampler is easy to operate, operates over a wide range of ambient conditions, produces a measurement that is comparable to large sets of previously collected PM data in existing databases, and provides a physical sample that can be further analyzed for chemical composition.

3. *Public comments and responses*—a. *Sampler design.* The EPA received many general comments concerning the proposed sampler design. Commenters suggested the use of a different indicator, use of a different size cut, inclusion of additional constituents (e.g., acid aerosols, carbon, metals, and semi-volatiles), and/or use of a multi-filter method. Early in the development process, design decisions were based on public input and the advice of CASAC on these and other basic design issues. Other factors affecting the basic design of the method were the need for historical continuity, high measurement precision, and simplicity of operation, all in response to current national monitoring objectives and available resources. In selecting the basic measurement approach, substantial weight was given to maintaining comparability to $PM_{2.5}$ samplers, such as the ''dichotomous sampler,'' that were widely used to obtain the data upon which the new standards are based. Given this objective, EPA concludes that the conventional PM measurement approach is appropriate and will provide $PM_{2.5}$ measurements that are comparable to the air quality data used in the health studies that provide the basis for the $PM_{2.5}$ standards.

Although the sampler is conventional in configuration, its design is much more sophisticated than that of previous PM samplers. This more sophisticated sampler, together with improved manufacturing and operational quality assurance, is necessary to achieve the more stringent data quality objectives established for $PM_{2.5}$ monitoring data. To meet precision requirements, the critical mechanical components of the inlet, particle size separator, downtube, and upper portion of the filter holder

are specified by design. All other aspects of the sampler are specified by performance-based specifications.

Several commenters felt that the portions of the sampler that were specified by design would stifle further improvements and innovations. Although the EPA specifies methods by performance whenever possible, for the $PM_{2.5}$ reference method, development of adequate performance specifications for inlet aspiration and particle size discrimination would have been a very difficult, costly, lengthy, and problematic process. Moreover, manufacturer testing of proposed inlet and particle size discrimination devices against such performance specifications would require elaborate specialized facilities and would be extremely costly. For these reasons, the EPA believes that specification of these critical components by design is a prudent and very cost-effective way to ensure good inter-manufacturer and intra-manufacturer precision of the $PM_{2.5}$ measurements. Therefore, these components are specified by design, and other aspects of the sampler are specified by performance, as proposed. Innovations and improved samplers or measurement methods are encouraged and provided for as Class II and III equivalent methods (see 40 CFR part 53).

b. *Inlet and impactor design.* Several commenters addressed the inlet design, noting that the inlet could allow entrance of precipitation and possibly insects. In fact, the inlet selected for the sampler has been used effectively for many years to obtain many of the $PM_{2.5}$ measurements that formed the basis of the epidemiological studies. While EPA acknowledges that there have been some reports of intrusion of precipitation, the Agency believes the problem is relatively minor. Nevertheless, a modification of the inlet has been developed to further reduce the possibility of precipitation (and possibly small insects) reaching the sample filter to damage the $PM_{2.5}$ sample. Extensive wind tunnel tests have shown no significant compromise in the $PM_{2.5}$ aspiration performance of the modified inlet.

In addition, a new provision has been added, in 40 CFR part 50, Appendix L, section 7.3.8, to require that the sampling air entrance of the inlet be at a height of 2 ± 0.2 meters above the supporting surface to help ensure homogeneous air samples when collocated samplers of different types are operated simultaneously.

Other commenters addressed the sharpness of the size cut and how it is obtained, e.g., whether more than two stages should be used and what size cut should be used for each stage. These aspects were carefully considered in selecting the sampler configuration. The selection by EPA of the previously used PM_{10} inlet established the size cut for the first stage, and the second stage was designed to be simple, reliable, and low in cost for user agencies. In EPA's estimation, the advantages of this configuration outweigh any modest advantage that might have been gained by designing a new inlet/separation configuration that would further refine the cut points at each of two (or more) stages.

A few commenters questioned whether the inlet was wind speed dependent at high wind speeds. The selected inlet has been shown to perform well up to 24 km/hr with 10 µm aerosols and is expected to perform well at higher speeds with 2.5 µm aerosols. The EPA again determined that the advantages of using the selected inlet outweighed the possible minor improvement in wind-speed characteristics that might have been obtained by a newly-designed inlet.

Some commenters felt that other types of particle discrimination techniques such as cyclones and virtual impactors, should be allowed. Again, these alternatives were evaluated previously and the specified inlet and impactor were determined to best meet the various objectives of the sampler. However, EPA has provided for considerations of other particle size selection techniques or devices for approval if incorporated into candidate equivalent methods for $PM_{2.5}$.

Several commenters addressed the impactor design, noting that the impactor should be changed to sharpen the size-cut characteristic, to address concerns regarding possible contamination and/or performance loss due to impactor oil, and to improve ease of access to service. To address the first concern, the initial prototype impactor has been modified slightly to sharpen its size-cut. The current impactor is designed to lower cost and to optimize cut sharpness, loading capacity, manufacturing simplicity, manufacturing quality control, serviceability, and reliability. A report containing the penetration efficiency of the impactor is available in Docket No. A-95-54. With regard to impactor oil concerns, the impactor oil selected has a very low vapor pressure, and testing has indicated no contamination of the sample filters with impactor oil. The EPA believes that the impactor design is as accessible as possible, given the design objectives. Some flexibility may be allowed for manufacturers to develop improved closure devices or other external modifications. Proper maintenance will, of course, be very important and will be stressed in the associated operator instruction manuals and in other training and guidance materials. The EPA has been performing field and laboratory tests that will provide detailed guidance for all necessary preventive maintenance. Proper installation procedures for the oil and the impactor filter, as well as all other maintenance requirements, will be available in the quality assurance procedures and guidance contained in the new section 2.12 of Appendix L to be added to EPA's Quality Assurance Handbook for Air Pollution Measurement Systems (EPA/600/R-94/038b).

c. *Anodized aluminum surface.* All internal surfaces exposed to sample air prior to the filter are required to be anodized aluminum as stated in 40 CFR part 50, Appendix L, section 7.3.7. A few commenters expressed concern that the anodized aluminum surfaces in high volume PM_{10} samplers have shown substantial pitting, particularly in the venturi flow control device. The anodized aluminum surfaces are required in the $PM_{2.5}$ sampler to maintain comparability to previously used samplers. The EPA believes that the much lower flow rate in the $PM_{2.5}$ sampler will greatly reduce the pitting tendency, and the active flow control in the $PM_{2.5}$ sampler is not dependent on the physical dimensions of a critical orifice as it is in a venturi flow control device.

d. *Filter for $PM_{2.5}$ sample collection.* The proposed reference method called for the sample to be collected on a 47 mm Teflon filter. Many of the comments received on the measurement method concerned the proposed filter medium and its performance. Commenters expressed concerns with the use of Teflon filters and with the selection of a single-filter method. Several commenters recommended that alternative filter media be allowed, in most cases to support speciation and/or to allow the capture of all PM components. Other comments noted potential advantages of other media in operating characteristics or chemistry requirements. Operational concerns expressed about Teflon filters included tearing, possible loss of integrity, and high cost. Other concerns were that Teflon is generally not conducive to carbon analysis, and that Teflon filters may not hold deposited PM. Many commenters recommended use of a multi-filter sampler to support chemical speciation in addition to compliance determination.

To address some of these general concerns about the performance of the specified filter material, some minor refinements to the filter specifications concerning the filter diameter and the filter support ring have been made to ensure proper performance of the filter in the specified filter holder. Additional clarifications have been made to the maximum moisture pickup and the filter weight stability requirements. Although Teflon may preclude certain chemical analyses (e.g., elemental and organic carbon), the EPA believes that Teflon filter material is the best overall choice to meet the objectives of compliance monitoring and to provide good measurement precision. Other filter media are likely to provide reduced gravimetric precision and preclude more types of subsequent chemical analysis. Additional or alternative samplers or filter types can be considered as candidate equivalent methods under 40 CFR part 53 and can be used for non-compliance monitoring, where necessary.

Compliance monitoring based on mass concentration of $PM_{2.5}$ is the primary objective of the reference method. Multi-filter capability would have substantially increased the cost and complexity of the sampler. However, multi-filter samplers can be considered as candidate equivalent methods. In addition, multi-filter samplers can be used as special purpose monitors (SPMs) to perform characterization studies, develop control strategies, and conduct other special studies as has been done previously for PM_{10}.

In response to numerous comments received on 40 CFR part 50, Appendix L and on the provisions of 40 CFR part 58 regarding the need for chemical speciation, the EPA is assigning a high priority to a chemical speciation trends network through section 105 of the Act grant allocation program and will issue guidance describing the monitoring methods and scenarios under which speciation should be performed. The program will incorporate additional $PM_{2.5}$ samplers that allow for the simultaneous collection of aerosols on multiple filter media.

The associated requirement for archiving filters has been removed from 40 CFR part 50, Appendix L, section 10.17 and relocated to 40 CFR part 58, Appendix A. This change has been made because this is a supplemental monitoring requirement and not an integral part of the reference method for determining compliance with the $PM_{2.5}$ NAAQS.

Provisions of 40 CFR part 50, Appendix L have been clarified to apply not only to a single-sample sampler, but also to a sequential-sample sampler, provided that all specifications are met and no deviations, modifications, or exceptions are made to the inlet, downtube, impactor, or the upper portion of the filter holder. Samplers that have minor changes or modifications in these components, have changes that alter the aerosol's flow path, or contain other significant deviations will be required to meet the requirements of Class I equivalent methods, in the amendments to 40 CFR part 53. Further, a provision has been added to require that sequential sample filters stored in a sequential sampler be adequately covered and protected from contamination during storage periods in the sampler.

A few commenters expressed concern about who must carry out filter tests to determine if they meet the filter specifications. In response, the filter specifications have been clarified to indicate that filter manufacturers should generally carry out most or all of the filter performance tests in order to certify that their filters meet the filter specifications for the $PM_{2.5}$ reference method. In addition, EPA conducts acceptance tests on filters procured for NAMS/SLAMS networks prior to distribution to State and local agencies.

Some commenters requested additional information on the requirement that an ID number be attached to each filter. Preliminary information indicates that it is not practical at this time for either filter manufacturers or users to print an ID number directly on the filter. However, EPA is continuing to pursue this goal. In the meantime, alternative means, such as attaching an appropriate ID number to the filter's storage container, will be necessary. Additional details and possible alternative filter identification methods will be provided in new section 2.12 of the Quality Assurance Handbook for Air Pollution Measurement Systems.

e. *Filter handling/weighing/conditioning requirements.* Many commenters felt that the filter handling requirements for collected $PM_{2.5}$ samples were too burdensome. However, handling of the exposed filter between retrieval from the sampler and commencement of the conditioning period is expected to be one of the most significant sources of $PM_{2.5}$ measurement variability. Thus, EPA concludes that specific requirements for this activity are necessary, and this position was supported by several commenters.

Some commenters felt that the samples should be kept cold until analysis to prevent volatile losses. In response to this concern, the restriction on the maximum temperature exposure for collected samples has been reduced from 32 to 25° C, and a recommendation has been added for sampler operators to keep the samples as cool as practical between retrieval from the sampler and delivery to the conditioning environment. Further, the length of time permitted between retrieval of the filter and post-collection weighing is increased from 10 to 30 days, provided that the sample is maintained at 4° C or less between retrieval and the start of the conditioning period. The new section 2.12 of the Quality Assurance Handbook for Air Pollution Measurement Systems will provide guidance and techniques for keeping samples cool during this period and may suggest devices to document maximum temperature exposure of the sample.

Commenters also requested additional specifications and guidance for field blanks. The EPA will provide additional clarification and detailed procedures and guidance regarding field blanks in the new section 2.12 of the Quality Assurance Handbook for Air Pollution Measurement Systems.

Other commenters felt that the filter weighing requirements were too restrictive. Because filter weighing is one of the most significant sources of $PM_{2.5}$ measurement variability, specific requirements and restrictions are deemed necessary. However, in response to some of the concerns expressed, the proposed requirement that both pre- and post-weighings be carried out by the same analyst has been reduced to a non-mandatory recommendation. Detailed recommendations and guidance on filter weighing, based on information obtained in current field tests, will be provided in the new section 2.12 of the Quality Assurance Handbook for Air Pollution Measurement Systems.

Several commenters questioned the filter conditioning requirements, with some requesting a lower humidity range. Since humidity can profoundly affect the weight of the $PM_{2.5}$ on the filter, EPA maintains that filter conditioning requirements need to be tight to control measurement variability and to ensure satisfactory precision. But in response to at least one of the concerns, the filter conditioning humidity requirement has been changed to allow conditioning at a relative humidity within ±5 RH percent of the mean ambient humidity during sampling (down to a minimum of 20 RH percent) for samples collected at average ambient humidities lower than 30

percent. The EPA will provide further details on filter conditioning controls in the new section 2.12 of the Quality Assurance Handbook for Air Pollution Measurement Systems.

f. *Sampler performance requirements.* Several commenters addressed sampler performance requirements, including sampler flow control specifications, filter temperature control, sampler performance under extreme conditions, and data reporting. In response to concerns that various sampler flow control specifications are too tight, EPA contends that good flow control is necessary to maintain uniform sampling, to ensure correct particle size discrimination, and to control measurement variability. Sampler manufacturers have been able to meet the specified flow control requirements, and field studies to date confirm that prototype samplers are able to meet these flow control requirements.

In response to comments about the ambient temperature plus 3° C filter temperature control requirement, EPA believes that fairly tight control of the sample filter temperature is necessary to minimize losses of semi-volatile components over a wide temperature range, and tight temperature control has been strongly recommended by the CASAC. Monitoring of the filter temperature difference from ambient temperature is necessary to verify that the sampler filter temperature control is functioning properly. Testing to date indicates that the proposed 3° C (above ambient temperature) limit is somewhat difficult to meet; however, a 5° C limit can be reasonably met. Therefore, the filter temperature control requirement has been relaxed slightly from 3° C to not more than 5° C above the concurrent ambient temperature. Ambient and filter temperature sensors will require periodic calibration or verification of accuracy. In response to a frequent comment, the method has been clarified to indicate that exceedance of the filter temperature difference limit would not necessarily invalidate the sample.

In response to concerns about the performance of the sampler under extreme weather conditions (e.g., high or low temperatures, low pressures, high winds, high or low humidity, fog, dust storms), the EPA has established sampler specifications that are intended to cover reasonably normal environmental conditions at about 95 percent of expected monitoring sites. Qualification test requirements in 40 CFR part 53 address most, if not all, of these operational requirements. Specification of the sampler performance for sites with extreme environmental conditions would substantially raise the cost of the sampler for other users, most of whom do not require the extra capability. Users requiring operation of samplers under extreme conditions are encouraged to develop supplemental specifications for modified samplers to cover those specific conditions. Sampler manufacturers have indicated a commitment to respond to the need for modified samplers for such extreme conditions.

Although concerns were expressed that the amount of data required to be reported from each sampler is excessive, EPA stresses that only a portion of the data collected by the sampler needs to be reported to AIRS. These limited data reporting requirements (i.e., ambient and filter temperature, barometric pressure, sample volume, variation in sample run flow rate) are important to establish or verify the reliability and confidence of the $PM_{2.5}$ measurements and to aid in utilization of those data. The substantial amount of additional data generated by the sampler are of use to the site operator to provide confirmation of a given sample's validity, and to aid in troubleshooting should outlier measurements appear in the monitoring data. A variety of current electronic devices and systems may be used to acquire and handle the data, and these devices can easily accommodate the amount of data required to be reported, as well as the additional, optional data. Printers, modem connections, and alternative data output connections or devices are not precluded.

4. *Additional changes.* Additional clarifying changes have also been made throughout 40 CFR part 50, Appendix L, based on comments received or recently obtained field test information. In 40 CFR part 50, Appendix L, section 3.1, the lower concentration of the method has been revised from 1 to 2 $\mu g/m^3$, based on the results of field blanks associated with available field test data. In 40 CFR part 50, Appendix L, section 3.3, the sample period specification has been augmented to clarify that a measured $PM_{2.5}$ concentration for a sample period less than 23 hours that is greater than the NAAQS level(s) is to be considered a valid measurement for comparison to the NAAQS, even though not valid for other purposes. Sections 4 (Accuracy) and 5 (Precision) have been revised to properly reflect associated changes to the data quality and method performance assessment requirements set forth in 40 CFR part 58, Appendix A.

A provision has been added in 40 CFR part 50, Appendix L, section 7.4.17 to require sampler manufacturers to make available computer software to input sampler output data and translate the data into a standard spreadsheet format (since no specific format is specified for output of the sample data acquired by the sampler).

The requirements for the sampler to display current flow rate, temperature, filter temperature, and barometric pressure readings have been changed to require updating of these readings at least every 30 seconds. This change is based on operational experience of prototype samplers in 40 CFR part 50, Appendix L, section 7.4.5.1, and will make it easier for the operators to perform status checks and calibrations. In 40 CFR part 50, Appendix L, section 7.4.8.1, the requirements for the ambient temperature sensor have been changed to specify an external sensor with a passive sun shield, to provide better uniformity in the ambient temperature measurements among different types of reference method samplers. The reference method has also been clarified to indicate that $PM_{2.5}$ samples for which the sampler reported an out-of-specification (FLAG) occurrence during or after the sample period are not necessarily invalid, and that such samples should be reviewed by a quality assurance officer (40 CFR part 50, Appendix L, section 10.12). Finally, a new reference has been added in section 13 of the Act to provide applicable standards for meteorological measurements and measurement systems.

5. *Decision on 40 CFR part 50, Appendix L.* After fully considering the public comments on the proposed new reference method for $PM_{2.5}$, EPA has concluded that the proposed design and performance specifications for the reference sampler, with the modifications discussed in this unit, will achieve the design objectives set forth in the proposal and outlined above. Therefore, EPA is adopting the sampler and other method requirements specified in 40 CFR part 50, Appendix L as the reference method for measuring $PM_{2.5}$ in the ambient air.

Since proposal, a series of field tests have been performed using prototype samplers manufactured in accordance with the proposed design and performance specifications. The results of these field tests confirm that the prototype samplers perform in accordance with design expectations. Operational experience gained through these field tests did, however, identify the need for minor modifications as discussed above in this unit. In addition, EPA made other modifications to the proposed design and performance specification in response to public

comment as discussed above. As part of this process, EPA performed laboratory tests to ensure that the modifications achieved the intended objective.

While the results of these field tests and laboratory tests were largely confirmatory in nature and did not indicate a need to alter the basic design and performance specifications, they did identify areas that needed further refinement. Given that these tests were performed, by necessity, during and after the close of the public comment period and because the results were not available for placement in the docket until late in the rulemaking process, EPA is announcing, in a separate **Federal Register** notice being signed today, a supplemental comment period for the limited purpose of taking comments on these field and laboratory test results.

VII. Effective Date of the Revised PM Standards and Applicability of the Current PM_{10} Standards

In summary, the primary and secondary NAAQS for PM have been revised by establishing annual and 24-hour $PM_{2.5}$ standards; and by changing the form of the existing 24-hour PM_{10} standards. The existing PM_{10} annual standards have been retained. Section 50.3 (reference conditions) of 40 CFR part 50 has been revised to remove the adjustment of measured PM_{10} concentrations to standard conditions of temperature and pressure with respect to the revised PM standards. (Although EPA is retaining the current annual PM_{10} standards, the revision of 40 CFR 50.3 potentially may affect the effective stringency of the annual standards.) A new Appendix M has been added to 40 CFR part 50 that reflects the revision of 40 CFR 50.3. A new Appendix N to 40 CFR part 50 has been added to reflect the forms of the $PM_{2.5}$ and revised PM_{10} standards. Finally, a new Appendix L to 40 CFR part 50 has been added that specifies the reference method for measuring $PM_{2.5}$ in the ambient air.

The revised PM NAAQS, the revisions to 40 CFR 50.3, and the new Appendices M, N, and L to 40 CFR part 50 will become effective September 16, 1997. Inherent in the establishment of this revised set of PM standards and related provisions is the revocation of the current set of PM_{10} standards and associated provisions. To provide for an effective transition from the existing PM standards to the revised PM standards —in light of the need to establish $PM_{2.5}$ monitoring networks, designate areas, and develop control strategies for $PM_{2.5}$—the Administrator has determined that the effective date of the revocation of the current set of PM_{10} standards and associated provisions should be delayed so that the existing standards and associated provisions will continue to apply for an interim period. The duration of the interim period would depend on whether the area in question has attained the current PM_{10} standards, as described below in this unit.

First, section 172(e) of the Act provides that, if the Administrator relaxes a national primary ambient air quality standard, she shall, within 12 months after the relaxation, promulgate requirements applicable to all areas that have not attained that standard as of the date of the relaxation. Those requirements shall provide for controls that are not less stringent than the controls applicable to areas designated nonattainment before such relaxation. Although the set of revised PM standards, viewed as a whole, is more stringent than the set of current PM standards, it appears that the shift from the current PM_{10} standards to the revised PM_{10} standards, viewed in and of itself, represents a relaxation of the current PM_{10} standards. As a result, section 172(e) of the Act requires EPA to issue a rule within 12 months to apply implementation requirements no less stringent than the currently applicable requirements for those areas that have not yet attained the current PM_{10} standard(s) by today's promulgation. However, the Act does not specifically provide how to ensure that States with current PM_{10} problems should maintain the necessary public health protection in the interim between promulgation of a relaxed standard and issuance of a rule under section l72(e) of the Act. For that reason, EPA believes that it is both necessary and appropriate to defer the effective date of the revocation of the current PM_{10} standards, for areas that have not attained those standards, until EPA issues the rule called for by section 172(e) of the Act.

Second, since it will take many years for States to identify PM problems under the revised standards and to develop effective means for addressing those problems, EPA believes it is necessary for even those areas that have already attained the current PM_{10} standards (and hence are not subject to the terms of section 172(e) of the Act) to continue their current PM_{10} implementation efforts for the purpose of protecting public health in the transition to implementation of the revised standards.

In order to deal with both of these categories of areas—those that are not attaining the current PM_{10} standards and those that are in attainment of the current PM_{10} standards—EPA is taking a two-pronged approach towards deferral of the effective date of the revocation of the current PM_{10} standards. For those areas that are not attaining the current PM_{10} standards at the time of the promulgation of the revised PM_{10} standards, the current standards will continue to apply until EPA has completed its rulemaking under section 172(e) of the Act to prevent backsliding in those areas. This will assure that no backsliding can occur in the interim period between the promulgation of the revised standards and the completion of the rulemaking under section 172(e) of the Act. For those areas that are attaining the current PM_{10} standards at the time of promulgation of the revised PM_{10} standards, the existing PM_{10} standards will continue to apply until the areas have an approved SIP that includes any control measures that had been adopted and implemented at the State level to meet the current PM_{10} NAAQS and have an approved section 110 SIP for purposes of implementing the revised PM standards. If an area has already received approval of a PM_{10} SIP embodying all of the measures that had been adopted and implemented at the State level, no further Part D submission or approval would be necessary. If an area has already submitted such measures, EPA would need to take action to approve them. Finally, if an area has not yet submitted such measures to EPA for inclusion in the SIP, the area would need to submit them and EPA would need to approve them. This submission and approval would serve to satisfy both the area's remaining subpart D obligations and, in part, its new obligations under section 110(a)(1) of the Act regarding the implementation of the revised PM NAAQS. EPA emphasizes that it is not requiring an approval of a modeled attainment demonstration for the current PM_{10} NAAQS, only an approval of the control measures that had in fact been adopted and implemented and that, therefore, were responsible for the area's attainment of the current PM_{10} standards.

The existing definition of reference conditions and 40 CFR part 50, Appendices J and K will remain in force as long as the current PM_{10} standards apply to an area. Additional policies and guidance for assuring an effective transition will be set forth in future EPA guidance, policies, and/or rules.

VIII. Regulatory and Environmental Impact Analyses

As discussed in Unit IV of this preamble, the Clean Air Act and judicial

decisions make clear that the economic and technological feasibility of attaining ambient standards are not to be considered in setting NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although, as described below, a Regulatory Impact Analysis (RIA) has been prepared, neither the RIA nor the associated contractor reports have been considered in issuing this final rule.

A. Executive Order 12866

Under Executive Order 12866, 58 FR 51735 (October 4, 1993), the Agency must determine whether a regulatory action is ''significant'' and, therefore, subject to Office of Management and Budget (OMB) review and other requirements of the Executive Order. The order defines ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency.

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

In view of its important policy implications, this action has been judged to be a ''significant regulatory action'' within the meaning of the Executive Order. As a result, under section 6 of the Executive Order, EPA has prepared an RIA, entitled ''Regulatory Impact Analysis for Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule (July 1997).'' This RIA assesses the costs, economic impacts, and benefits associated with potential State implementation strategies for attaining the PM and O_3 NAAQS and the proposed Regional Haze Rule. Changes made in response to OMB suggestions or recommendations will be documented in the public docket and made available for public inspection at EPA's Air and Radiation Docket Information Center (Docket No. A-95-58). The RIA will be publicly available in hard copy by contacting the U.S. Environmental Protection Agency Library at the address under ''Availability of Related Information'' and in electronic form as discussed above in ''Electronic Availability.''

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, provides that, whenever an agency is required to publish a general notice of rulemaking for a proposal, the agency must prepare an initial regulatory flexibility analysis for the proposal unless the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities (section 605(b)). The EPA certified the proposed NAAQS rule based on its conclusion that the rule would not establish requirements applicable to small entities and therefore would not have a significant economic impact on small entities within the meaning of the RFA. See 61 FR 65638, 65668 (PM proposal) and 61 FR 65716, 65764 (ozone proposal), both published December 13, 1996. Accordingly, the Agency did not prepare an initial regulatory flexibility analysis for the proposal, but it did conduct a more general analysis of the potential impact on small entities of possible State strategies for implementing any new or revised NAAQS.

At the heart of EPA's certification of the proposed NAAQS rule was the Agency's interpretation of the word ''impact'' as used in the RFA. Is the ''impact'' to be analyzed under the RFA a rule's impact on the small entities that will be subject to the rule's requirements, or the rule's impact on small entities in general, whether or not they will be subject to the rule? In the case of NAAQS rules, the question arises because of the congressionally designed mixture of Federal and State responsibilities in setting and implementing the NAAQS.

As EPA explained in the proposal, NAAQS rules establish air quality standards that States are primarily responsible for meeting. Under section 110 and Part D of Title I of the Act, every State develops a State Implementation Plan (SIP) containing the control measures that will achieve a newly promulgated NAAQS. States have broad discretion in the choice of control measures. As the U.S. Supreme Court noted in *Train* v. *NRDC*, 421 U.S. 60 (1975), 95 S. Ct. 1470:

> [P]rimary [NAAQS] deal with the quality of outdoor air and are fixed on a nationwide basis at a level which the agency determines will protect the public health. It is the attainment and maintenance of these standards which section 110(a)(2)(A) requires that State plans provide. In complying with this requirement, a State's plan must include ''emission limitations'' which are regulations of the composition of substances emitted into the ambient air from such sources as power plants, service stations and the like. They are the specific rules to which operators of pollution sources are subject and which, if enforced, should result in ambient air which meets the national standards.
>
> The Agency is plainly charged by the Act with the responsibility for setting the national ambient air standards. Just as plainly, it is relegated to a secondary role in the process of determining and enforcing the specific, source-by-source emission limitations which are necessary if the national standards are to be met. Under 110(a)(2), the Agency *is required* to approve a State plan which provides for the timely attainment and maintenance of the ambient air standards, and which also satisfies that sections other general requirements. The Act gives the agency no authority to question the wisdom of a state's choices of emission limitations if they are part of a plan which satisfies the standards of 110(a)(2) and the Agency may devise and promulgate a plan of its own only if the State fails to submit an implementation plan which satisfies those standards. Section 110(c).

421 U.S. 60 at 78–79 (emphasis in original). In short, NAAQS rules themselves do not establish any control requirements applicable to small entities. State rules implementing the NAAQS may establish such requirements and the extent to which they do depends primarily on each State's strategy for meeting the NAAQS.[95]

To determine the proper interpretation of impact under the RFA, EPA considered the RFA's stated purpose, its requirements for regulatory flexibility analyses, its legislative history, the amendments made by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121), and caselaw. The EPA concluded that all of these traditional tools of statutory construction point in one direction—that an agency is required to assess the impact of a rule on the small entities that will be subject to the rule's requirements, because the purpose of a regulatory flexibility analysis is to consider ways of easing or even waiving a rule's requirements as they will apply to small entities, consistent with the statute authorizing

[95] It is worth noting that Federal rules that apply nationally also play a role in reducing emissions governed by NAAQS. For instance, EPA rules under Title II of the Act require reductions in ozone-forming emissions from on and off-road vehicles and the fuels that power them. When EPA issues such rules, it conducts the analysis required under the RFA. For example, EPA performed regulatory flexibility analyses for the reformulated gasoline rule issued under section 211(k) of the Act. See 59 FR 7716, February 16, 1994.

the rule. That purpose cannot be served in the case of the rules like the NAAQS that do not have requirements that apply to small entities.

More specifically, EPA noted that its interpretation of ''impact'' flows from the express purpose of the RFA itself. As the RFA's ''Findings and Purposes'' section (Pub. L. 96–354, section 2) makes clear, Congress enacted the RFA in 1980 out of concern that agencies were writing one-size-fits-all regulations that in fact did not fit the size and resources of small entities. Congress noted that it is generally easier for big businesses to comply with regulations, and that small businesses are therefore at a competitive disadvantage in complying with uniform rules. Congress also noted that small entities' relative contribution to the problem a rule is supposed to solve may not warrant applying the same requirements to large and small entities alike. In the RFA itself, Congress therefore stated:

> It is the purpose of this Act to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.

(Pub. L. 96–354, section 2(b))

The EPA further noted that the RFA sections governing initial and final regulatory flexibility analyses reflect this statement of purpose. Sections 603 and 604 of the RFA require that initial and final regulatory flexibility analyses identify the types and estimate the numbers of small entities ''to which the proposed will apply'' (sections 603(b)(3) and 604(a)(3) of the RFA). Similarly, they require a description of the ''projected reporting, recordkeeping, and other compliance requirements of the proposal, including an estimate of the classes of small entities which will be subject to the requirement'' (sections 603(b)(4) and 604(a)(4)). At the core of the analyses is the requirement that agencies identify and consider ''significant regulatory alternatives'' that would ''accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposal on small entities'' (sections 603(c) and 604(a)(5)). Among the types of alternatives agencies are to consider are the establishment of different ''compliance or reporting requirements or timetables'' for small entities and the exemption of small entities ''from coverage of the rule, or any part'' of the rule (section 603(c)(1) and (4) of the RFA). The RFA thus makes clear that regulatory flexibility analyses are to focus on how to minimize rule requirements on small entities.

As EPA further explained, since regulatory flexibility analyses are not required for a rule that will not have a ''significant economic impact on a substantial number of small entities'', it makes sense to interpret ''impact'' in light of the requirements for such analyses. Regulatory flexibility analyses, as described in this unit, are to consider how a rule will apply to small entities and how its requirements may be minimized with respect to small entities. In this context, ''impact'' is appropriately interpreted to mean the impact of a rule on the small entities subject to the rule's requirements.

The Agency cited two Federal court cases in support of its interpretation. In *Mid-Tex Elec. Co-op* v. *FERC*, 773 F.2d 327, 342 (D.C. Cir. 1985), petitioners claimed that the RFA required an agency to analyze the effects of a rule on small entities that were not regulated by the rule but might be indirectly impacted by it. Petitioners noted that the Small Business Administration (SBA) also interpreted the RFA to require analysis of a rule's impact on small entities not regulated by the rule, and argued that the court should defer to the SBA's position in light of its compliance monitoring role under the RFA. After reviewing the RFA's ''Findings and Purposes'' section, its legislative history, and its requirements for regulatory flexibility analyses, the Mid-Tex court rejected petitioners' interpretation. As the court explained:

> The problem Congress stated it discerned was the high cost to small entities of compliance with uniform regulations, and the remedy Congress fashioned—careful consideration of those costs in regulatory flexibility analyses—is accordingly limited to small entities subject to the proposed regulation * * *. [W]e conclude that an agency may properly certify that no regulatory flexibility analysis is necessary when it determines that the rule will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule.

Id. at 342. Notably, Congress let this interpretation stand when it recently amended the RFA in enacting SBREFA.

The EPA also cited a recent case affirming the Mid-Tex court's interpretation. In *United Distribution Companies* v. *FERC*, 88 F.3d 1105, 1170 (D.C. Cir. 1996), the court noted that the Mid-Tex court:

> * * * conducted an extensive analysis of RFA provisions governing when a regulatory flexibility analysis is required and concluded that no analysis is necessary when an agency determines ''that the rule will not have a significant economic impact on a substantial number of small entities *that are subject to the requirements of the rule*''.

Id., citing and quoting Mid-Tex (emphasis added by United Distribution court). The Agency went on to explain that given the Federal/State partnership for attaining healthy air, the proposed NAAQS, if adopted, would not establish any requirements applicable to small entities. Instead, any new or revised standard would establish levels of air quality that States would be primarily responsible for achieving by adopting plans containing specific control measures for that purpose. The proposed NAAQS rule was thus not susceptible to regulatory flexibility analysis as prescribed by the amended RFA. Since it would establish no requirements applicable to small entities, it afforded no opportunity for EPA to fashion for small entities less burdensome compliance or reporting requirements or timetables, or exemptions from all or part of the rule. For these reasons, EPA certified that the proposal ''will not, if promulgated, have a significant economic impact on a substantial number of small entities,'' within the meaning of the RFA. Because EPA was not required to prepare an initial regulatory flexibility analysis for the rule, it was also not required to convene a Small Business Advocacy Review Panel for the rule under section 609(b) of the RFA, as added by SBREFA.

Notwithstanding its certification of the proposal, EPA recognized that the proposed NAAQS, if adopted, would begin a process of State implementation that could eventually lead to small entities having to comply with new or different control measures, depending on the implementation plans developed by the States. EPA also recognized that the Act does not allow EPA to dictate or second-guess how States should exercise their discretion in regulating to attain any new or revised NAAQS. Under those circumstances, EPA concluded that the best way to take account of small entity concerns regarding any new or revised NAAQS was to work with small entity representatives and States to provide information and guidance on how States could address small entity concerns when they write their implementation plans.

In line with this approach, as part of RIA it prepared for the proposed NAAQS, EPA analyzed how hypothetical State plans for implementing the proposal might affect small entities. The analysis was necessarily speculative and limited, since it depended on projections about what States might do several years in the future and did not take into account

any new strategies that might be developed and recommended by the FACA subcommittee formed to help devise potential strategies for implementing a new or revised NAAQS (see discussion of RIA and FACA process in this document). Nevertheless, the analysis provided as much information on potential small entity impacts as was reasonably available at the time of the proposal.

The Agency also took steps to ensure that small entities' voices were heard in the NAAQS rulemaking itself. With Jere Glover, Chief Counsel for Advocacy of the SBA, EPA convened outreach meetings modeled on the SBREFA panel process to solicit and convey small entities' concerns with the proposed NAAQS. Two meetings were held as part of that process, on January 7 and February 28, 1997, with a total attendance of 41 representatives of small businesses, small governments, and small nonprofit organizations. Both meetings were attended by representatives of SBA and OMB, as well as of EPA. The key concerns raised by small entities at those meetings related to the scientific foundation of the proposed NAAQS and the potential cost of implementing it, the same concerns raised by other industry commenters on the proposal. The Agency produced a report on the meetings to ensure that small entity concerns were part of the rulemaking record when EPA made its final decision on the proposal.

In light of States' pivotal role in NAAQS implementation, EPA also undertook a number of additional activities to assist and encourage the States to be sensitive to small entity impacts as they implement any new or revised NAAQS. With the SBA, EPA began an interagency panel process to collect advice and recommendations from small entity representatives on how States could lessen any impacts on small entities. The EPA plans to issue materials in two phases to help States develop their implementation plans. In view of States' discretion in implementing the NAAQS, these materials will mostly take the form of guidance, which is not subject to the RFA's requirement for initial regulatory flexibility analysis. (Under section 603 of the RFA, that requirement applies only to binding rules that are required to undergo notice and comment rulemaking procedures.) But regardless of the form such materials take, EPA is employing panel procedures to ensure that small entities have an opportunity to raise any concerns prior to the materials being issued in draft form.

To supplement the input the Agency receives from the ongoing FACA process (described previously in this document), EPA also added more small entity representatives to the Subcommittee on implementation of any new or revised NAAQS. These representatives have formed a small entity caucus to develop and bring to the Subcommittee a focused approach to small entity issues. These new Subcommittee members are also part of the group in the aforementioned panel process. By means of these various processes, EPA hopes to promote the consideration of small entity concerns and advice throughout the NAAQS implementation process.

In response to the proposal, a number of commenters questioned EPA's decision to certify that the proposed NAAQS will not have a significant impact on a substantial number of small entities. Some commenters disagreed with EPA's view that the proposed NAAQS would not establish regulatory requirements applicable to small entities. These commenters argued that a number of control requirements applicable to small entities would automatically result from promulgation of the proposed NAAQS, such as new reasonable further progress, SIP and Federal Implementation Plan (FIP) requirements. Other commenters stated that it is possible for EPA to assess the impacts of the NAAQS revision on small entities and that, to a limited extent, EPA has already done so. Further, a number of commenters argued that EPA has a legal obligation under the RFA, as amended by SBREFA, to choose a NAAQS alternative that minimizes the impact on small entities. Some commenters questioned EPA's interpretations of the Mid-Tex and United Distribution cases. In addition, other commenters stated that EPA's position regarding the NAAQS and the RFA is inconsistent with its past practice and the legislative history of the RFA. Finally, a few commenters noted that the panel process EPA conducted for the proposed NAAQS did not satisfy the requirements of SBREFA.

EPA disagrees that promulgation of the NAAQS will automatically result in control requirements applicable to small entities that EPA can and must analyze under the RFA. As noted previously in this unit, a NAAQS rule only establishes a standard of air quality that other provisions of the Act call on States (or in case of State inaction, the Federal government) to achieve by adopting implementation plans containing specific control measures for that purpose. Following promulgation of a new or revised NAAQS, section 110 of the Act requires States and EPA to engage in a designation process to determine what areas within each State's borders are attaining or not attaining the NAAQS. Under section 110 and Parts C and D of Title I of the Act, States then conduct a planning process to develop and adopt their SIPS. Depending on an area's designation for the particular NAAQS, these and other Title I provisions of the Act require a State's SIP to contain certain control programs in addition to the control measures that the State decides are also needed to attain and maintain the NAAQS.

The fact that the Act requires SIPs to contain certain control programs under certain circumstances does not mean that EPA either can or must conduct a regulatory flexibility analysis of a rule establishing a NAAQS. Just from the standpoint of feasibility, EPA cannot know which areas will be subject to what mandatory SIP programs until after the designation process is completed. Beyond that, any mandatory SIP programs are still implemented by the States, and States have considerable discretion in how they implement them. For instance, the reasonable further progress requirement under section 172 of the Act leaves States broad discretion to determine the rate of progress and the control measures to achieve that progress.[96] As a result, EPA cannot be certain where and how any mandatory programs will be implemented with respect to small (or large) entities. Much less can EPA know about how States will exercise their discretion to develop additional controls needed to attain and maintain the NAAQS.

Even if EPA could know exactly how any mandatory SIP programs would apply to small entities, the purpose of the RFA is not served by attempting a regulatory flexibility analysis of State implementation of those programs. As explained previously in this unit, the RFA and the caselaw interpreting it clearly establish that the purpose of the RFA is to promote Federal agency efforts to tailor a rule's requirements to the scale of the small entities that will be subject to it. That purpose cannot be served in the case of a NAAQS rule since the rule does not establish requirements applicable to small

[96]The SIP requirements of subpart 4 of Part D of Title I of the Act apply to SIPs for areas designated as not attaining NAAQS for PM_{10}. Those requirements will not apply to SIPs to implement the $PM_{2.5}$ NAAQS. Further, to the extent SIPs for areas in nonattainment with the applicable PM_{10} NAAQS remain subject to subpart 4 requirements, there will be no incremental change in the impact on sources regulated by the States' SIPs pursuant to those requirements as a result of this promulgation.

entities. In promulgating a NAAQS, the only choice before EPA concerns the level of the standard, not its implementation. While mandatory SIP programs may ultimately follow from promulgation of the NAAQS, there is nothing EPA can do in setting the NAAQS to tailor those programs as they apply to small entities. Whether and how the programs will apply in particular nonattainment areas is beyond the scope of the NAAQS rulemaking and, indeed, beyond EPA's reach in any rulemaking to the extent the applicability and terms of the programs are prescribed by statute.[97] Moreover, any mandatory SIP programs are supplemented by discretionary State controls that EPA has no power to tailor under the RFA or the Act (see *Train* v. *NRDC*, quoted previously in this unit).

The commenters' suggestions for minimizing the potential impact of the NAAQS rule on small entities run afoul of both the RFA and the Act. Some suggested that EPA set a less stringent standard (or no standard at all in the case of $PM_{2.5}$) to reduce the chance that small entities would become subject to new or tighter SIP requirements. Others suggested that EPA require States to exempt small entities from new or tighter SIP requirements. However, as explained previously in this document, the RFA neither requires nor authorizes EPA to set a less stringent NAAQS than the applicable Clean Air Act provisions allow in order to reduce potential small entity impacts. Indeed, the RFA provides that any means of providing regulatory flexibility to small entities be consistent with the statute authorizing the rule. Moreover, even if EPA set a less stringent standard, States could still exercise their discretion to obtain any needed emission reductions from small entities. As the Supreme Court in *Train* v. *NRDC* made clear, EPA has no authority to forbid States from obtaining reductions from any particular category of stationary sources, including small entities. See also, *Virginia* v. *EPA*, No. 108 F.3d 1397, 1408 (D.C. Cir. 1997), quoting *Union Electric* v. *EPA*, 427 U.S. 246, 269 (1976) (''section 110 left to the states the power to determine which sources would be burdened by regulations and to what extent'').

EPA's approval of SIPs for the new or revised NAAQS also will not establish new requirements, but will instead simply approve requirements that a State is already imposing. And again, EPA does not have authority to disapprove a State's plan except to the extent that the plan fails to demonstrate attainment and maintenance of the NAAQS as required by Title I of the Clean Air Act. In cases where EPA promulgates a FIP, EPA might establish control requirements applicable to small entities, and in such a circumstance, EPA would conduct the analyses required by the RFA.

Some commenters argued that under the RFA as amended by SBREFA, EPA now has an obligation to choose the alternative that minimizes the impact on small entities when setting the NAAQS. As indicated previously in this unit, EPA disagrees with the commenters' argument for the reasons stated in this document's discussion of the Agency's authority to consider costs and other factors not related to public health in setting and revising primary NAAQS. In a nutshell, both the text and legislative history of the RFA make clear that the RFA does not override the substantive provisions of the statute authorizing the rule, but only requires agencies to identify and consider ways of minimizing the economic impact on small entities subject to the rule in a manner consistent with the authorizing statute.

Some commenters disagreed with EPA's interpretation of the Mid-Tex and United Distribution cases. In particular, these commenters noted that in those cases the relevant regulatory agency, Federal Energy Regulatory Commission (FERC), wholly lacked jurisdiction to regulate the small entities at issue. According to these commenters, EPA does have the ability and jurisdiction to regulate small entities in the case of the NAAQS, and therefore EPA's reliance on Mid-Tex and United Distribution is misplaced.

The commenters' attempt to distinguish the FERC cases from the NAAQS rulemaking wholly overlooks the courts' reasoning, which in fact fully supports EPA's certification of the proposed NAAQS. As described previously in this unit, the Mid-Tex court exhaustively reviewed the relevant sections of the RFA and its legislative history. Its analysis revealed that Congress passed the RFA out of concern with one-size-fits-all regulations and fashioned a remedy limited to regulations that apply to small entities. This principle is fully applicable to the NAAQS, which creates no rule requirements that apply to small entities.

The fact that FERC had no regulatory authority over the small entities indirectly affected by its rules played no essential role in the court's rationale. FERC could (and apparently did in the Mid-Tex rulemaking) estimate the potential indirect impact of its rules on small entities. Presumably, FERC could have also mitigated any indirect impact by changing some aspect of the rule (or else the small entities would have had no incentive to sue the agency). The court nevertheless found it unnecessary for FERC to do either, based on its reading of the RFA as limited to analysis of a rule's impact on the small entities subject to the rule's requirements. In reaching its decision, the court noted that requiring agencies to ''consider every indirect effect that any regulation might have on small businesses * * * is a very broad and ambitious agenda, * * * that Congress is unlikely to have embarked on * * * without airing the matter.'' Mid-Tex, 773 F.d. at 343.

The commenters also overstate EPA's regulatory authority over small entities with respect to the regulation of criteria pollutants. Various provisions of the Clean Air Act authorize EPA to regulate various types of sources at the Federal level to accomplish specified goals. However, EPA's authority to more generally regulate sources, including small entities, in the manner of SIPs is limited to instances of State default of SIP responsibilities. When that occurs, EPA may issue a FIP containing specific control measures, and to the extent a proposed FIP would establish control measures applicable to small entities, EPA would analyze the small entity impact of those measures as required by the RFA. In 1994, for example, EPA prepared an initial regulatory flexibility analysis when it proposed a FIP for Los Angeles. See 59 FR 23264 (May 5, 1994).

As noted previously in this unit, Congress let the Mid-Tex interpretation stand when it recently amended the RFA in enacting SBREFA. If it had disagreed with the court's decision, it would have revised the relevant statutory provisions or otherwise indicated its disagreement when it enacted SBREFA. Instead, Congress actually reinforced the Mid-Tex court's interpretation of the RFA in enacting section 212(a) of SBREFA. That section requires that an agency issue a ''small entity compliance guide'' for ''each rule * * * for which an agency is required to prepare a final regulatory flexibility analysis under section 604'' of the RFA. The guide is ''to assist small entities in complying with the rule'' by ''explain[ing] the actions a small entity is required to take to comply'' with the rule (section 212(a) of SBREFA). Obviously, it makes no sense to prepare a small entity compliance guide for a rule that does not apply to small entities. Thus SBREFA stands as further confirmation that Congress intended the

[97] If and when the Agency issues any rules addressing State implementation of any statutorily required actions, EPA would analyze and address the impact of those rules on small entities as appropriate under the RFA.

RFA to address only rules that establish requirements small entities must meet. Since SBREFA's passage, the United Distribution court has affirmed the Mid-Tex court's interpretation.

Some commenters noted that EPA's informal panel process did not comply with the requirements of SBREFA. The EPA did not convene a SBREFA panel because such a panel is not required for rules like the NAAQS that do not apply to small entities. Under the RFA as amended by SBREFA, since the Agency certified the proposal, it was not required to convene a panel for it. Nevertheless, EPA conducted the voluntary panel process described previously in this unit, as well as other voluntary small business outreach efforts. The process could not comply with the analytical requirements of the RFA for the reasons given in this unit. However, it could and did ensure that EPA heard directly from small entities about the NAAQS proposals.

A few commenters stated that EPA's view of the NAAQS and the RFA is inconsistent with EPA's past positions regarding the RFA and NAAQS revisions. Some commenters also cited the RIA for the proposed NAAQS and noted that this analysis demonstrates EPA's ability to estimate the impact of the NAAQS on small entities, thereby undercutting EPA's argument that it is not able to perform a regulatory flexibility analysis when setting the NAAQS.

Past **Federal Register** documents make clear that the nature of the NAAQS makes a regulatory flexibility analysis inapplicable to NAAQS rulemakings. For instance, in 1984, EPA stated that a ''NAAQS for NO_x by itself has no direct impact on small entities. However, it forces each State to design and implement control strategies for areas not in attainment.'' See 49 FR 6866, 6876 (February 23, 1984); see also, 50 FR 37484, 37499 (September 13, 1985); 50 FR 25532, 25542 (June 19, 1985) (NAAQS for NO_2 do not impact small entities directly). EPA stated again in 1987 that the NAAQS ''themselves do not contain emission limits or other pollution controls. Rather, such controls are contained in state implementation plans.'' See 52 FR 24634, 24654 (July 1, 1987).

EPA has typically performed an analysis to assess, to the extent practicable, the potential impact of retaining or revising the NAAQS on small entities, depending on possible State strategies for implementing the NAAQS. These analyses have provided as much insight into the potential small entity impacts of implementing revised NAAQS as could be provided at the NAAQS rulemaking stage. In some instances, these preliminary analyses were described as ''regulatory flexibility analys[es]'' or as analyses ''pursuant to this [Regulatory Flexibility] Act.'' See, e.g., 52 FR 24634, 24654 (July 1, 1987); 50 FR 37484, 37499 (September 13, 1985).

However, these analyses were based on hypothetical State control strategies, and EPA made the point on various occasions that any conclusions to be drawn from such analyses were speculative, given that the NAAQS themselves do not impose requirements on small entities. Although these past analyses reflected the Agency's best efforts to evaluate potential impacts, they were not regulatory flexibility analyses containing the necessary elements required by the RFA. These analyses, for example, did not describe the reporting, recordkeeping, and other compliance requirements of the proposed NAAQS rules that would apply to small entities, since the NAAQS rules did not apply to small entities. Nor did they determine how the proposed NAAQS rules could be eased or waived for small entities. Such an analysis is not possible in the case of the NAAQS. To the extent EPA labeled these analyses regulatory flexibility analyses in the past, that label was inappropriate. EPA's current practice is to describe such an analysis more accurately as a general analysis of the potential cost impacts on small entities. See, e.g., 61 FR 65638, 65669, 65747 (December 13, 1996) (current O_3 and PM NAAQS proposals).[98] EPA's analytical approach to small entity impacts of the NAAQS has thus remained consistent over time.

One commenter noted that the legislative history of the RFA suggests that the RFA was intended to apply to the NAAQS. As noted previously in this unit, EPA's reading of both the RFA and SBREFA, based on the language of the statute as amended and its legislative histories and applicable caselaw, is that the RFA requirements at issue do not apply to the NAAQS. The legislative history cited by the commenter does not change this conclusion.

In fact, the statement by Senator Culver on which the commenter relies does not indicate that the NAAQS should be subject to regulatory flexibility analyses. Rather, Senator Culver uses the NAAQS as an example of the type of standard that agencies would not change as a result of the RFA. According to Senator Culver, section 606 of the RFA ''succinctly states that this bill does not alter the substantive standard contained in underlying statutes which defines the agency's mandate.'' 126 Cong. Rec. S 21455 (August 6, 1980) daily ed. After citing section 109 of the Act, Senator Culver goes on to describe EPA's bubble policy (which addresses the limits on emissions from a particular facility) as the type of flexible regulation that agencies should consider, once EPA has set a NAAQS. ''The important point for purposes of this discussion is that the 'bubble concept,' a type of flexible regulation, in no manner altered the basic statutory substantive standard of the EPA * * *. No regulatory flexibility analysis alters the substantive standard otherwise applicable by law to agency action.'' *Id.* Thus, contrary to the suggestion of the commenter, Senator Culver's statement actually confirms that the time to consider regulatory flexibility is when regulations applicable to sources are being established, not when a NAAQS itself is being set.

Under section 604 of the RFA, whenever an agency promulgates a final rule under section 553 of the Administrative Procedure Act, after being required by that section or any other law to publish a general notice of proposed rulemaking (NPRM), the agency is required to prepare a final regulatory flexibility analysis. RFA section 605(b) provides, however, that section 603 (re initial regulatory flexibility analyses) and section 604 do not apply if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities and publishes such certification at the time of publication of the NPRM or at the time of the final rule.

As noted above, EPA certified this final rule at the time of the NPRM. After considering the public comments on the certification, EPA continues to believe that this final rule will not have a significant economic impact on a substantial number of small entities for the reasons explained above and that it

[98] As commenters pointed out, the RIA for the proposed PM NAAQS does state that ''[t]he screening analysis * * * provides enough information for an initial regulatory flexibility analysis (RFA) if such an analysis were to be done.'' That statement was mistaken and was not made in the RIA for the proposed ozone NAAQS. While both RIAs attempted to gauge the potential impact on small entities of State implementation of the proposed NAAQS, neither could or did identify any specific control or information requirements contained in the NAAQS rule that would apply to small entities. Indeed, both RIAs made clear that the impact being analyzed was that of potential State measures to attain the NAAQS, and that such an analysis was inherently speculative and uncertain. Thus, the RIAs actually confirm EPA's statement in the preambles for the proposed NAAQS that conducting a complete regulatory flexibility analysis is not feasible for rules setting or revising a NAAQS.

therefore appropriately certified the rule. Further, as required by the Clean Air Act, EPA is promulgating this final rule under section 307(d) of the Clean Air Act. For all the foregoing reasons, EPA has not prepared a final regulatory flexibility analysis for the rule. The Agency has nonetheless analyzed in the final RIA for the rule the potential impact on small entities of hypothetical State plans for implementing the NAAQS. The Agency also plans to issue guidance to the States on reducing the potential impact on small entities of implementing the NAAQS.

C. Impact on Reporting Requirements

There are no reporting requirements directly associated with the finalization of ambient air quality standards under section 109 of the Act (42 U.S.C. 7400). There are, however, reporting requirements associated with related sections of the Act, particularly sections 107, 110, 160, and 317 (42 U.S.C. 7407, 7410, 7460, and 7617).

In EPA's final revisions to the air quality surveillance requirements (40 CFR part 58) for PM, the associated RIA addresses the Paperwork Reduction Act requirements through an Information Collection Request.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of certain regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any 1 year. This requirement does not apply if EPA is prohibited by law from considering section 202 of UMRA estimates and analyses in adopting the rule in question. Before promulgating a final rule for which a written statement is needed, section 205 of UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. These requirements do not apply when they are inconsistent with applicable law. Moreover, section 205 of UMRA allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements. Section 204 of UMRA requires each agency to develop ''an effective process to permit elected officers of state, local and tribal governments * * * to provide meaningful and timely input'' in the development of regulatory proposals containing a significant Federal intergovernmental mandate.[99]

The EPA has determined that the provisions of sections 202 and 205 of UMRA do not apply to this decision.''Unless otherwise prohibited by law,'' EPA is to prepare a written statement under section 202 of UMRA that is to contain assessments and estimates of the costs and benefits of a rule containing a Federal mandate. Congress clarified that ''unless otherwise prohibited by law'' referred to whether an agency was prohibited from considering the information in the rulemaking process, not to whether an agency was prohibited from collecting the information. The Conference Report on UMRA states, ''This section [202] does not require the preparation of any estimate or analysis if the agency is prohibited by law from considering the estimate or analysis in adopting the rule.'' 141 Cong. Rec. H3063 (daily ed. March 13, 1995). Because the Clean Air Act prohibits EPA, when setting the NAAQS, from considering the types of estimates and assessments described in section 202 of UMRA, UMRA does not require EPA to prepare a written statement under section 202.[100] The requirements in section 205 of UMRA do not apply because those requirements only apply to rules ''for which a written statement is required under section 202 * * *.''

The EPA has determined that the provisions of section 203 of UMRA do not apply to this decision. Section 203 of UMRA only requires the development of a small government agency plan for requirements with which small governments might have to comply. Since setting the NAAQS does not establish requirements with which small governments might have to comply, section 203 of UMRA does not apply. The EPA acknowledges, however, that any corresponding revisions to associated SIP requirements and air quality surveillance requirements, 40 CFR parts 51 and 58, respectively, might result in such effects.Accordingly, EPA did address unfunded mandates when it proposed revisions to 40 CFR part 58, and will do so, as appropriate, when it proposes any revision to 40 CFR part 51.

With regard to the outreach described in section 204 of UMRA, EPA did follow a process for providing elected officials with an opportunity for meaningful and timely input into the proposed NAAQS revisions, although EPA did not describe this process in the proposal. The EPA conducted a series of pre-proposal outreach meetings with State and local officials and their representatives that permitted these officials to provide meaningful and timely input on issues related to the NAAQS and the monitoring issues associated with them. Beginning in January, 1996, EPA briefed State and local air pollution control officials at national meetings with State and Territorial Air Pollution Program Administrators (STAPPA) / Association of Local Air Pollution Control Officials (ALAPCO) in Washington, DC, North Carolina, Chicago, and Nevada. The EPA also held briefings for the Washington, DC representatives of several State and local organizations, including National Conference of State Legislators, U.S. Conference of Mayors,

[99] As noted in unit VIII.B., a NAAQS rule only establishes a standard of air quality that other provisions of the Act call on States (or in the case of State inaction, the Federal government) to achieve by adopting implementation plans containing specific control measures for the purpose. Thus, it is questionable whether the NAAQS itself imposes an enforceable duty and thus whether it is a significant Federal mandate within the meaning of UMRA. EPA need not and does not reach this issue in this document. For the reasons given in this unit, even if the NAAQS were determined to be a significant Federal mandate, EPA does not have any obligations under sections 202 and 205 of UMRA, and EPA has met any obligations it would have under section 204 of UMRA.

[100] In addition to the estimates and assessments described in section 202 of UMRA, written statements are also to include an identification of the Federal law under which the rule is promulgated (section 202(a)(1) of UMRA) and a description of outreach efforts under section 204 of UMRA (section 202(a)(5) of UMRA). Although these requirements do not apply here because a written statement is not required under section 202 of UMRA, this preamble identifies the Federal law under which this rule is being promulgated and a written statement describing EPA's outreach efforts with State, local, and tribal governments will be placed in the docket.

National Governors Association, National League of Cities, and STAPPA/ALAPCO. EPA also held separate briefings and discussions with State and local officials at meetings set up by the National Governors Association, the U.S. Conference of Mayors and the Council of State Governments. The EPA also conducted in-depth briefings at each EPA regional office and regional staff also had several meetings and discussions with their State counterparts about the standards. The efforts described in this paragraph of this preamble, which provided elected officials with opportunity for meaningful and timely input into the proposed NAAQS revisions, met any requirements imposed by section 204 of UMRA. The docket will contain a written statement describing these outreach efforts, including a summary of the comments and concerns presented by State, local, and tribal governments and a summary of EPA's evaluation of those comments and concerns.

Several commenters disagreed with EPA that sections 202, 203, and 205 of UMRA do not apply to this decision. These commenters argued that EPA is not prohibited from considering costs in setting NAAQS under the Clean Air Act and applicable judicial decisions. Some commenters also expressed the view that there is no conflict between UMRA and the Clean Air Act with regard to the NAAQS. These commenters argued that UMRA and the NAAQS can be harmonized by reading UMRA as an information gathering statute and that EPA should therefore perform the analyses required by UMRA, regardless of whether costs may be considered. Finally, at least one commenter argued that in past NAAQS reviews, EPA did not dispute its UMRA obligations.

As discussed more fully in Unit IV. of this preamble, EPA is prohibited from considering cost in setting the NAAQS. Given that fact (as noted in Unit IV. of this preamble), sections 202 and 205 of UMRA do not apply.[101] As the Conference Report clarifies, UMRA itself states that the section 202 estimates and analyses are not required in cases such as the NAAQS, where an agency is prohibited by law from considering section 202 estimates and analyses. Reading UMRA in the manner suggested by the commenters would effectively read this provision out of UMRA; UMRA contains an exception for rules like the NAAQS, it must be given effect.

With regard to EPA's position regarding UMRA in previous NAAQS review exercises, EPA simply made plain in those situations that because it did not plan on revising the NAAQS, it determined, without further review, that sections 202, 203, and 205 of UMRA did not apply. EPA thus stated that:

> Because the Administrator has decided not to revise the existing primary NAAQS for SO_2, this action will not impose any new expenditures on governments or on the private sector, or establish any new regulatory requirements affecting small governments. Accordingly, EPA has determined that the provisions of sections 202, 203 and 205 do not apply to this final decision.

61 FR 25566, 25577, May 22, 1996; see also 61 FR 52852, 52856, October 8, 1996 (Same statement for NO_2 NAAQS). As this statement makes clear, EPA only determined that sections 202, 203, and 205 of UMRA did not apply to the NAAQS when EPA fails to revise the standard. Having made that determination, EPA had no reason to catalog additional bases for finding UMRA inapplicable. Nothing in that statement was intended to preclude EPA, or precludes EPA, from concluding for other reasons (such as those discussed in this unit) that UMRA also does not apply when EPA in fact revises an applicable NAAQS.

E. Environmental Justice

Executive Order 12848 (58 FR 7629, February 11, 1994) requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. These requirements have been addressed to the extent practicable in the RIA cited in this unit.

F. Submission to Congress and the Comptroller General

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in this issue of the **Federal Register**. This rule is a ''major rule'' for purposes of SBREFA.

IX. Response to Petition for Administrator Browner's Rescusal

On March 13, 1997, the Washington Legal Foundation (WLF), filed a petition with EPA asking that I, Carol Browner, disqualify myself in rulemaking regarding the NAAQS for PM and ozone. The petition claims that my public statements indicate a ''clear and convincing showing'' that I had ''already decided to revise the NAAQS for PM and ozone'' and that I therefore ''could not give meaningful consideration'' to comments adverse to the proposed rule. On May 12, 1997, EPA's General Counsel, Jonathan Z. Cannon, sent a letter to WLF regarding the petition. This letter and the WLF petition were then placed in the dockets for the proposed ozone and PM standards pending ''consideration and final response in connection with the Agency's final actions.''

Contrary to WLF's assertions, I have maintained an open mind throughout these proceedings, and have based today's decisions on the rulemaking record—including consideration of comments opposed to the proposal. The law does not require the Administrator of EPA to disqualify herself merely for expressing views on a proposed regulation; in fact, it is part of my responsibility to engage in the public debate on the proposals. Moreover, the assertions in WLF's petition do not accurately represent my views. The petition takes quotes out of context and repeatedly misinterprets my statements. For example, WLF quotes a statement that I made at the Children's Environmental Health Network Research Conference as an indication that I had ''prejudged the issue.'' However, my statement that ''I will not be swayed'' did not refer to adopting the NAAQS as proposed. Instead, as is clear from reviewing the entire speech, I was addressing my broader concern about children's health and the range of EPA standards affecting children's health. I also appeared at several congressional hearings and testified before members of Congress, some of whom were strongly opposed to the proposals. At those hearings, I explained the basis for the proposals and put forward the reasons why I concluded the proposals were appropriate, given the information before me at the time. At the same time, I made clear that I took very seriously

[101] One commenter argued that in reviewing the SO_2 NAAQS, EPA determined that it need not revise the $S0_2$ NAAQS, but could instead pursue an alternative regulatory program under other authority. This commenter argued that EPA has similar flexibility in reviewing the PM and Ozone NAAQS, and thus UMRA requires EPA to identify the least burdensome alternative (such as retaining the current NAAQS) as part of that process. As discussed more fully in Unit IV. of this preamble, EPA does not agree that it has flexibility to choose such an alternative; nor does EPA agree with the commenter's characterization of the action it took in deciding not to revise the SO_2 NAAQS. In fact, in deciding not to revise the SO_2 NAAQS, EPA determined, for reasons independent of section 303 of the Clean Air Act that a NAAQS revision was not warranted. See 61 FR 25566, 25575 (May 22, 1996).

my obligation to keep an open mind, and to consider fully and fairly all significant comments that the Agency received. For these reasons and others, as set forth in Mr. Cannon's May 12, 1997 response to WLF, which I adopt in full, I have decided not to recuse myself from any aspect of considering revisions to the NAAQS for ozone and PM. Accordingly, I am hereby denying WLF's petition.

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List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated: July 16, 1997.

Carol M. Browner,

Administrator.

Therefore, 40 CFR Chapter I is amended as follows:

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

1. The authority citation for part 50 continues to read as follows:

Authority: Secs. 109 and 301(a), Clean Air Act, as amended (42 U.S.C. 7409, 7601(a)).

2. Section 50.3 is revised to read as follows:

§ 50.3 Reference conditions.

All measurements of air quality that are expressed as mass per unit volume (e.g., micrograms per cubic meter) other than for the particulate matter (PM_{10} and $PM_{2.5}$) standards contained in § 50.7 shall be corrected to a reference temperature of 25 °C and a reference pressure of 760 millimeters of mercury (1,013.2 millibars). Measurements of PM_{10} and $PM_{2.5}$ for purposes of comparison to the standards contained in § 50.7 shall be reported based on actual ambient air volume measured at the actual ambient temperature and pressure at the monitoring site during the measurement period.

3. Section 50.6 is amended by revising the section heading and adding paragraph (d) to read as follows:

§ 50.6 National primary and secondary ambient air quality standards for PM_{10}.

* * * * *

(d) The PM_{10} standards set forth in this section will no longer apply to an area not attaining these standards as of September 16, 1997, once EPA takes final action to promulgate a rule pursuant to section 172(e) of the Clean Air Act, as amended (42 U.S.C. 7472(e)) applicable to the area. The PM_{10} standards set forth in this section will no longer apply to an area attaining these standards as of September 16, 1997, once EPA approves a State Implementation Plan (SIP) applicable to the area containing all PM_{10} control measures adopted and implemented by the state prior to September 16, 1997, and a section 110 SIP implementing the PM standards published on July 18, 1997. SIP approvals are codified in 40 CFR part 52.

4. Section 50.7 is added to read as follows:

§ 50.7 National primary and secondary ambient air quality standards for particulate matter.

(a) The national primary and secondary ambient air quality standards for particulate matter are:

(1) 15.0 micrograms per cubic meter ($\mu g/m^3$) annual arithmetic mean concentration, and 65 $\mu g/m^3$ 24-hour average concentration measured in the ambient air as $PM_{2.5}$ (particles with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers) by either:

(i) A reference method based on Appendix L of this part and designated in accordance with part 53 of this chapter; or

(ii) An equivalent method designated in accordance with part 53 of this chapter.

(2) 50 micrograms per cubic meter ($\mu g/m^3$) annual arithmetic mean

concentration, and 150 μg/m^3 24-hour average concentration measured in the ambient air as PM_{10} (particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers) by either:

(i) A reference method based on Appendix M of this part and designated in accordance with part 53 of this chapter; or

(ii) An equivalent method designated in accordance with part 53 of this chapter.

(b) The annual primary and secondary $PM_{2.5}$ standards are met when the annual arithmetic mean concentration, as determined in accordance with Appendix N of this part, is less than or equal to 15.0 micrograms per cubic meter.

(c) The 24-hour primary and secondary $PM_{2.5}$ standards are met when the 98th percentile 24-hour concentration, as determined in accordance with Appendix N of this part, is less than or equal to 65 micrograms per cubic meter.

(d) The annual primary and secondary PM_{10} standards are met when the annual arithmetic mean concentration, as determined in accordance with Appendix N of this part, is less than or equal to 50 micrograms per cubic meter.

(e) The 24-hour primary and secondary PM_{10} standards are met when the 99th percentile 24-hour concentration, as determined in accordance with Appendix N of this part, is less than or equal to 150 micrograms per cubic meter.

5. Appendix K is revised (for conformity with the format of the other appendices in this part) to read as follows:

Appendix K to Part 50—Interpretation of the National Ambient Air Quality Standards for Particulate Matter

1.0 *General.*

(a) This appendix explains the computations necessary for analyzing particulate matter data to determine attainment of the 24-hour and annual standards specified in 40 CFR 50.6. For the primary and secondary standards, particulate matter is measured in the ambient air as PM_{10} (particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers) by a reference method based on appendix J of this part and designated in accordance with part 53 of this chapter, or by an equivalent method designated in accordance with part 53 of this chapter. The required frequency of measurements is specified in part 58 of this chapter.

(b) The terms used in this appendix are defined as follows:

Average refers to an arithmetic mean. All particulate matter standards are expressed in terms of expected annual values: Expected number of exceedances per year for the 24-hour standards and expected annual arithmetic mean for the annual standards.

Daily value for PM_{10} refers to the 24-hour average concentration of PM_{10} calculated or measured from midnight to midnight (local time).

Exceedance means a daily value that is above the level of the 24-hour standard after rounding to the nearest 10 μg/m^3 (i.e., values ending in 5 or greater are to be rounded up).

Expected annual value is the number approached when the annual values from an increasing number of years are averaged, in the absence of long-term trends in emissions or meteorological conditions.

Year refers to a calendar year.

(c) Although the discussion in this appendix focuses on monitored data, the same principles apply to modeling data, subject to EPA modeling guidelines.

2.0 *Attainment Determinations.*

2.1 *24-Hour Primary and Secondary Standards.*

(a) Under 40 CFR 50.6(a) the 24-hour primary and secondary standards are attained when the expected number of exceedances per year at each monitoring site is less than or equal to one. In the simplest case, the number of expected exceedances at a site is determined by recording the number of exceedances in each calendar year and then averaging them over the past 3 calendar years. Situations in which 3 years of data are not available and possible adjustments for unusual events or trends are discussed in sections 2.3 and 2.4 of this appendix. Further, when data for a year are incomplete, it is necessary to compute an estimated number of exceedances for that year by adjusting the observed number of exceedances. This procedure, performed by calendar quarter, is described in section 3.0 of this appendix. The expected number of exceedances is then estimated by averaging the individual annual estimates for the past 3 years.

(b) The comparison with the allowable expected exceedance rate of one per year is made in terms of a number rounded to the nearest tenth (fractional values equal to or greater than 0.05 are to be rounded up; e.g., an exceedance rate of 1.05 would be rounded to 1.1, which is the lowest rate for nonattainment).

2.2 *Annual Primary and Secondary Standards.* Under 40 CFR 50.6(b), the annual primary and secondary standards are attained when the expected annual arithmetic mean PM_{10} concentration is less than or equal to the level of the standard. In the simplest case, the expected annual arithmetic mean is determined by averaging the annual arithmetic mean PM_{10} concentrations for the past 3 calendar years. Because of the potential for incomplete data and the possible seasonality in PM_{10} concentrations, the annual mean shall be calculated by averaging the four quarterly means of PM_{10} concentrations within the calendar year. The equations for calculating the annual arithmetic mean are given in section 4.0 of this appendix. Situations in which 3 years of data are not available and possible adjustments for unusual events or trends are discussed in sections 2.3 and 2.4 of this appendix. The expected annual arithmetic mean is rounded to the nearest 1 μg/m^3 before comparison with the annual standards (fractional values equal to or greater than 0.5 are to be rounded up).

2.3 *Data Requirements.*

(a) 40 CFR 58.13 specifies the required minimum frequency of sampling for PM_{10}. For the purposes of making comparisons with the particulate matter standards, all data produced by National Air Monitoring Stations (NAMS), State and Local Air Monitoring Stations (SLAMS) and other sites submitted to EPA in accordance with the Part 58 requirements must be used, and a minimum of 75 percent of the scheduled PM_{10} samples per quarter are required.

(b) To demonstrate attainment of either the annual or 24-hour standards at a monitoring site, the monitor must provide sufficient data to perform the required calculations of sections 3.0 and 4.0 of this appendix. The amount of data required varies with the sampling frequency, data capture rate and the number of years of record. In all cases, 3 years of representative monitoring data that meet the 75 percent criterion of the previous paragraph should be utilized, if available, and would suffice. More than 3 years may be considered, if all additional representative years of data meeting the 75 percent criterion are utilized. Data not meeting these criteria may also suffice to show attainment; however, such exceptions will have to be approved by the appropriate Regional Administrator in accordance with EPA guidance.

(c) There are less stringent data requirements for showing that a monitor has failed an attainment test and thus has recorded a violation of the particulate matter standards. Although it is generally necessary to meet the minimum 75 percent data capture requirement per quarter to use the computational equations described in sections 3.0 and 4.0 of this appendix, this criterion does not apply when less data is sufficient to unambiguously establish nonattainment. The following examples illustrate how nonattainment can be demonstrated when a site fails to meet the completeness criteria. Nonattainment of the 24-hour primary standards can be established by the observed annual number of exceedances (e.g., four observed exceedances in a single year), or by the estimated number of exceedances derived from the observed number of exceedances and the required number of scheduled samples (e.g., two observed exceedances with every other day sampling). Nonattainment of the annual standards can be demonstrated on the basis of quarterly mean concentrations developed from observed data combined with one-half the minimum detectable concentration substituted for missing values. In both cases, expected annual values must exceed the levels allowed by the standards.

2.4 *Adjustment for Exceptional Events and Trends.*

(a) An exceptional event is an uncontrollable event caused by natural sources of particulate matter or an event that is not expected to recur at a given location. Inclusion of such a value in the computation of exceedances or averages could result in inappropriate estimates of their respective expected annual values. To reduce the effect of unusual events, more than 3 years of

representative data may be used. Alternatively, other techniques, such as the use of statistical models or the use of historical data could be considered so that the event may be discounted or weighted according to the likelihood that it will recur. The use of such techniques is subject to the approval of the appropriate Regional Administrator in accordance with EPA guidance.

(b) In cases where long–term trends in emissions and air quality are evident, mathematical techniques should be applied to account for the trends to ensure that the expected annual values are not inappropriately biased by unrepresentative data. In the simplest case, if 3 years of data are available under stable emission conditions, this data should be used. In the event of a trend or shift in emission patterns, either the most recent representative year(s) could be used or statistical techniques or models could be used in conjunction with previous years of data to adjust for trends. The use of less than 3 years of data, and any adjustments are subject to the approval of the appropriate Regional Administrator in accordance with EPA guidance.

3.0 *Computational Equations for the 24-hour Standards.*

3.1 *Estimating Exceedances for a Year.*

(a) If PM_{10} sampling is scheduled less frequently than every day, or if some scheduled samples are missed, a PM_{10} value will not be available for each day of the year. To account for the possible effect of incomplete data, an adjustment must be made to the data collected at each monitoring location to estimate the number of exceedances in a calendar year. In this adjustment, the assumption is made that the fraction of missing values that would have exceeded the standard level is identical to the fraction of measured values above this level. This computation is to be made for all sites that are scheduled to monitor throughout the entire year and meet the minimum data requirements of section 2.3 of this appendix. Because of possible seasonal imbalance, this adjustment shall be applied on a quarterly basis. The estimate of the expected number of exceedances for the quarter is equal to the observed number of exceedances plus an increment associated with the missing data. The following equation must be used for these computations:

Equation 1

$$e_q = v_q + \left[\left(v_q/n_q\right)\times\left(N_q - n_q\right)\right] = v_q \times N_q/n_q$$

where:

e_q=the estimated number of exceedances for calendar quarter q;

v_q=the observed number of exceedances for calendar quarter q;

N_q=the number of days in calendar quarter q;

n_q=the number of days in calendar quarter q with PM_{10} data; and

q=the index for calendar quarter, q=1, 2, 3 or 4.

(b) The estimated number of exceedances for a calendar quarter must be rounded to the nearest hundredth (fractional values equal to or greater than 0.005 must be rounded up).

(c) The estimated number of exceedances for the year, e, is the sum of the estimates for each calendar quarter.

Equation 2

$$e = \sum_{q=1}^{4} e_q$$

(d) The estimated number of exceedances for a single year must be rounded to one decimal place (fractional values equal to or greater than 0.05 are to be rounded up). The expected number of exceedances is then estimated by averaging the individual annual estimates for the most recent 3 or more representative years of data. The expected number of exceedances must be rounded to one decimal place (fractional values equal to or greater than 0.05 are to be rounded up).

(e) The adjustment for incomplete data will not be necessary for monitoring or modeling data which constitutes a complete record, i.e., 365 days per year.

(f) To reduce the potential for overestimating the number of expected exceedances, the correction for missing data will not be required for a calendar quarter in which the first observed exceedance has occurred if:

(1) There was only one exceedance in the calendar quarter;

(2) Everyday sampling is subsequently initiated and maintained for 4 calendar quarters in accordance with 40 CFR 58.13; and

(3) Data capture of 75 percent is achieved during the required period of everyday sampling. In addition, if the first exceedance is observed in a calendar quarter in which the monitor is already sampling every day, no adjustment for missing data will be made to the first exceedance if a 75 percent data capture rate was achieved in the quarter in which it was observed.

Example 1

a. During a particular calendar quarter, 39 out of a possible 92 samples were recorded, with one observed exceedance of the 24-hour standard. Using Equation 1, the estimated number of exceedances for the quarter is:

e_q=1×92/39=2.359 or 2.36.

b. If the estimated exceedances for the other 3 calendar quarters in the year were 2.30, 0.0 and 0.0, then, using Equation 2, the estimated number of exceedances for the year is 2.36+2.30+0.0+0.0 which equals 4.66 or 4.7. If no exceedances were observed for the 2 previous years, then the expected number of exceedances is estimated by: (1/3)×(4.7+0+0)=1.57 or 1.6. Since 1.6 exceeds the allowable number of expected exceedances, this monitoring site would fail the attainment test.

Example 2

In this example, everyday sampling was initiated following the first observed exceedance as required by 40 CFR 58.13. Accordingly, the first observed exceedance would not be adjusted for incomplete sampling. During the next three quarters, 1.2 exceedances were estimated. In this case, the estimated exceedances for the year would be 1.0+1.2+0.0+0.0 which equals 2.2. If, as before, no exceedances were observed for the two previous years, then the estimated exceedances for the 3–year period would then be (1/3)×(2.2+0.0+0.0)=0.7, and the monitoring site would *not* fail the attainment test.

3.2 *Adjustments for Non-Scheduled Sampling Days.*

(a) If a systematic sampling schedule is used and sampling is performed on days in addition to the days specified by the systematic sampling schedule, e.g., during episodes of high pollution, then an adjustment must be made in the eqution for the estimation of exceedances. Such an adjustment is needed to eliminate the bias in the estimate of the quarterly and annual number of exceedances that would occur if the chance of an exceedance is different for scheduled than for non-scheduled days, as would be the case with episode sampling.

(b) The required adjustment treats the systematic sampling schedule as a stratified sampling plan. If the period from one scheduled sample until the day preceding the next scheduled sample is defined as a sampling stratum, then there is one stratum for each scheduled sampling day. An average number of observed exceedances is computed for each of these sampling strata. With nonscheduled sampling days, the estimated number of exceedances is defined as:

Equation 3

$$e_q = \left(N_q/m_q\right)\times\sum_{j=1}^{m_q}\left(v_j/k_j\right)$$

where:

e_q=the estimated number of exceedances for the quarter;

N_q=the number of days in the quarter;

m_q=the number of strata with samples during the quarter;

v_j=the number of observed exceedances in stratum j; and

k_j=the number of actual samples in stratum j.

(c) Note that if only one sample value is recorded in each stratum, then Equation 3 reduces to Equation 1.

Example 3

A monitoring site samples according to a systematic sampling schedule of one sample every 6 days, for a total of 15 scheduled samples in a quarter out of a total of 92 possible samples. During one 6-day period, potential episode levels of PM_{10} were suspected, so 5 additional samples were taken. One of the regular scheduled samples was missed, so a total of 19 samples in 14 sampling strata were measured. The one 6-day sampling stratum with 6 samples recorded 2 exceedances. The remainder of the quarter with one sample per stratum recorded zero exceedances. Using Equation 3, the estimated number of exceedances for the quarter is:

e_q=(92/14)×(2/6+0+. . .+0)=2.19.

4.0 *Computational Equations for Annual Standards.*

4.1 *Calculation of the Annual Arithmetic Mean.* (a) An annual arithmetic mean value for PM_{10} is determined by averaging the quarterly means for the 4 calendar quarters of the year. The following equation is to be used for calculation of the mean for a calendar quarter:

Equation 4

$$\bar{x}_q = \left(1/n_q\right) \times \sum_{i=1}^{n_q} x_i$$

where:

$\bar{x}_q$= the quarterly mean concentration for quarter q, q=1, 2, 3, or 4,

n_q= the number of samples in the quarter, and

x_i= the ith concentration value recorded in the quarter.

(b) The quarterly mean, expressed in μg/m³, must be rounded to the nearest tenth (fractional values of 0.05 should be rounded up).

(c) The annual mean is calculated by using the following equation:

Equation 5

$$\bar{x} = \left(1/4\right) \times \sum_{q=1}^{4} \bar{x}_q$$

where:

$\bar{x}$=the annual mean; and

$\bar{x}_q$=the mean for calendar quarter q.

(d) The average of quarterly means must be rounded to the nearest tenth (fractional values of 0.05 should be rounded up).

(e) The use of quarterly averages to compute the annual average will not be necessary for monitoring or modeling data which results in a complete record, i.e., 365 days per year.

(f) The expected annual mean is estimated as the average of three or more annual means. This multi-year estimate, expressed in μg/m³, shall be rounded to the nearest integer for comparison with the annual standard (fractional values of 0.5 should be rounded up).

Example 4

Using Equation 4, the quarterly means are calculated for each calendar quarter. If the quarterly means are 52.4, 75.3, 82.1, and 63.2 μg/m³, then the annual mean is:

$\bar{x}$ = (1/4)×(52.4+75.3+82.1+63.2)= 68.25 or 68.3.

4.2 *Adjustments for Non-scheduled Sampling Days.* (a) An adjustment in the calculation of the annual mean is needed if sampling is performed on days in addition to the days specified by the systematic sampling schedule. For the same reasons given in the discussion of estimated exceedances, under section 3.2 of this appendix, the quarterly averages would be calculated by using the following equation:

Equation 6

$$\bar{x}_q = \left(1/m_q\right) \times \sum_{j=1}^{m_q} \sum_{i=1}^{k_j} \left(x_{ij}/k_j\right)$$

where:

$\bar{x}_q$=the quarterly mean concentration for quarter q, q=1, 2, 3, or 4;

x_{ij}=the ith concentration value recorded in stratum j;

k_j=the number of actual samples in stratum j; and

m_q=the number of strata with data in the quarter.

(b) If one sample value is recorded in each stratum, Equation 6 reduces to a simple arithmetic average of the observed values as described by Equation 4.

Example 5

a. During one calendar quarter, 9 observations were recorded. These samples were distributed among 7 sampling strata, with 3 observations in one stratum. The concentrations of the 3 observations in the single stratum were 202, 242, and 180 μg/m³. The remaining 6 observed concentrations were 55, 68, 73, 92, 120, and 155 μg/m³. Applying the weighting factors specified in Equation 6, the quarterly mean is:

$\bar{x}_q$ = (1/7) × [(1/3) × (202 + 242 + 180) + 155 + 68 + 73 + 92 + 120 + 155] = 110.1

b. Although 24–hour measurements are rounded to the nearest 10 μg/m³ for determinations of exceedances of the 24–hour standard, note that these values are rounded to the nearest 1 μg/m³ for the calculation of means.

6. Appendix L is added to read as follows:

Appendix L to Part 50—Reference Method For the Determination of Fine Particulate Matter as $PM_{2.5}$ in the Atmosphere

1.0 *Applicability.*

1.1 This method provides for the measurement of the mass concentration of fine particulate matter having an aerodynamic diameter less than or equal to a nominal 2.5 micrometers ($PM_{2.5}$) in ambient air over a 24-hour period for purposes of determining whether the primary and secondary national ambient air quality standards for fine particulate matter specified in § 50.6 of this part are met. The measurement process is considered to be nondestructive, and the $PM_{2.5}$ sample obtained can be subjected to subsequent physical or chemical analyses. Quality assessment procedures are provided in part 58, Appendix A of this chapter, and quality assurance guidance are provided in references 1, 2, and 3 in section 13.0 of this appendix.

1.2 This method will be considered a reference method for purposes of part 58 of this chapter only if:

(a) The associated sampler meets the requirements specified in this appendix and the applicable requirements in part 53 of this chapter, and

(b) The method and associated sampler have been designated as a reference method in accordance with part 53 of this chapter.

1.3 $PM_{2.5}$ samplers that meet nearly all specifications set forth in this method but have minor deviations and/or modifications of the reference method sampler will be designated as ''Class I'' equivalent methods for $PM_{2.5}$ in accordance with part 53 of this chapter.

2.0 *Principle.*

2.1 An electrically powered air sampler draws ambient air at a constant volumetric flow rate into a specially shaped inlet and through an inertial particle size separator (impactor) where the suspended particulate matter in the $PM_{2.5}$ size range is separated for collection on a polytetrafluoroethylene (PTFE) filter over the specified sampling period. The air sampler and other aspects of this reference method are specified either explicitly in this appendix or generally with reference to other applicable regulations or quality assurance guidance.

2.2 Each filter is weighed (after moisture and temperature conditioning) before and after sample collection to determine the net gain due to collected $PM_{2.5}$. The total volume of air sampled is determined by the sampler from the measured flow rate at actual ambient temperature and pressure and the sampling time. The mass concentration of $PM_{2.5}$ in the ambient air is computed as the total mass of collected particles in the $PM_{2.5}$ size range divided by the actual volume of air sampled, and is expressed in micrograms per cubic meter of air (μg/m³).

3.0 *$PM_{2.5}$ Measurement Range.*

3.1 *Lower concentration limit.* The lower detection limit of the mass concentration measurement range is estimated to be approximately 2 μg/am³, based on noted mass changes in field blanks in conjunction with the 24 m³ nominal total air sample volume specified for the 24-hour sample.

3.2 *Upper concentration limit.* The upper limit of the mass concentration range is determined by the filter mass loading beyond which the sampler can no longer maintain the operating flow rate within specified limits due to increased pressure drop across the loaded filter. This upper limit cannot be specified precisely because it is a complex function of the ambient particle size distribution and type, humidity, the individual filter used, the capacity of the sampler flow rate control system, and perhaps other factors. Nevertheless, all samplers are estimated to be capable of measuring 24-hour $PM_{2.5}$ mass concentrations of at least 200 μg/m³ while maintaining the operating flow rate within the specified limits.

3.3 *Sample period.* The required sample period for $PM_{2.5}$ concentration measurements by this method shall be 1,380 to 1500 minutes (23 to 25 hours). However, when a sample period is less than 1,380 minutes, the measured concentration (as determined by the collected $PM_{2.5}$ mass divided by the actual sampled air volume), multiplied by the actual number of minutes in the sample period and divided by 1,440, may be used as if it were a valid concentration measurement for the specific purpose of determining a violation of the NAAQS. This value assumes

that the $PM_{2.5}$ concentration is zero for the remaining portion of the sample period and therefore represents the minimum concentration that could have been measured for the full 24-hour sample period. Accordingly, if the value thus calculated is high enough to be an exceedance, such an exceedance would be a valid exceedance for the sample period. When reported to AIRS, this data value should receive a special code to identify it as not to be commingled with normal concentration measurements or used for other purposes.

4.0 *Accuracy.*

4.1 Because the size and volatility of the particles making up ambient particulate matter vary over a wide range and the mass concentration of particles varies with particle size, it is difficult to define the accuracy of $PM_{2.5}$ measurements in an absolute sense. The accuracy of $PM_{2.5}$ measurements is therefore defined in a relative sense, referenced to measurements provided by this reference method. Accordingly, accuracy shall be defined as the degree of agreement between a subject field $PM_{2.5}$ sampler and a collocated $PM_{2.5}$ reference method audit sampler operating simultaneously at the monitoring site location of the subject sampler and includes both random (precision) and systematic (bias) errors. The requirements for this field sampler audit procedure are set forth in part 58, Appendix A of this chapter.

4.2 Measurement system bias. Results of collocated measurements where the duplicate sampler is a reference method sampler are used to assess a portion of the measurement system bias according to the schedule and procedure specified in part 58, Appendix A of this chapter.

4.3 Audits with reference method samplers to determine system accuracy and bias. According to the schedule and procedure specified in part 58, Appendix A of this chapter, a reference method sampler is required to be located at each of selected $PM_{2.5}$ SLAMS sites as a duplicate sampler. The results from the primary sampler and the duplicate reference method sampler are used to calculate accuracy of the primary sampler on a quarterly basis, bias of the primary sampler on an annual basis, and bias of a single reporting organization on an annual basis. Reference 2 in section 13.0 of this appendix provides additional information and guidance on these reference method audits.

4.4 Flow rate accuracy and bias. Part 58, Appendix A of this chapter requires that the flow rate accuracy and bias of individual $PM_{2.5}$ samplers used in SLAMS monitoring networks be assessed periodically via audits of each sampler's operational flow rate. In addition, part 58, Appendix A of this chapter requires that flow rate bias for each reference and equivalent method operated by each reporting organization be assessed quarterly and annually. Reference 2 in section 13.0 of this appendix provides additional information and guidance on flow rate accuracy audits and calculations for accuracy and bias.

5.0 *Precision.* A data quality objective of 10 percent coefficient of variation or better has been established for the operational precision of $PM_{2.5}$ monitoring data.

5.1 Tests to establish initial operational precision for each reference method sampler are specified as a part of the requirements for designation as a reference method under § 53.58 of this chapter.

5.2 Measurement System Precision. Collocated sampler results, where the duplicate sampler is not a reference method sampler but is a sampler of the same designated method as the primary sampler, are used to assess measurement system precision according to the schedule and procedure specified in part 58, Appendix A of this chapter. Part 58, Appendix A of this chapter requires that these collocated sampler measurements be used to calculate quarterly and annual precision estimates for each primary sampler and for each designated method employed by each reporting organization. Reference 2 in section 13.0 of this appendix provides additional information and guidance on this requirement.

6.0 *Filter for $PM_{2.5}$ Sample Collection.* Any filter manufacturer or vendor who sells or offers to sell filters specifically identified for use with this $PM_{2.5}$ reference method shall certify that the required number of filters from each lot of filters offered for sale as such have been tested as specified in this section 6.0 and meet all of the following design and performance specifications.

6.1 *Size.* Circular, 46.2 mm diameter ±0.25 mm.

6.2 *Medium.* Polytetrafluoroethylene (PTFE Teflon), with integral support ring.

6.3 *Support ring.* Polymethylpentene (PMP) or equivalent inert material, 0.38 ±0.04 mm thick, outer diameter 46.2 mm ±0.25 mm, and width of 3.68 mm (±0.00, -0.51 mm).

6.4 *Pore size.* 2 µm as measured by ASTM F 316–94.

6.5 *Filter thickness.* 30 to 50 µm.

6.6 *Maximum pressure drop (clean filter).* 30 cm H_2O column @ 16.67 L/min clean air flow.

6.7 *Maximum moisture pickup.* Not more than 10 µg weight increase after 24-hour exposure to air of 40 percent relative humidity, relative to weight after 24-hour exposure to air of 35 percent relative humidity.

6.8 *Collection efficiency.* Greater than 99.7 percent, as measured by the DOP test (ASTM D 2986–91) with 0.3 µm particles at the sampler's operating face velocity.

6.9 *Filter weight stability.* Filter weight loss shall be less than 20 µg, as measured in each of the following two tests specified in sections 6.9.1 and 6.9.2 of this appendix. The following conditions apply to both of these tests: Filter weight loss shall be the average difference between the initial and the final filter weights of a random sample of test filters selected from each lot prior to sale. The number of filters tested shall be not less than 0.1 percent of the filters of each manufacturing lot, or 10 filters, whichever is greater. The filters shall be weighed under laboratory conditions and shall have had no air sample passed through them, i.e., filter blanks. Each test procedure must include initial conditioning and weighing, the test, and final conditioning and weighing. Conditioning and weighing shall be in accordance with sections 8.0 through 8.2 of this appendix and general guidance provided in reference 2 of section 13.0 of this appendix.

6.9.1 *Test for loose, surface particle contamination.* After the initial weighing, install each test filter, in turn, in a filter cassette (Figures L–27, L–28, and L–29 of this appendix) and drop the cassette from a height of 25 cm to a flat hard surface, such as a particle-free wood bench. Repeat two times, for a total of three drop tests for each test filter. Remove the test filter from the cassette and weigh the filter. The average change in weight must be less than 20 µg.

6.9.2 *Test for temperature stability.* After weighing each filter, place the test filters in a drying oven set at 40 °C ±2 °C for not less than 48 hours. Remove, condition, and reweigh each test filter. The average change in weight must be less than 20 µg.

6.10 *Alkalinity.* Less than 25 microequivalents/gram of filter, as measured by the guidance given in reference 2 in section 13.0 of this appendix.

6.11 *Supplemental requirements.* Although not required for determination of $PM_{2.5}$ mass concentration under this reference method, additional specifications for the filter must be developed by users who intend to subject $PM_{2.5}$ filter samples to subsequent chemical analysis. These supplemental specifications include background chemical contamination of the filter and any other filter parameters that may be required by the method of chemical analysis. All such supplemental filter specifications must be compatible with and secondary to the primary filter specifications given in this section 6.0 of this appendix.

7.0 *$PM_{2.5}$ Sampler.*

7.1 *Configuration.* The sampler shall consist of a sample air inlet, downtube, particle size separator (impactor), filter holder assembly, air pump and flow rate control system, flow rate measurement device, ambient and filter temperature monitoring system, barometric pressure measurement system, timer, outdoor environmental enclosure, and suitable mechanical, electrical, or electronic control capability to meet or exceed the design and functional performance as specified in this section 7.0 of this appendix. The performance specifications require that the sampler:

(a) Provide automatic control of sample volumetric flow rate and other operational parameters.

(b) Monitor these operational parameters as well as ambient temperature and pressure.

(c) Provide this information to the sampler operator at the end of each sample period in digital form, as specified in Table L–1 of section 7.4.19 of this appendix.

7.2 *Nature of specifications.* The $PM_{2.5}$ sampler is specified by a combination of design and performance requirements. The sample inlet, downtube, particle size discriminator, filter cassette, and the internal configuration of the filter holder assembly are specified explicitly by design figures and associated mechanical dimensions, tolerances, materials, surface finishes, assembly instructions, and other necessary specifications. All other aspects of the

sampler are specified by required operational function and performance, and the design of these other aspects (including the design of the lower portion of the filter holder assembly) is optional, subject to acceptable operational performance. Test procedures to demonstrate compliance with both the design and performance requirements are set forth in subpart E of part 53 of this chapter.

7.3 *Design specifications.* Except as indicated in this section 7.3 of this appendix, these components must be manufactured or reproduced exactly as specified, in an ISO 9001-registered facility, with registration initially approved and subsequently maintained during the period of manufacture. See § 53.1(t) of this chapter for the definition of an ISO-registered facility. Minor modifications or variances to one or more components that clearly would not affect the aerodynamic performance of the inlet, downtube, impactor, or filter cassette will be considered for specific approval. Any such proposed modifications shall be described and submitted to the EPA for specific individual acceptability either as part of a reference or equivalent method application under part 53 of this chapter or in writing in advance of such an intended application under part 53 of this chapter.

7.3.1 *Sample inlet assembly.* The sample inlet assembly, consisting of the inlet, downtube, and impactor shall be configured and assembled as indicated in Figure L–1 of this appendix and shall meet all associated requirements. A portion of this assembly shall also be subject to the maximum overall sampler leak rate specification under section 7.4.6 of this appendix.

7.3.2 *Inlet.* The sample inlet shall be fabricated as indicated in Figures L–2 through L–18 of this appendix and shall meet all associated requirements.

7.3.3 *Downtube.* The downtube shall be fabricated as indicated in Figure L–19 of this appendix and shall meet all associated requirements.

7.3.4 *Impactor.*

7.3.4.1 The impactor (particle size separator) shall be fabricated as indicated in Figures L–20 through L–24 of this appendix and shall meet all associated requirements. Following the manufacture and finishing of each upper impactor housing (Figure L–21 of this appendix), the dimension of the impaction jet must be verified by the manufacturer using Class ZZ go/no-go plug gauges that are traceable to NIST.

7.3.4.2 Impactor filter specifications:

(a) Size. Circular, 35 to 37 mm diameter.

(b) Medium. Borosilicate glass fiber, without binder.

(c) Pore size. 1 to 1.5 micrometer, as measured by ASTM F 316–80.

(d) Thickness. 300 to 500 micrometers.

7.3.4.3 Impactor oil specifications:

(a) Composition. Tetramethyltetraphenyltrisiloxane, single-compound diffusion oil.

(b) Vapor pressure. Maximum 2 x 10^{-8} mm Hg at 25 °C.

(c) Viscosity. 36 to 40 centistokes at 25 °C.

(d) Density. 1.06 to 1.07 g/cm^3 at 25 °C.

(e) Quantity. 1 mL ±0.1 mL.

7.3.5 *Filter holder assembly.* The sampler shall have a sample filter holder assembly to adapt and seal to the down tube and to hold and seal the specified filter, under section 6.0 of this appendix, in the sample air stream in a horizontal position below the downtube such that the sample air passes downward through the filter at a uniform face velocity. The upper portion of this assembly shall be fabricated as indicated in Figures L–25 and L–26 of this appendix and shall accept and seal with the filter cassette, which shall be fabricated as indicated in Figures L–27 through L–29 of this appendix.

(a) The lower portion of the filter holder assembly shall be of a design and construction that:

(1) Mates with the upper portion of the assembly to complete the filter holder assembly,

(2) Completes both the external air seal and the internal filter cassette seal such that all seals are reliable over repeated filter changings, and

(3) Facilitates repeated changing of the filter cassette by the sampler operator.

(b) Leak–test performance requirements for the filter holder assembly are included in section 7.4.6 of this appendix.

(c) If additional or multiple filters are stored in the sampler as part of an automatic sequential sample capability, all such filters, unless they are currently and directly installed in a sampling channel or sampling configuration (either active or inactive), shall be covered or (preferably) sealed in such a way as to:

(1) Preclude significant exposure of the filter to possible contamination or accumulation of dust, insects, or other material that may be present in the ambient air, sampler, or sampler ventilation air during storage periods either before or after sampling; and

(2) To minimize loss of volatile or semi-volatile PM sample components during storage of the filter following the sample period.

7.3.6 *Flow rate measurement adapter.* A flow rate measurement adapter as specified in Figure L–30 of this appendix shall be furnished with each sampler.

7.3.7 *Surface finish.* All internal surfaces exposed to sample air prior to the filter shall be treated electrolytically in a sulfuric acid bath to produce a clear, uniform anodized surface finish of not less than 1000 mg/ft^2 (1.08 mg/cm^2) in accordance with military standard specification (mil. spec.) 8625F, Type II, Class 1 in reference 4 of section 13.0 of this appendix. This anodic surface coating shall not be dyed or pigmented. Following anodization, the surfaces shall be sealed by immersion in boiling deionized water for not less than 15 minutes. Section 53.51(d)(2) of this chapter should also be consulted.

7.3.8 *Sampling height.* The sampler shall be equipped with legs, a stand, or other means to maintain the sampler in a stable, upright position and such that the center of the sample air entrance to the inlet, during sample collection, is maintained in a horizontal plane and is 2.0 ±0.2 meters above the floor or other horizontal supporting surface. Suitable bolt holes, brackets, tie-downs, or other means should be provided to facilitate mechanically securing the sample to the supporting surface to prevent toppling of the sampler due to wind.

7.4 *Performance specifications.*

7.4.1 *Sample flow rate.* Proper operation of the impactor requires that specific air velocities be maintained through the device. Therefore, the design sample air flow rate through the inlet shall be 16.67 L/min (1.000 m^3/hour) measured as actual volumetric flow rate at the temperature and pressure of the sample air entering the inlet.

7.4.2 *Sample air flow rate control system.* The sampler shall have a sample air flow rate control system which shall be capable of providing a sample air volumetric flow rate within the specified range, under section 7.4.1 of this appendix, for the specified filter, under section 6.0 of this appendix, at any atmospheric conditions specified, under section 7.4.7 of this appendix, at a filter pressure drop equal to that of a clean filter plus up to 75 cm water column (55 mm Hg), and over the specified range of supply line voltage, under section 7.4.15.1 of this appendix. This flow control system shall allow for operator adjustment of the operational flow rate of the sampler over a range of at least ±15 percent of the flow rate specified in section 7.4.1 of this appendix.

7.4.3 *Sample flow rate regulation.* The sample flow rate shall be regulated such that for the specified filter, under section 6.0 of this appendix, at any atmospheric conditions specified, under section 7.4.7 of this appendix, at a filter pressure drop equal to that of a clean filter plus up to 75 cm water column (55 mm Hg), and over the specified range of supply line voltage, under section 7.4.15.1 of this appendix, the flow rate is regulated as follows:

7.4.3.1 The volumetric flow rate, measured or averaged over intervals of not more than 5 minutes over a 24-hour period, shall not vary more than ±5 percent from the specified 16.67 L/min flow rate over the entire sample period.

7.4.3.2 The coefficient of variation (sample standard deviation divided by the mean) of the flow rate, measured over a 24-hour period, shall not be greater than 2 percent.

7.4.3.3 The amplitude of short-term flow rate pulsations, such as may originate from some types of vacuum pumps, shall be attenuated such that they do not cause significant flow measurement error or affect the collection of particles on the particle collection filter.

7.4.4 *Flow rate cut off.* The sampler's sample air flow rate control system shall terminate sample collection and stop all sample flow for the remainder of the sample period in the event that the sample flow rate deviates by more than 10 percent from the sampler design flow rate specified in section 7.4.1 of this appendix for more than 60 seconds. However, this sampler cut-off provision shall not apply during periods when the sampler is inoperative due to a temporary power interruption, and the elapsed time of the inoperative period shall not be included in the total sample time measured and reported by the sampler, under section 7.4.13 of this appendix.

7.4.5 *Flow rate measurement.*

7.4.5.1 The sampler shall provide a means to measure and indicate the instantaneous sample air flow rate, which shall be measured as volumetric flow rate at the

temperature and pressure of the sample air entering the inlet, with an accuracy of ±2 percent. The measured flow rate shall be available for display to the sampler operator at any time in either sampling or standby modes, and the measurement shall be updated at least every 30 seconds. The sampler shall also provide a simple means by which the sampler operator can manually start the sample flow temporarily during non-sampling modes of operation, for the purpose of checking the sample flow rate or the flow rate measurement system.

7.4.5.2 During each sample period, the sampler's flow rate measurement system shall automatically monitor the sample volumetric flow rate, obtaining flow rate measurements at intervals of not greater than 30 seconds.

(a) Using these interval flow rate measurements, the sampler shall determine or calculate the following flow-related parameters, scaled in the specified engineering units:

(1) The instantaneous or interval-average flow rate, in L/min.

(2) The value of the average sample flow rate for the sample period, in L/min.

(3) The value of the coefficient of variation (sample standard deviation divided by the average) of the sample flow rate for the sample period, in percent.

(4) The occurrence of any time interval during the sample period in which the measured sample flow rate exceeds a range of ±5 percent of the average flow rate for the sample period for more than 5 minutes, in which case a warning flag indicator shall be set.

(5) The value of the integrated total sample volume for the sample period, in m^3.

(b) Determination or calculation of these values shall properly exclude periods when the sampler is inoperative due to temporary interruption of electrical power, under section 7.4.13 of this appendix, or flow rate cut off, under section 7.4.4 of this appendix.

(c) These parameters shall be accessible to the sampler operator as specified in Table L–1 of section 7.4.19 of this appendix. In addition, it is strongly encouraged that the flow rate for each 5-minute interval during the sample period be available to the operator following the end of the sample period.

7.4.6 *Leak test capability.*

7.4.6.1 *External leakage.* The sampler shall include an external air leak-test capability consisting of components, accessory hardware, operator interface controls, a written procedure in the associated Operation/Instruction Manual, under section 7.4.18 of this appendix, and all other necessary functional capability to permit and facilitate the sampler operator to conveniently carry out a leak test of the sampler at a field monitoring site without additional equipment. The sampler components to be subjected to this leak test include all components and their interconnections in which external air leakage would or could cause an error in the sampler's measurement of the total volume of sample air that passes through the sample filter.

(a) The suggested technique for the operator to use for this leak test is as follows:

(1) Remove the sampler inlet and installs the flow rate measurement adapter supplied with the sampler, under section 7.3.6 of this appendix.

(2) Close the valve on the flow rate measurement adapter and use the sampler air pump to draw a partial vacuum in the sampler, including (at least) the impactor, filter holder assembly (filter in place), flow measurement device, and interconnections between these devices, of at least 55 mm Hg (75 cm water column), measured at a location downstream of the filter holder assembly.

(3) Plug the flow system downstream of these components to isolate the components under vacuum from the pump, such as with a built-in valve.

(4) Stop the pump.

(5) Measure the trapped vacuum in the sampler with a built-in pressure measuring device.

(6) (i) Measure the vacuum in the sampler with the built-in pressure measuring device again at a later time at least 10 minutes after the first pressure measurement.

(ii) **Caution:** Following completion of the test, the adaptor valve should be opened slowly to limit the flow rate of air into the sampler. Excessive air flow rate may blow oil out of the impactor.

(7) Upon completion of the test, open the adaptor valve, remove the adaptor and plugs, and restore the sampler to the normal operating configuration.

(b) The associated leak test procedure shall require that for successful passage of this test, the difference between the two pressure measurements shall not be greater than the number of mm of Hg specified for the sampler by the manufacturer, based on the actual internal volume of the sampler, that indicates a leak of less than 80 mL/min.

(c) Variations of the suggested technique or an alternative external leak test technique may be required for samplers whose design or configuration would make the suggested technique impossible or impractical. The specific proposed external leak test procedure, or particularly an alternative leak test technique, proposed for a particular candidate sampler may be described and submitted to the EPA for specific individual acceptability either as part of a reference or equivalent method application under part 53 of this chapter or in writing in advance of such an intended application under part 53 of this chapter.

7.4.6.2 *Internal, filter bypass leakage.* The sampler shall include an internal, filter bypass leak-check capability consisting of components, accessory hardware, operator interface controls, a written procedure in the Operation/Instruction Manual, and all other necessary functional capability to permit and facilitate the sampler operator to conveniently carry out a test for internal filter bypass leakage in the sampler at a field monitoring site without additional equipment. The purpose of the test is to determine that any portion of the sample flow rate that leaks past the sample filter without passing through the filter is insignificant relative to the design flow rate for the sampler.

(a) The suggested technique for the operator to use for this leak test is as follows:

(1) Carry out an external leak test as provided under section 7.4.6.1 of this appendix which indicates successful passage of the prescribed external leak test.

(2) Install a flow-impervious membrane material in the filter cassette, either with or without a filter, as appropriate, which effectively prevents air flow through the filter.

(3) Use the sampler air pump to draw a partial vacuum in the sampler, downstream of the filter holder assembly, of at least 55 mm Hg (75 cm water column).

(4) Plug the flow system downstream of the filter holder to isolate the components under vacuum from the pump, such as with a built-in valve.

(5) Stop the pump.

(6) Measure the trapped vacuum in the sampler with a built-in pressure measuring device.

(7) Measure the vacuum in the sampler with the built-in pressure measuring device again at a later time at least 10 minutes after the first pressure measurement.

(8) Remove the flow plug and membrane and restore the sampler to the normal operating configuration.

(b) The associated leak test procedure shall require that for successful passage of this test, the difference between the two pressure measurements shall not be greater than the number of mm of Hg specified for the sampler by the manufacturer, based on the actual internal volume of the portion of the sampler under vacuum, that indicates a leak of less than 80 mL/min.

(c) Variations of the suggested technique or an alternative internal, filter bypass leak test technique may be required for samplers whose design or configuration would make the suggested technique impossible or impractical. The specific proposed internal leak test procedure, or particularly an alternative internal leak test technique proposed for a particular candidate sampler may be described and submitted to the EPA for specific individual acceptability either as part of a reference or equivalent method application under part 53 of this chapter or in writing in advance of such intended application under part 53 of this chapter.

7.4.7 *Range of operational conditions.* The sampler is required to operate properly and meet all requirements specified in this appendix over the following operational ranges.

7.4.7.1 *Ambient temperature.* -30 to +45 °C (Note: Although for practical reasons, the temperature range over which samplers are required to be tested under part 53 of this chapter is -20 to +40 °C, the sampler shall be designed to operate properly over this wider temperature range.).

7.4.7.2 *Ambient relative humidity.* 0 to 100 percent.

7.4.7.3 *Barometric pressure range.* 600 to 800 mm Hg.

7.4.8 *Ambient temperature sensor.* The sampler shall have capability to measure the temperature of the ambient air surrounding the sampler over the range of -30 to +45 °C, with a resolution of 0.1 °C and accuracy of ±2.0 °C, referenced as described in reference 3 in section 13.0 of this appendix, with and without maximum solar insolation.

7.4.8.1 The ambient temperature sensor shall be mounted external to the sampler enclosure and shall have a passive, naturally ventilated sun shield. The sensor shall be located such that the entire sun shield is at least 5 cm above the horizontal plane of the sampler case or enclosure (disregarding the inlet and downtube) and external to the vertical plane of the nearest side or protuberance of the sampler case or enclosure. The maximum temperature measurement error of the ambient temperature measurement system shall be less than 1.6 °C at 1 m/s wind speed and 1000 W/m2 solar radiation intensity.

7.4.8.2 The ambient temperature sensor shall be of such a design and mounted in such a way as to facilitate its convenient dismounting and immersion in a liquid for calibration and comparison to the filter temperature sensor, under section 7.4.11 of this appendix.

7.4.8.3 This ambient temperature measurement shall be updated at least every 30 seconds during both sampling and standby (non-sampling) modes of operation. A visual indication of the current (most recent) value of the ambient temperature measurement, updated at least every 30 seconds, shall be available to the sampler operator during both sampling and standby (non-sampling) modes of operation, as specified in Table L–1 of section 7.4.19 of this appendix.

7.4.8.4 This ambient temperature measurement shall be used for the purpose of monitoring filter temperature deviation from ambient temperature, as required by section 7.4.11 of this appendix, and may be used for purposes of effecting filter temperature control, under section 7.4.10 of this appendix, or computation of volumetric flow rate, under sections 7.4.1 to 7.4.5 of this appendix, if appropriate.

7.4.8.5 Following the end of each sample period, the sampler shall report the maximum, minimum, and average temperature for the sample period, as specified in Table L–1 of section 7.4.19 of this appendix.

7.4.9 *Ambient barometric sensor.* The sampler shall have capability to measure the barometric pressure of the air surrounding the sampler over a range of 600 to 800 mm Hg referenced as described in reference 3 in section 13.0 of this appendix; also see part 53, subpart E of this chapter. This barometric pressure measurement shall have a resolution of 5 mm Hg and an accuracy of ±10 mm Hg and shall be updated at least every 30 seconds. A visual indication of the value of the current (most recent) barometric pressure measurement, updated at least every 30 seconds, shall be available to the sampler operator during both sampling and standby (non-sampling) modes of operation, as specified in Table L–1 of section 7.4.19 of this appendix. This barometric pressure measurement may be used for purposes of computation of volumetric flow rate, under sections 7.4.1 to 7.4.5 of this appendix, if appropriate. Following the end of a sample period, the sampler shall report the maximum, minimum, and mean barometric pressures for the sample period, as specified in Table L–1 of section 7.4.19 of this appendix.

7.4.10 *Filter temperature control (sampling and post-sampling).* The sampler shall provide a means to limit the temperature rise of the sample filter (all sample filters for sequential samplers), from insolation and other sources, to no more 5 °C above the temperature of the ambient air surrounding the sampler, during both sampling and post-sampling periods of operation. The post-sampling period is the non-sampling period between the end of the active sampling period and the time of retrieval of the sample filter by the sampler operator.

7.4.11 *Filter temperature sensor(s).*

7.4.11.1 The sampler shall have the capability to monitor the temperature of the sample filter (all sample filters for sequential samplers) over the range of -30 to +45 °C during both sampling and non-sampling periods. While the exact location of this temperature sensor is not explicitly specified, the filter temperature measurement system must demonstrate agreement, within 1 °C, with a test temperature sensor located within 1 cm of the center of the filter downstream of the filter during both sampling and non-sampling modes, as specified in the filter temperature measurement test described in part 53, subpart E of this chapter. This filter temperature measurement shall have a resolution of 0.1 °C and accuracy of ±1.0 °C, referenced as described in reference 3 in section 13.0 of this appendix. This temperature sensor shall be of such a design and mounted in such a way as to facilitate its reasonably convenient dismounting and immersion in a liquid for calibration and comparison to the ambient temperature sensor under section 7.4.8 of this appendix.

7.4.11.2 The filter temperature measurement shall be updated at least every 30 seconds during both sampling and standby (non-sampling) modes of operation. A visual indication of the current (most recent) value of the filter temperature measurement, updated at least every 30 seconds, shall be available to the sampler operator during both sampling and standby (non-sampling) modes of operation, as specified in Table L–1 of section 7.4.19 of this appendix.

7.4.11.3 For sequential samplers, the temperature of each filter shall be measured individually unless it can be shown, as specified in the filter temperature measurement test described in § 53.57 of this chapter, that the temperature of each filter can be represented by fewer temperature sensors.

7.4.11.4 The sampler shall also provide a warning flag indicator following any occurrence in which the filter temperature (any filter temperature for sequential samplers) exceeds the ambient temperature by more than 5 °C for more than 30 consecutive minutes during either the sampling or post-sampling periods of operation, as specified in Table L–1 of section 7.4.19 of this appendix, under section 10.12 of this appendix, regarding sample validity when a warning flag occurs. It is further recommended (not required) that the sampler be capable of recording the maximum differential between the measured filter temperature and the ambient temperature and its time and date of occurrence during both sampling and post-sampling (non-sampling) modes of operation and providing for those data to be accessible to the sampler operator following the end of the sample period, as suggested in Table L–1 of section 7.4.19 of this appendix.

7.4.12 *Clock/timer system.*

(a) The sampler shall have a programmable real-time clock timing/control system that:

(1) Is capable of maintaining local time and date, including year, month, day-of-month, hour, minute, and second to an accuracy of ±1.0 minute per month.

(2) Provides a visual indication of the current system time, including year, month, day-of-month, hour, and minute, updated at least each minute, for operator verification.

(3) Provides appropriate operator controls for setting the correct local time and date.

(4) Is capable of starting the sample collection period and sample air flow at a specific, operator-settable time and date, and stopping the sample air flow and terminating the sampler collection period 24 hours (1440 minutes) later, or at a specific, operator-settable time and date.

(b) These start and stop times shall be readily settable by the sampler operator to within ±1.0 minute. The system shall provide a visual indication of the current start and stop time settings, readable to ±1.0 minute, for verification by the operator, and the start and stop times shall also be available via the data output port, as specified in Table L–1 of section 7.4.19 of this appendix. Upon execution of a programmed sample period start, the sampler shall automatically reset all sample period information and warning flag indications pertaining to a previous sample period. Refer also to section 7.4.15.4 of this appendix regarding retention of current date and time and programmed start and stop times during a temporary electrical power interruption.

7.4.13 *Sample time determination.* The sampler shall be capable of determining the elapsed sample collection time for each $PM_{2.5}$ sample, accurate to within ±1.0 minute, measured as the time between the start of the sampling period, under section 7.4.12 of this appendix and the termination of the sample period, under section 7.4.12 of this appendix or section 7.4.4 of this appendix. This elapsed sample time shall not include periods when the sampler is inoperative due to a temporary interruption of electrical power, under section 7.4.15.4 of this appendix. In the event that the elapsed sample time determined for the sample period is not within the range specified for the required sample period in section 3.3 of this appendix, the sampler shall set a warning flag indicator. The date and time of the start of the sample period, the value of the elapsed sample time for the sample period, and the flag indicator status shall be available to the sampler operator following the end of the sample period, as specified in Table L–1 of section 7.4.19 of this appendix.

7.4.14 *Outdoor environmental enclosure.* The sampler shall have an outdoor enclosure (or enclosures) suitable to protect the filter and other non-weatherproof components of the sampler from precipitation, wind, dust, extremes of temperature and humidity; to help maintain temperature control of the

filter (or filters, for sequential samplers); and to provide reasonable security for sampler components and settings.

7.4.15 *Electrical power supply.*

7.4.15.1 The sampler shall be operable and function as specified herein when operated on an electrical power supply voltage of 105 to 125 volts AC (RMS) at a frequency of 59 to 61 Hz. Optional operation as specified at additional power supply voltages and/or frequencies shall not be precluded by this requirement.

7.4.15.2 The design and construction of the sampler shall comply with all applicable National Electrical Code and Underwriters Laboratories electrical safety requirements.

7.4.15.3 The design of all electrical and electronic controls shall be such as to provide reasonable resistance to interference or malfunction from ordinary or typical levels of stray electromagnetic fields (EMF) as may be found at various monitoring sites and from typical levels of electrical transients or electronic noise as may often or occasionally be present on various electrical power lines.

7.4.15.4 In the event of temporary loss of electrical supply power to the sampler, the sampler shall not be required to sample or provide other specified functions during such loss of power, except that the internal clock/timer system shall maintain its local time and date setting within ±1 minute per week, and the sampler shall retain all other time and programmable settings and all data required to be available to the sampler operator following each sample period for at least 7 days without electrical supply power. When electrical power is absent at the operator-set time for starting a sample period or is interrupted during a sample period, the sampler shall automatically start or resume sampling when electrical power is restored, if such restoration of power occurs before the operator-set stop time for the sample period.

7.4.15.5 The sampler shall have the capability to record and retain a record of the year, month, day-of-month, hour, and minute of the start of each power interruption of more than 1 minute duration, up to 10 such power interruptions per sample period. (More than 10 such power interruptions shall invalidate the sample, except where an exceedance is measured, under section 3.3 of this appendix.) The sampler shall provide for these power interruption data to be available to the sampler operator following the end of the sample period, as specified in Table L–1 of section 7.4.19 of this appendix.

7.4.16 *Control devices and operator interface.* The sampler shall have mechanical, electrical, or electronic controls, control devices, electrical or electronic circuits as necessary to provide the timing, flow rate measurement and control, temperature control, data storage and computation, operator interface, and other functions specified. Operator-accessible controls, data displays, and interface devices shall be designed to be simple, straightforward, reliable, and easy to learn, read, and operate under field conditions. The sampler shall have provision for operator input and storage of up to 64 characters of numeric (or alphanumeric) data for purposes of site, sampler, and sample identification. This information shall be available to the sampler operator for verification and change and for output via the data output port along with other data following the end of a sample period, as specified in Table L–1 of section 7.4.19 of this appendix. All data required to be available to the operator following a sample collection period or obtained during standby mode in a post-sampling period shall be retained by the sampler until reset, either manually by the operator or automatically by the sampler upon initiation of a new sample collection period.

7.4.17 *Data output port requirement.* The sampler shall have a standard RS–232C data output connection through which digital data may be exported to an external data storage or transmission device. All information which is required to be available at the end of each sample period shall be accessible through this data output connection. The information that shall be accessible though this output port is summarized in Table L–1 of section 7.4.19 of this appendix. Since no specific format for the output data is provided, the sampler manufacturer or vendor shall make available to sampler purchasers appropriate computer software capable of receiving exported sampler data and correctly translating the data into a standard spreadsheet format and optionally any other formats as may be useful to sampler users. This requirement shall not preclude the sampler from offering other types of output connections in addition to the required RS–232C port.

7.4.18 *Operation/instruction manual.* The sampler shall include an associated comprehensive operation or instruction manual, as required by part 53 of this chapter, which includes detailed operating instructions on the setup, operation, calibration, and maintenance of the sampler. This manual shall provide complete and detailed descriptions of the operational and calibration procedures prescribed for field use of the sampler and all instruments utilized as part of this reference method. The manual shall include adequate warning of potential safety hazards that may result from normal use or malfunction of the method and a description of necessary safety precautions. The manual shall also include a clear description of all procedures pertaining to installation, operation, periodic and corrective maintenance, and troubleshooting, and shall include parts identification diagrams.

7.4.19 *Data reporting requirements.* The various information that the sampler is required to provide and how it is to be provided is summarized in the following Table L–1.

TABLE L–1.—SUMMARY OF INFORMATION TO BE PROVIDED BY THE SAMPLER

Information to be provided	Appendix L section reference	Availability				Format	
		Anytime[1]	End of period[2]	Visual display[3]	Data output[4]	Digital reading[5]	Units
Flow rate, 30-second maximum interval.	7.4.5.1	✔		✔	*	XX.X	L/min
Flow rate, average for the sample period.	7.4.5.2	*	✔	*	✔	XX.X	L/min
Flow rate, CV, for sample period.	7.4.5.2	*	✔	*	✔■	XX.X	%
Flow rate, 5-min. average out of spec. (FLAG[6]).	7.4.5.2	✔	✔	✔	✔■	On/Off	
Sample volume, total	7.4.5.2	*	✔	✔	✔■	XX.X	m^3
Temperature, ambient, 30-second interval.	7.4.8	✔		✔		XX.X	°C
Temperature, ambient, min., max., average for the sample period.	7.4.8	*	✔	✔	✔■	XX.X	°C
Baro pressure, ambient, 30-second interval.	7.4.9	✔		✔		XXX	mm Hg

TABLE L–1.—SUMMARY OF INFORMATION TO BE PROVIDED BY THE SAMPLER—Continued

Information to be provided	Appendix L section reference	Availability				Format	
		Anytime[1]	End of period[2]	Visual display[3]	Data output[4]	Digital reading[5]	Units
Baro pressure, ambient, min., max., average for the sample period.	7.4.9	*	✔	✔	✔■	XXX	mm Hg
Filter temperature, 30-second interval.	7.4.11	✔		✔		XX.X	°C
Filter temperature differential, 30-second interval, out of spec. (FLAG[6]).	7.4.11	*	✔	✔	✔■	On/Off	
Filter temperature, maximum differential from ambient, date, time of occurrence.	7.4.11	*	*	*	*	X.X, YY/MM/DD HH:mm.	°C, Yr./Mon./Day Hrs. min
Date and time	7.4.12	✔		✔		YY/MM/DD HH:mm	Yr./Mon./Day Hrs. min
Sample start and stop time settings.	7.4.12	✔	✔	✔	✔	YY/MM/DD HH:mm	Yr./Mon./Day Hrs. min
Sample period start time.	7.4.12		✔	✔	✔■	YYYY/MM/DD HH:mm	Yr./Mon./Day Hrs. min
Elapsed sample time	7.4.13	*	✔	✔	✔■	HH:mm	Hrs. min
Elapsed sample time, out of spec. (FLAG[6]).	7.4.13		✔	✔	✔■	On/Off	
Power interruptions >1 min., start time of first 10.	7.4.15.5	*	✔	*	✔	1HH:mm, 2HH:mm, etc	Hrs. min
User-entered information, such as sampler and site identification.	7.4.16	✔	✔	✔	✔■	As entered	

✔ Provision of this information is required.

Provision of this information is optional. If information related to the entire sample period is optionally provided prior to the end of the sample period, the value provided should be the value calculated for the portion of the sampler period completed up to the time the information is provided.

■ Indicates that this information is also required to be provided to the AIRS data bank; see §§58.26 and 58.35 of this chapter.

[1] Information is required to be available to the operator at any time the sampler is operating, whether sampling or not.

[2] Information relates to the entire sampler period and must be provided following the end of the sample period until reset manually by the operator or automatically by the sampler upon the start of a new sample period.

[3] Information shall be available to the operator visually.

[4] Information is to be available as digital data at the sampler's data output port specified in section 7.4.16 of this appendix following the end of the sample period until reset manually by the operator or automatically by the sampler upon the start of a new sample period.

[5] Digital readings, both visual and data output, shall have not less than the number of significant digits and resolution specified.

[6] Flag warnings may be displayed to the operator by a single-flag indicator or each flag may be displayed individually. Only a set (on) flag warning must be indicated; an off (unset) flag may be indicated by the absence of a flag warning. Sampler users should refer to section 10.12 of this appendix regarding the validity of samples for which the sampler provided an associated flag warning.

8.0 *Filter Weighing.* See reference 2 in section 13.0 of this appendix, for additional, more detailed guidance.

8.1 *Analytical balance.* The analytical balance used to weigh filters must be suitable for weighing the type and size of filters specified, under section 6.0 of this appendix, and have a readability of ±1 µg. The balance shall be calibrated as specified by the manufacturer at installation and recalibrated immediately prior to each weighing session. See reference 2 in section 13.0 of this appendix for additional guidance.

8.2 *Filter conditioning.* All sample filters used shall be conditioned immediately before both the pre- and post-sampling weighings as specified below. See reference 2 in section 13.0 of this appendix for additional guidance.

8.2.1 *Mean temperature.* 20 - 23 °C.

8.2.2 *Temperature control.* ±2 °C over 24 hours.

8.2.3 *Mean humidity.* Generally, 30–40 percent relative humidity; however, where it can be shown that the mean ambient relative humidity during sampling is less than 30 percent, conditioning is permissible at a mean relative humidity within ±5 relative humidity percent of the mean ambient relative humidity during sampling, but not less than 20 percent.

8.2.4 *Humidity control.* ±5 relative humidity percent over 24 hours.

8.2.5 *Conditioning time.* Not less than 24 hours.

8.3 *Weighing procedure.*

8.3.1 New filters should be placed in the conditioning environment immediately upon arrival and stored there until the pre-sampling weighing. See reference 2 in section 13.0 of this appendix for additional guidance.

8.3.2 The analytical balance shall be located in the same controlled environment in which the filters are conditioned. The filters shall be weighed immediately following the conditioning period without intermediate or transient exposure to other conditions or environments.

8.3.3 Filters must be conditioned at the same conditions (humidity within ±5 relative humidity percent) before both the pre- and post-sampling weighings.

8.3.4 Both the pre- and post-sampling weighings should be carried out on the same analytical balance, using an effective technique to neutralize static charges on the filter, under reference 2 in section 13.0 of this appendix. If possible, both weighings should be carried out by the same analyst.

8.3.5 The pre-sampling (tare) weighing shall be within 30 days of the sampling period.

8.3.6 The post-sampling conditioning and weighing shall be completed within 240 hours (10 days) after the end of the sample period, unless the filter sample is maintained at 4 °C or less during the entire time between retrieval from the sampler and the start of the conditioning, in which case the period shall

not exceed 30 days. Reference 2 in section 13.0 of this appendix has additional guidance on transport of cooled filters.

8.3.7 Filter blanks.

8.3.7.1 New field blank filters shall be weighed along with the pre-sampling (tare) weighing of each lot of $PM_{2.5}$ filters. These blank filters shall be transported to the sampling site, installed in the sampler, retrieved from the sampler without sampling, and reweighed as a quality control check.

8.3.7.2 New laboratory blank filters shall be weighed along with the pre-sampling (tare) weighing of each set of $PM_{2.5}$ filters. These laboratory blank filters should remain in the laboratory in protective containers during the field sampling and should be reweighed as a quality control check.

8.3.8 Additional guidance for proper filter weighing and related quality assurance activities is provided in reference 2 in section 13.0 of this appendix.

9.0 *Calibration*. Reference 2 in section 13.0 of this appendix contains additional guidance.

9.1 *General requirements.*

9.1.1 Multipoint calibration and single-point verification of the sampler's flow rate measurement device must be performed periodically to establish and maintain traceability of subsequent flow measurements to a flow rate standard.

9.1.2 An authoritative flow rate standard shall be used for calibrating or verifying the sampler's flow rate measurement device with an accuracy of ±2 percent. The flow rate standard shall be a separate, stand-alone device designed to connect to the flow rate measurement adapter, Figure L–30 of this appendix. This flow rate standard must have its own certification and be traceable to a National Institute of Standards and Technology (NIST) primary standard for volume or flow rate. If adjustments to the sampler's flow rate measurement system calibration are to be made in conjunction with an audit of the sampler's flow measurement system, such adjustments shall be made following the audit. Reference 2 in section 13.0 of this appendix contains additional guidance.

9.1.3 The sampler's flow rate measurement device shall be re-calibrated after electromechanical maintenance or transport of the sampler.

9.2 *Flow rate calibration/verification procedure.*

9.2.1 $PM_{2.5}$ samplers may employ various types of flow control and flow measurement devices. The specific procedure used for calibration or verification of the flow rate measurement device will vary depending on the type of flow rate controller and flow rate measurement employed. Calibration shall be in terms of actual ambient volumetric flow rates (Q^a), measured at the sampler's inlet downtube. The generic procedure given here serves to illustrate the general steps involved in the calibration of a $PM_{2.5}$ sampler. The sampler operation/instruction manual required under section 7.4.18 of this appendix and the Quality Assurance Handbook in reference 2 in section 13.0 of this appendix provide more specific and detailed guidance for calibration.

9.2.2 The flow rate standard used for flow rate calibration shall have its own certification and be traceable to a NIST primary standard for volume or flow rate. A calibration relationship for the flow rate standard, e.g., an equation, curve, or family of curves relating actual flow rate (Q_a) to the flow rate indicator reading, shall be established that is accurate to within 2 percent over the expected range of ambient temperatures and pressures at which the flow rate standard may be used. The flow rate standard must be re-calibrated or re-verified at least annually.

9.2.3 The sampler flow rate measurement device shall be calibrated or verified by removing the sampler inlet and connecting the flow rate standard to the sampler's downtube in accordance with the operation/instruction manual, such that the flow rate standard accurately measures the sampler's flow rate. The sampler operator shall first carry out a sampler leak check and confirm that the sampler passes the leak test and then verify that no leaks exist between the flow rate standard and the sampler.

9.2.4 The calibration relationship between the flow rate (in actual L/min) indicated by the flow rate standard and by the sampler's flow rate measurement device shall be established or verified in accordance with the sampler operation/instruction manual. Temperature and pressure corrections to the flow rate indicated by the flow rate standard may be required for certain types of flow rate standards. Calibration of the sampler's flow rate measurement device shall consist of at least three separate flow rate measurements (multipoint calibration) evenly spaced within the range of -10 percent to +10 percent of the sampler's operational flow rate, section 7.4.1 of this appendix. Verification of the sampler's flow rate shall consist of one flow rate measurement at the sampler's operational flow rate. The sampler operation/instruction manual and reference 2 in section 13.0 of this appendix provide additional guidance.

9.2.5 If during a flow rate verification the reading of the sampler's flow rate indicator or measurement device differs by ±2 percent or more from the flow rate measured by the flow rate standard, a new multipoint calibration shall be performed and the flow rate verification must then be repeated.

9.2.6 Following the calibration or verification, the flow rate standard shall be removed from the sampler and the sampler inlet shall be reinstalled. Then the sampler's normal operating flow rate (in L/min) shall be determined with a clean filter in place. If the flow rate indicated by the sampler differs by ±2 percent or more from the required sampler flow rate, the sampler flow rate must be adjusted to the required flow rate, under section 7.4.1 of this appendix.

9.3 Periodic calibration or verification of the calibration of the sampler's ambient temperature, filter temperature, and barometric pressure measurement systems is also required. Reference 3 of section 13.0 of this appendix contains additional guidance.

10.0 *$PM_{2.5}$ Measurement Procedure* The detailed procedure for obtaining valid $PM_{2.5}$ measurements with each specific sampler designated as part of a reference method for $PM_{2.5}$ under part 53 of this chapter shall be provided in the sampler-specific operation or instruction manual required by section 7.4.18 of this appendix. Supplemental guidance is provided in section 2.12 of the Quality Assurance Handbook listed in reference 2 in section 13.0 of this appendix. The generic procedure given here serves to illustrate the general steps involved in the $PM_{2.5}$ sample collection and measurement, using a $PM_{2.5}$ reference method sampler.

10.1 The sampler shall be set up, calibrated, and operated in accordance with the specific, detailed guidance provided in the specific sampler's operation or instruction manual and in accordance with a specific quality assurance program developed and established by the user, based on applicable supplementary guidance provided in reference 2 in section 13.0 of this appendix.

10.2 Each new sample filter shall be inspected for correct type and size and for pinholes, particles, and other imperfections. Unacceptable filters should be discarded. A unique identification number shall be assigned to each filter, and an information record shall be established for each filter. If the filter identification number is not or cannot be marked directly on the filter, alternative means, such as a number-identified storage container, must be established to maintain positive filter identification.

10.3 Each filter shall be conditioned in the conditioning environment in accordance with the requirements specified in section 8.2 of this appendix.

10.4 Following conditioning, each filter shall be weighed in accordance with the requirements specified in section 8.0 of this appendix and the presampling weight recorded with the filter identification number.

10.5 A numbered and preweighed filter shall be installed in the sampler following the instructions provided in the sampler operation or instruction manual.

10.6 The sampler shall be checked and prepared for sample collection in accordance with instructions provided in the sampler operation or instruction manual and with the specific quality assurance program established for the sampler by the user.

10.7 The sampler's timer shall be set to start the sample collection at the beginning of the desired sample period and stop the sample collection 24 hours later.

10.8 Information related to the sample collection (site location or identification number, sample date, filter identification number, and sampler model and serial number) shall be recorded and, if appropriate, entered into the sampler.

10.9 The sampler shall be allowed to collect the $PM_{2.5}$ sample during the set 24-hour time period.

10.10 Within 96 hours of the end of the sample collection period, the filter, while still contained in the filter cassette, shall be carefully removed from the sampler, following the procedure provided in the sampler operation or instruction manual and the quality assurance program, and placed in a protective container. This protective container shall be made of metal and contain no loose material that could be transferred to the filter. The protective container shall hold

the filter cassette securely such that the cover shall not come in contact with the filter's surfaces. Reference 2 in section 13.0 of this appendix contains additional information.

10.11 The total sample volume in actual m^3 for the sampling period and the elapsed sample time shall be obtained from the sampler and recorded in accordance with the instructions provided in the sampler operation or instruction manual. All sampler warning flag indications and other information required by the local quality assurance program shall also be recorded.

10.12 All factors related to the validity or representativeness of the sample, such as sampler tampering or malfunctions, unusual meteorological conditions, construction activity, fires or dust storms, etc. shall be recorded as required by the local quality assurance program. The occurrence of a flag warning during a sample period shall not necessarily indicate an invalid sample but rather shall indicate the need for specific review of the QC data by a quality assurance officer to determine sample validity.

10.13 After retrieval from the sampler, the exposed filter containing the $PM_{2.5}$ sample should be transported to the filter conditioning environment as soon as possible ideally to arrive at the conditioning environment within 24 hours for conditioning and subsequent weighing. During the period between filter retrieval from the sampler and the start of the conditioning, the filter shall be maintained as cool as practical and continuously protected from exposure to temperatures over 25 °C. See section 8.3.6 of this appendix regarding time limits for completing the post-sampling weighing. See reference 2 in section 13.0 of this appendix for additional guidance on transporting filter samplers to the conditioning and weighing laboratory.

10.14. The exposed filter containing the $PM_{2.5}$ sample shall be re-conditioned in the conditioning environment in accordance with the requirements specified in section 8.2 of this appendix.

10.15. The filter shall be reweighed immediately after conditioning in accordance with the requirements specified in section 8.0 of this appendix, and the postsampling weight shall be recorded with the filter identification number.

10.16 The $PM_{2.5}$ concentration shall be calculated as specified in section 12.0 of this appendix.

11.0 *Sampler Maintenance*

The sampler shall be maintained as described by the sampler's manufacturer in the sampler-specific operation or instruction manual required under section 7.4.18 of this appendix and in accordance with the specific quality assurance program developed and established by the user based on applicable supplementary guidance provided in reference 2 in section 13.0 of this appendix.

12.0 *Calculations*

12.1 (a) The $PM_{2.5}$ concentration is calculated as:

$PM_{2.5} = (W_f - W_i)/V_a$

where:

$PM_{2.5}$ = mass concentration of $PM_{2.5}$, $\mu g/m^3$;

W_f, W_i = final and initial weights, respectively, of the filter used to collect the $PM_{2.5}$ particle sample, μg;

V_a = total air volume sampled in actual volume units, as provided by the sampler, m^3.

(b) Note: Total sample time must be between 1,380 and 1,500 minutes (23 and 25 hrs) for a fully valid $PM_{2.5}$ sample; however, see also section 3.3 of this appendix.

13.0 *References.*

1. Quality Assurance Handbook for Air Pollution Measurement Systems, Volume I, Principles. EPA/600/R–94/038a, April 1994. Available from CERI, ORD Publications, U.S. Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, Ohio 45268.

2. Copies of section 2.12 of the Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Specific Methods, EPA/600/R–94/038b, are available from Department E (MD-77B), U.S. EPA, Research Triangle Park, NC 27711.

3. Quality Assurance Handbook for Air Pollution Measurement Systems, Volume IV: Meteorological Measurements, (Revised Edition) EPA/600/R–94/038d, March, 1995. Available from CERI, ORD Publications, U.S. Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, Ohio 45268.

4. Military standard specification (mil. spec.) 8625F, Type II, Class 1 as listed in Department of Defense Index of Specifications and Standards (DODISS), available from DODSSP–Customer Service, Standardization Documents Order Desk, 700 Robbins Avenue, Building 4D, Philadelphia, PA 1911–5094.

14.0 *Figures L–1 through L–30 to Appendix L.*

FIGURE L-1. PM2.5 SAMPLER, ASSEMBLY

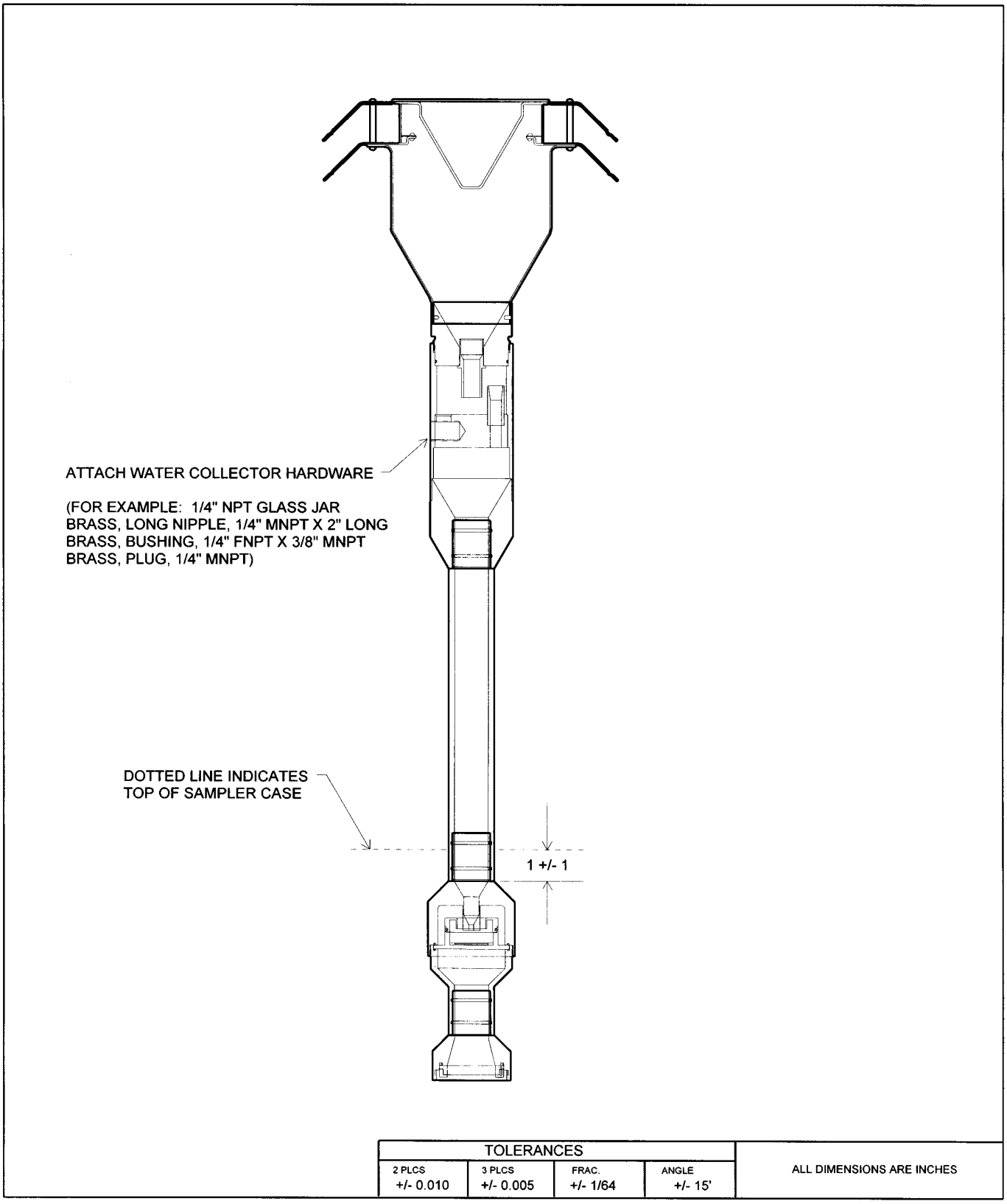


FIGURE L-2. 10-MICRON INLET, ASSEMBLY

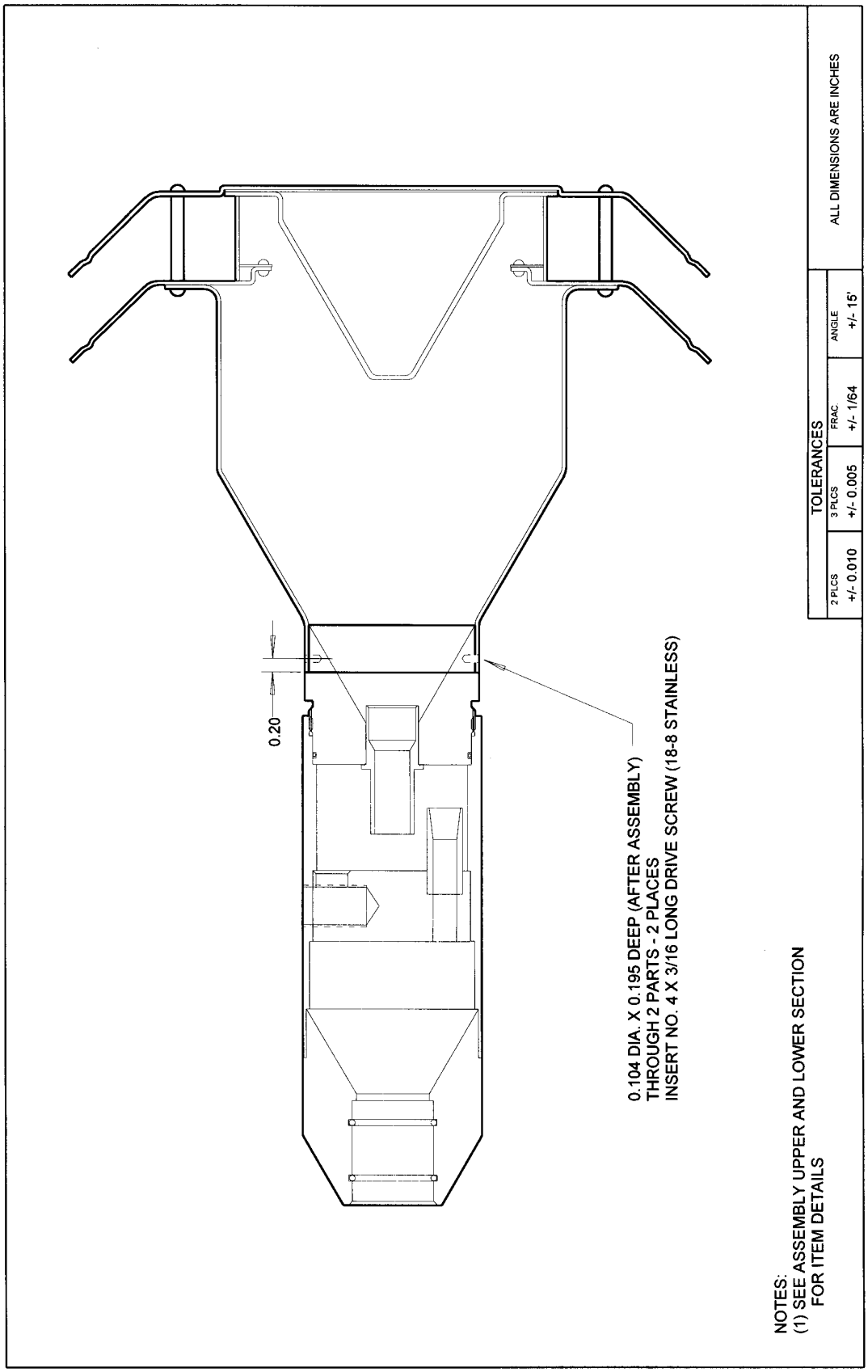
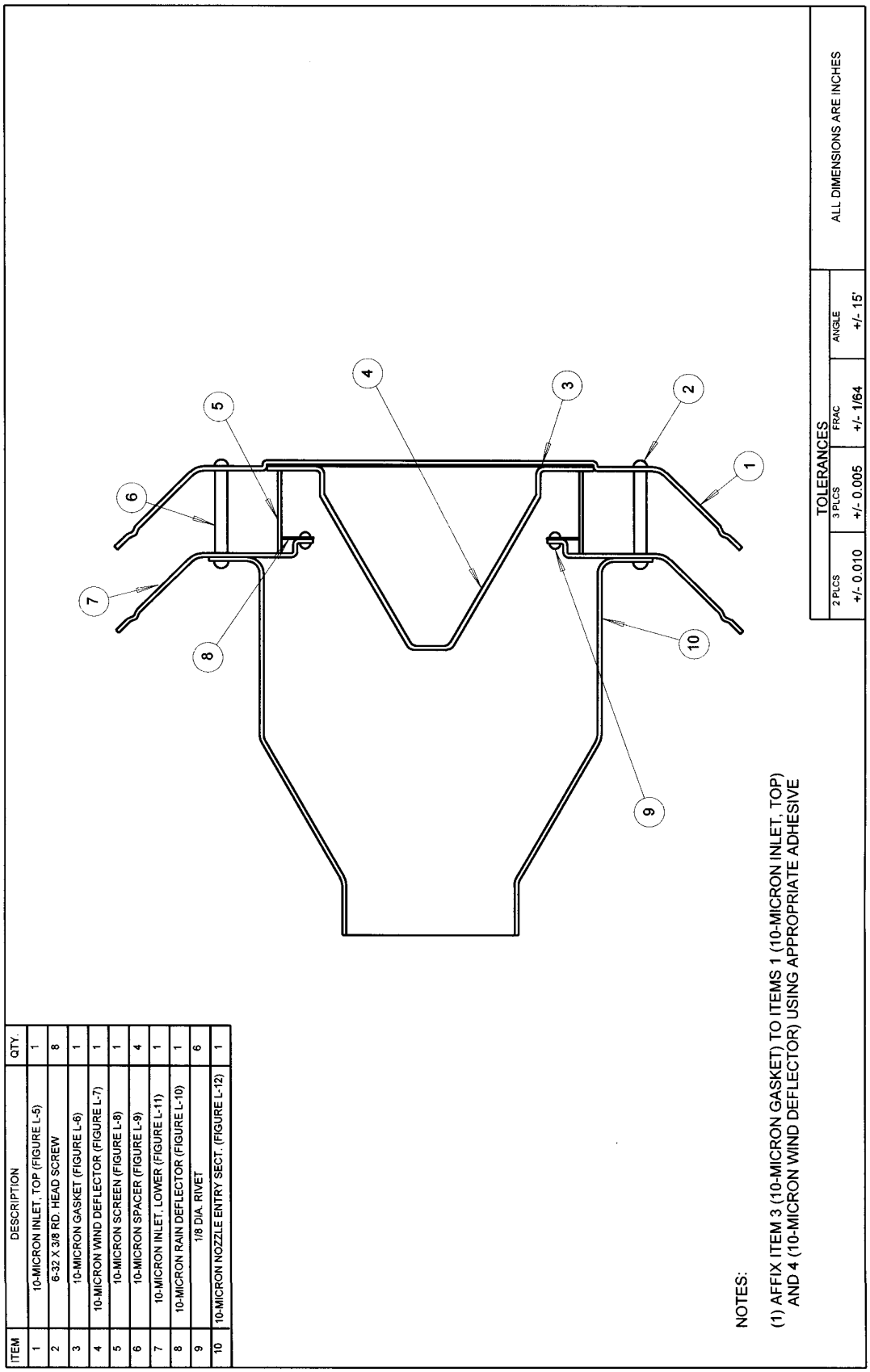
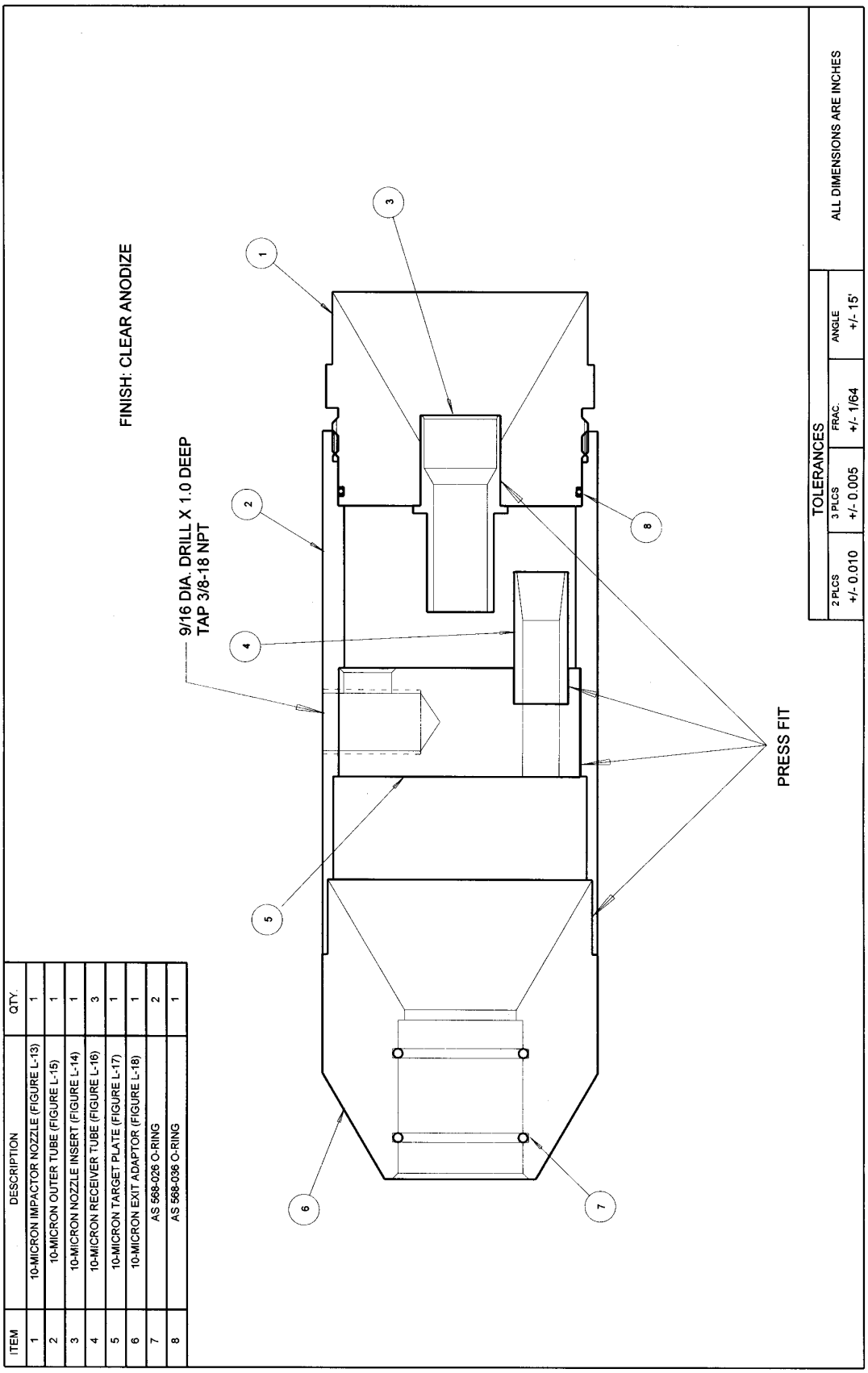


FIGURE L-3. 10-MICRON ASSEMBLY, UPPER SECTION



ITEM	DESCRIPTION	QTY.
1	10-MICRON INLET, TOP (FIGURE L-5)	1
2	6-32 X 3/8 RD. HEAD SCREW	8
3	10-MICRON GASKET (FIGURE L-6)	1
4	10-MICRON WIND DEFLECTOR (FIGURE L-7)	1
5	10-MICRON SCREEN (FIGURE L-8)	1
6	10-MICRON SPACER (FIGURE L-9)	4
7	10-MICRON INLET, LOWER (FIGURE L-11)	1
8	10-MICRON RAIN DEFLECTOR (FIGURE L-10)	1
9	1/8 DIA. RIVET	6
10	10-MICRON NOZZLE ENTRY SECT. (FIGURE L-12)	1

FIGURE L-4. 10-MICRON ASSEMBLY, LOWER SECTION



ITEM	DESCRIPTION	QTY.
1	10-MICRON IMPACTOR NOZZLE (FIGURE L-13)	1
2	10-MICRON OUTER TUBE (FIGURE L-15)	1
3	10-MICRON NOZZLE INSERT (FIGURE L-14)	1
4	10-MICRON RECEIVER TUBE (FIGURE L-16)	3
5	10-MICRON TARGET PLATE (FIGURE L-17)	1
6	10-MICRON EXIT ADAPTOR (FIGURE L-18)	1
7	AS 568-026 O-RING	2
8	AS 568-036 O-RING	1

FIGURE L-5. 10-MICRON INLET, TOP

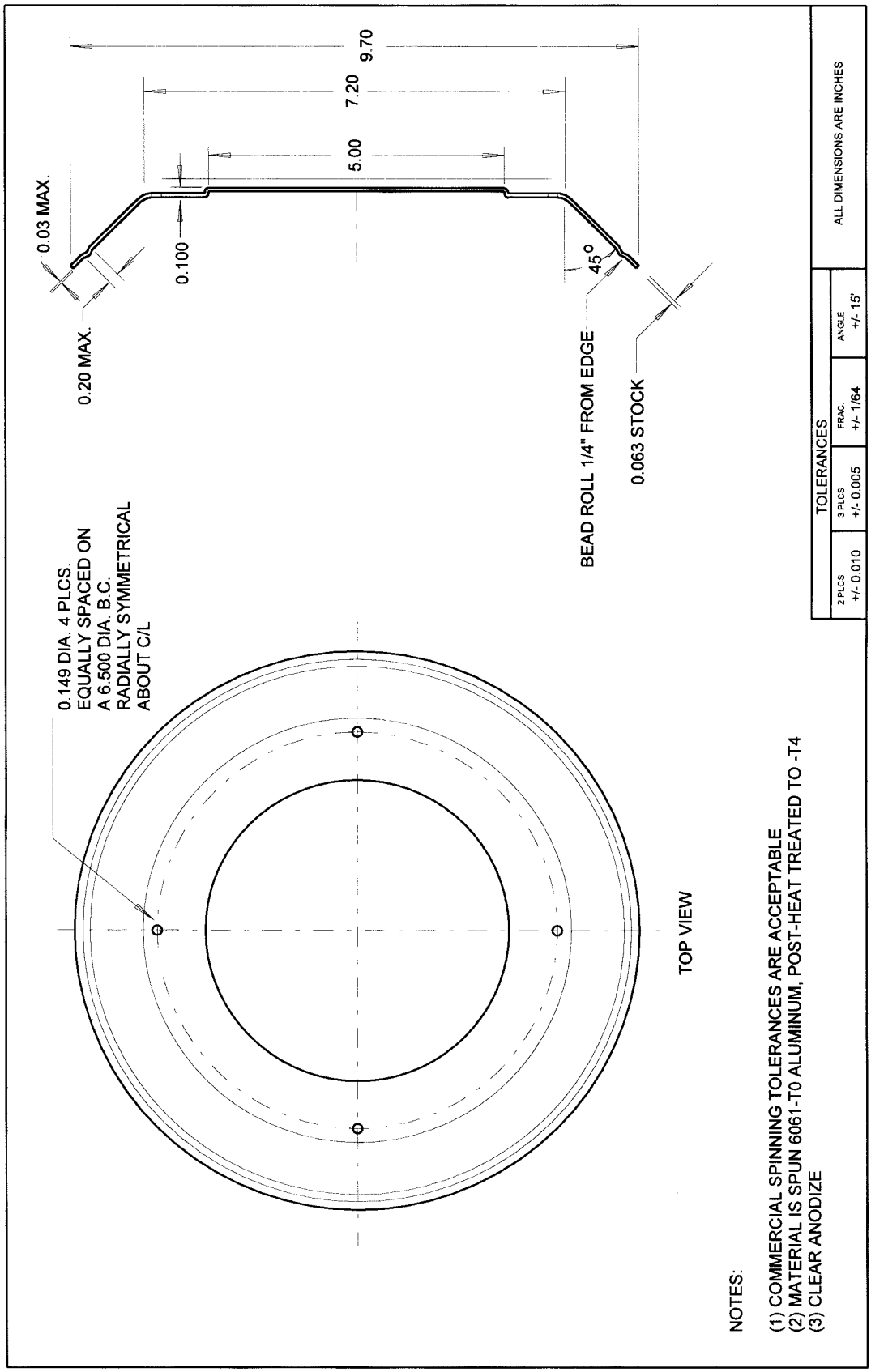


FIGURE L-6. 10-MICRON GASKET

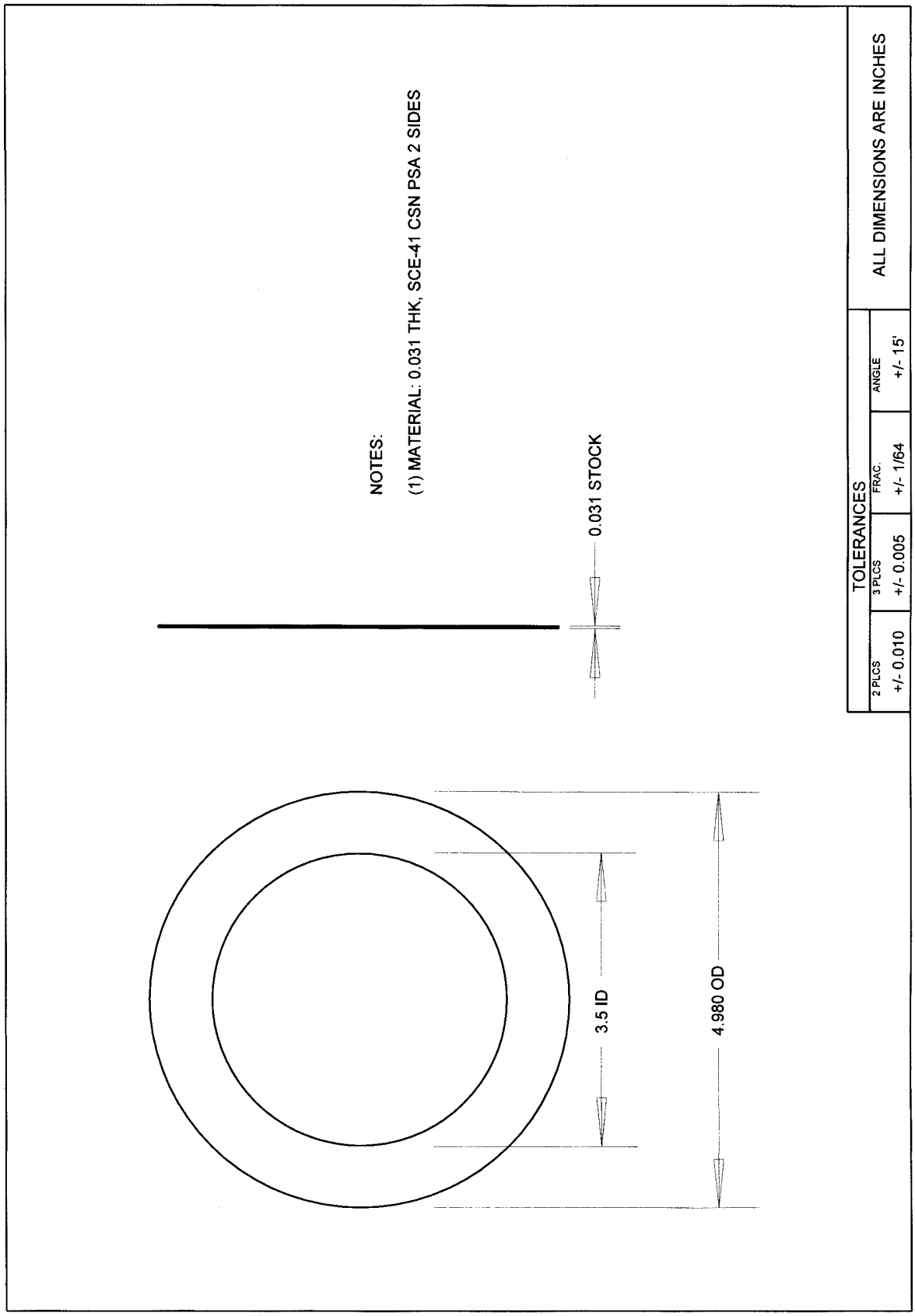


FIGURE L-7. 10-MICRON WIND DEFLECTOR

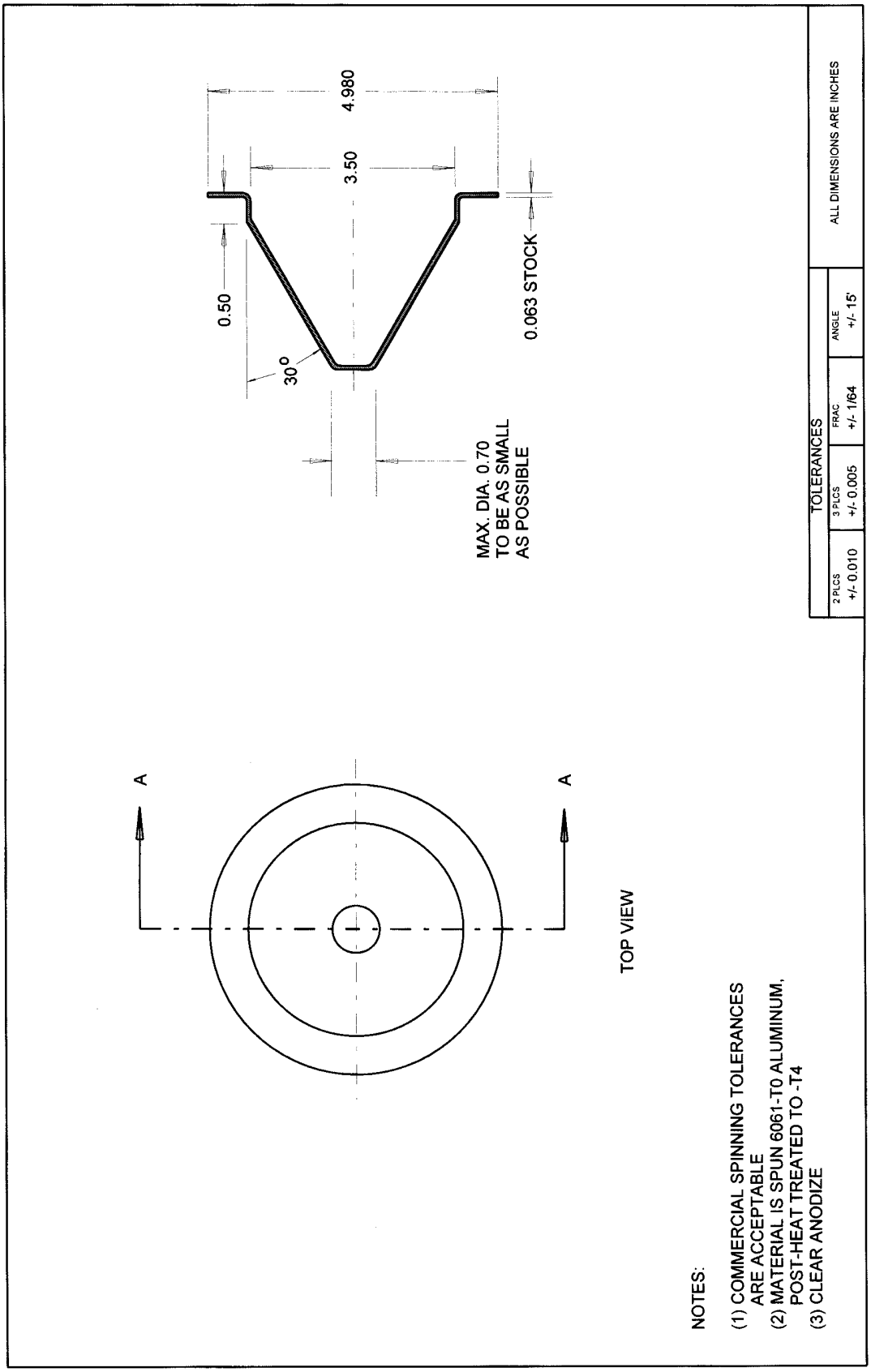


FIGURE L-8. 10-MICRON SCREEN

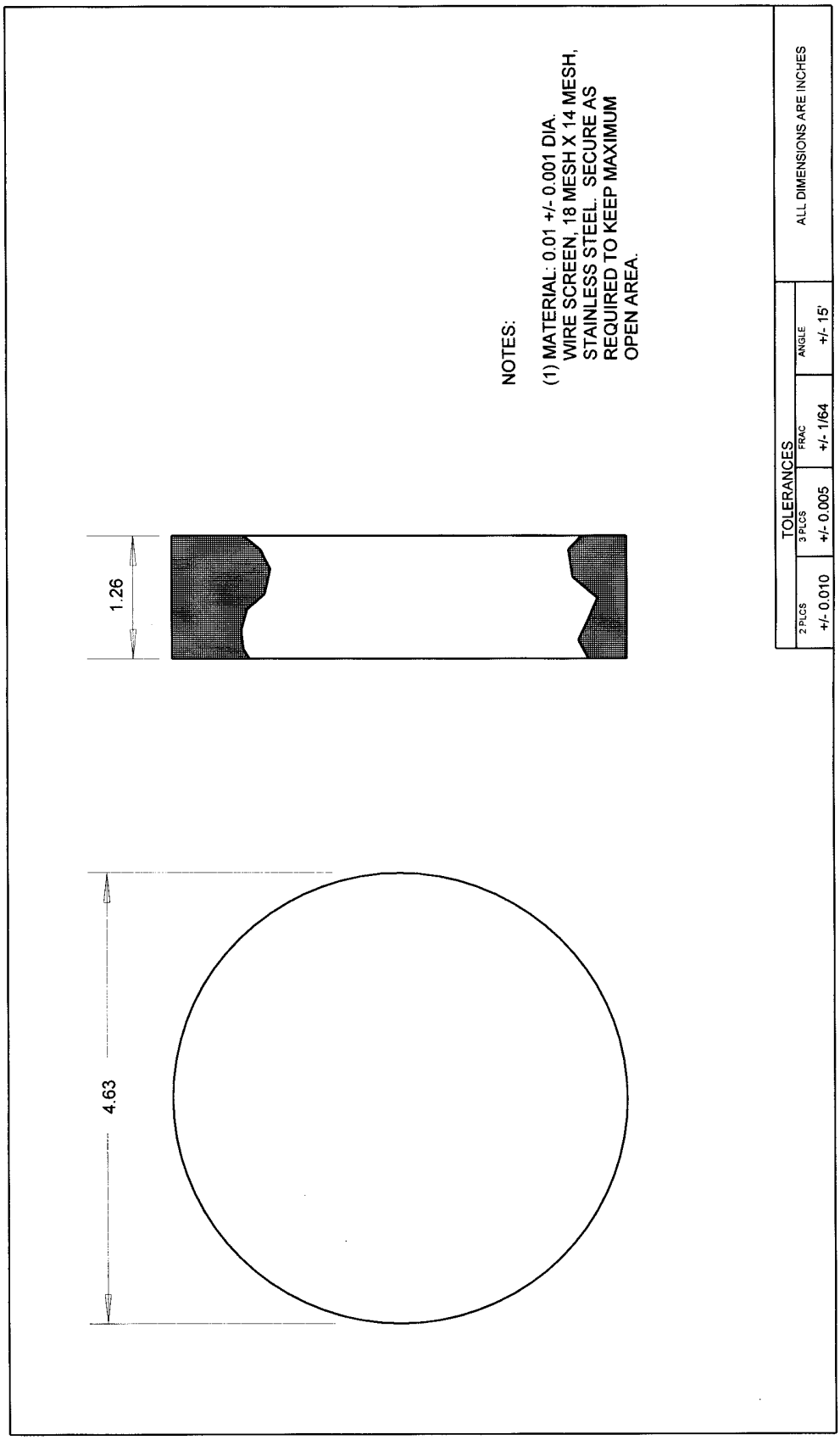


FIGURE L-9. 10-MICRON SPACER

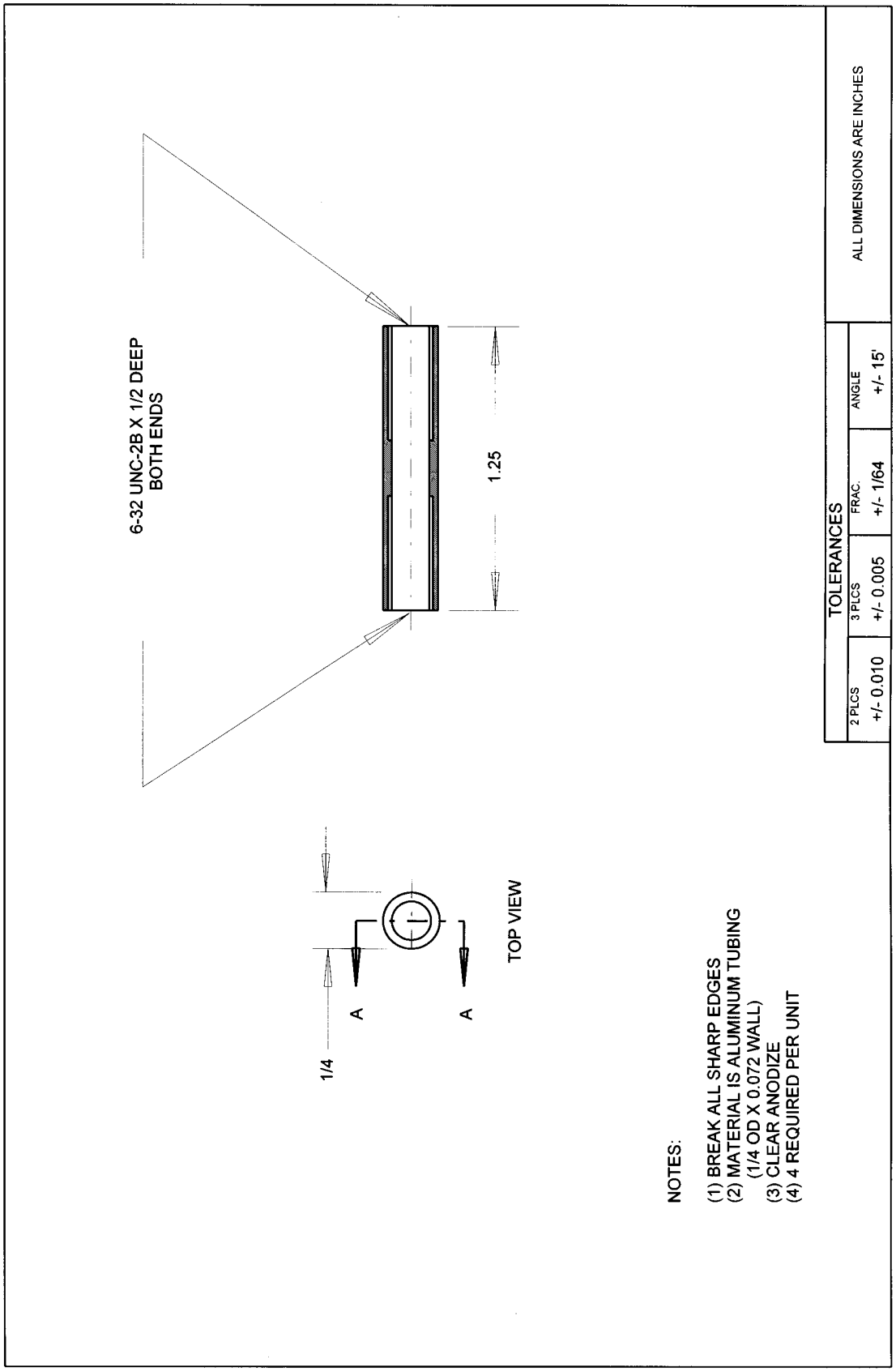


FIGURE L-10. 10-MICRON RAIN DEFLECTOR

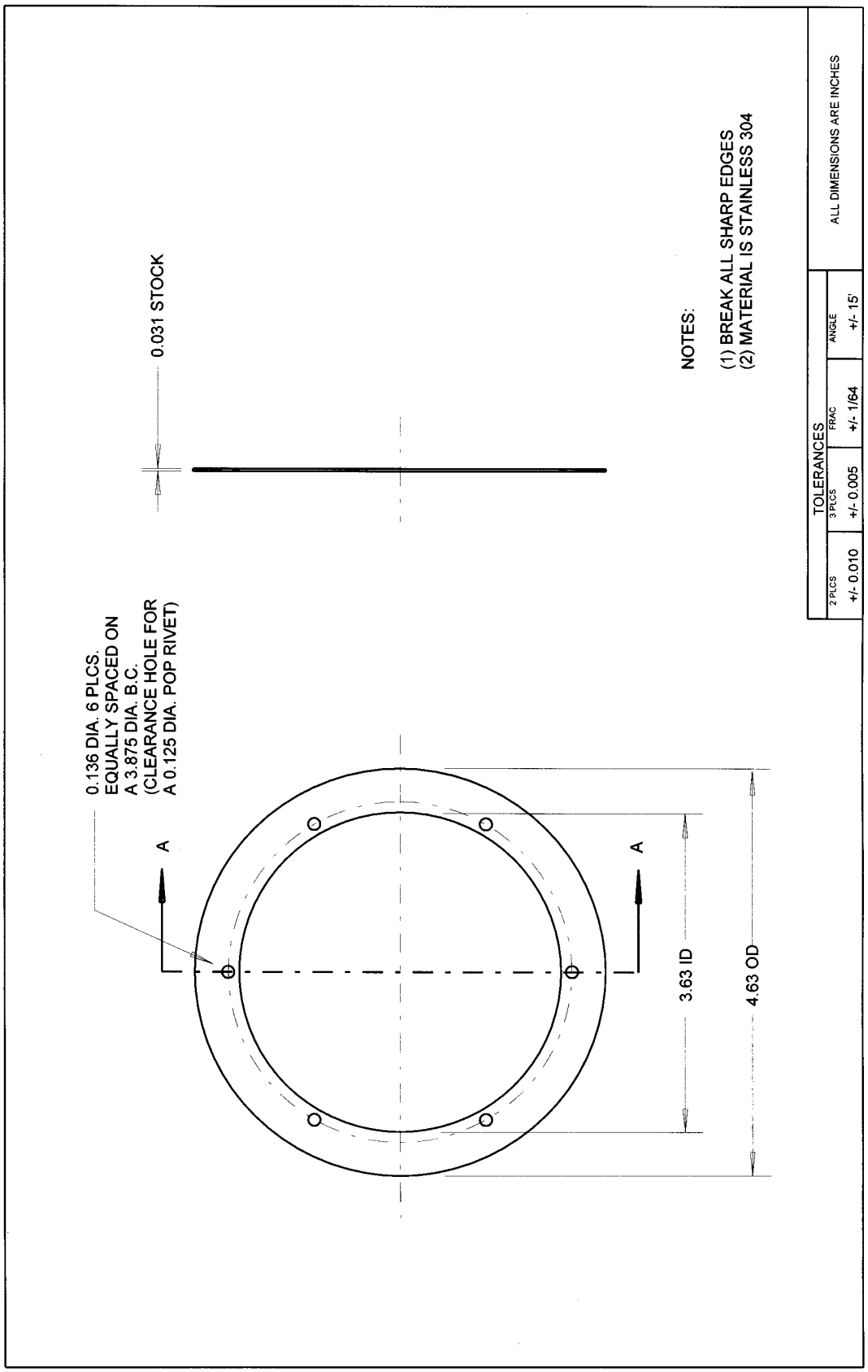


FIGURE L-11. 10-MICRON INLET, LOWER

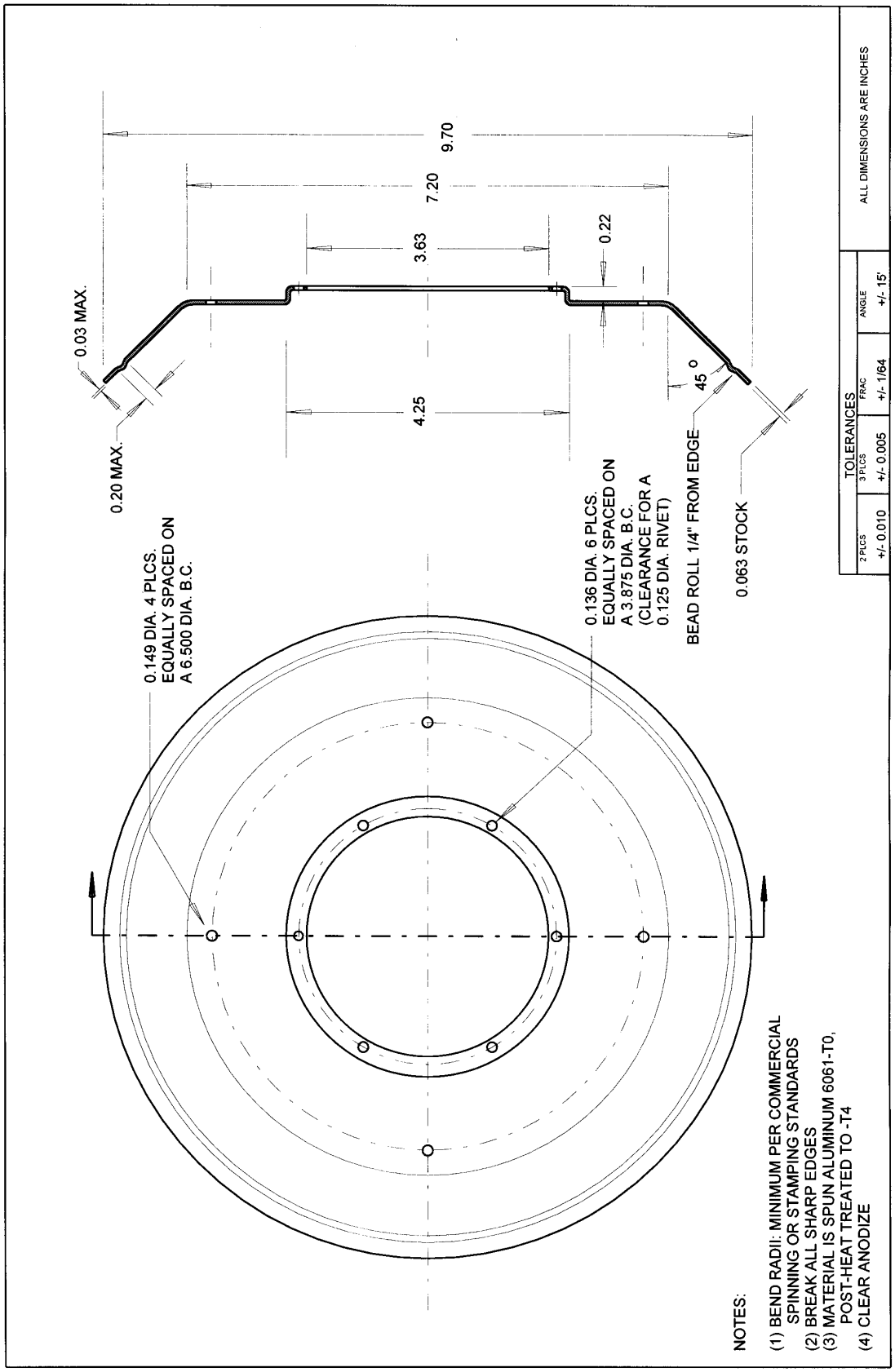


FIGURE L-12. 10-MICRON NOZZLE ENTRY SECTION

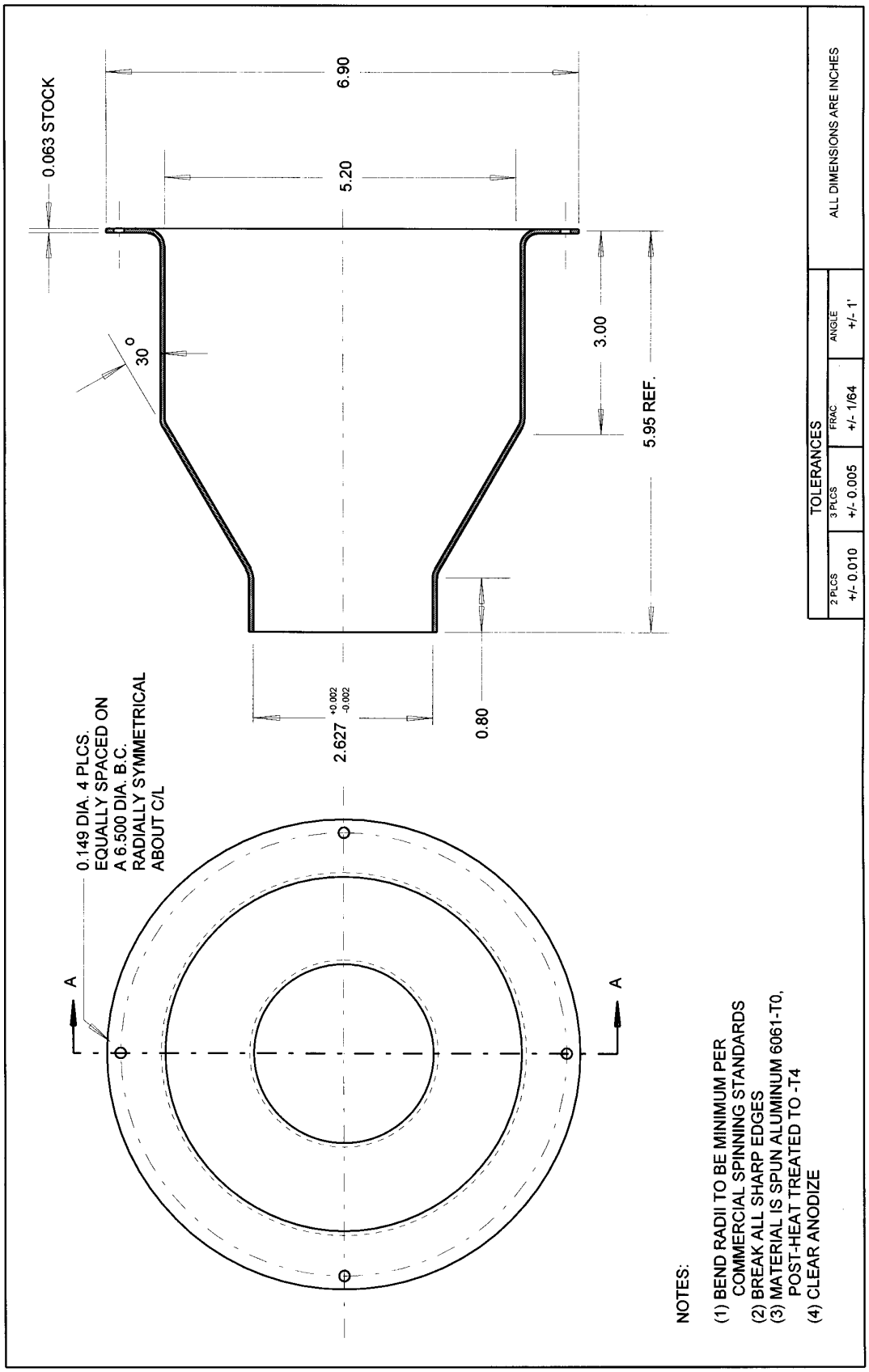


FIGURE L-13. 10-MICRON IMPACTOR NOZZLE

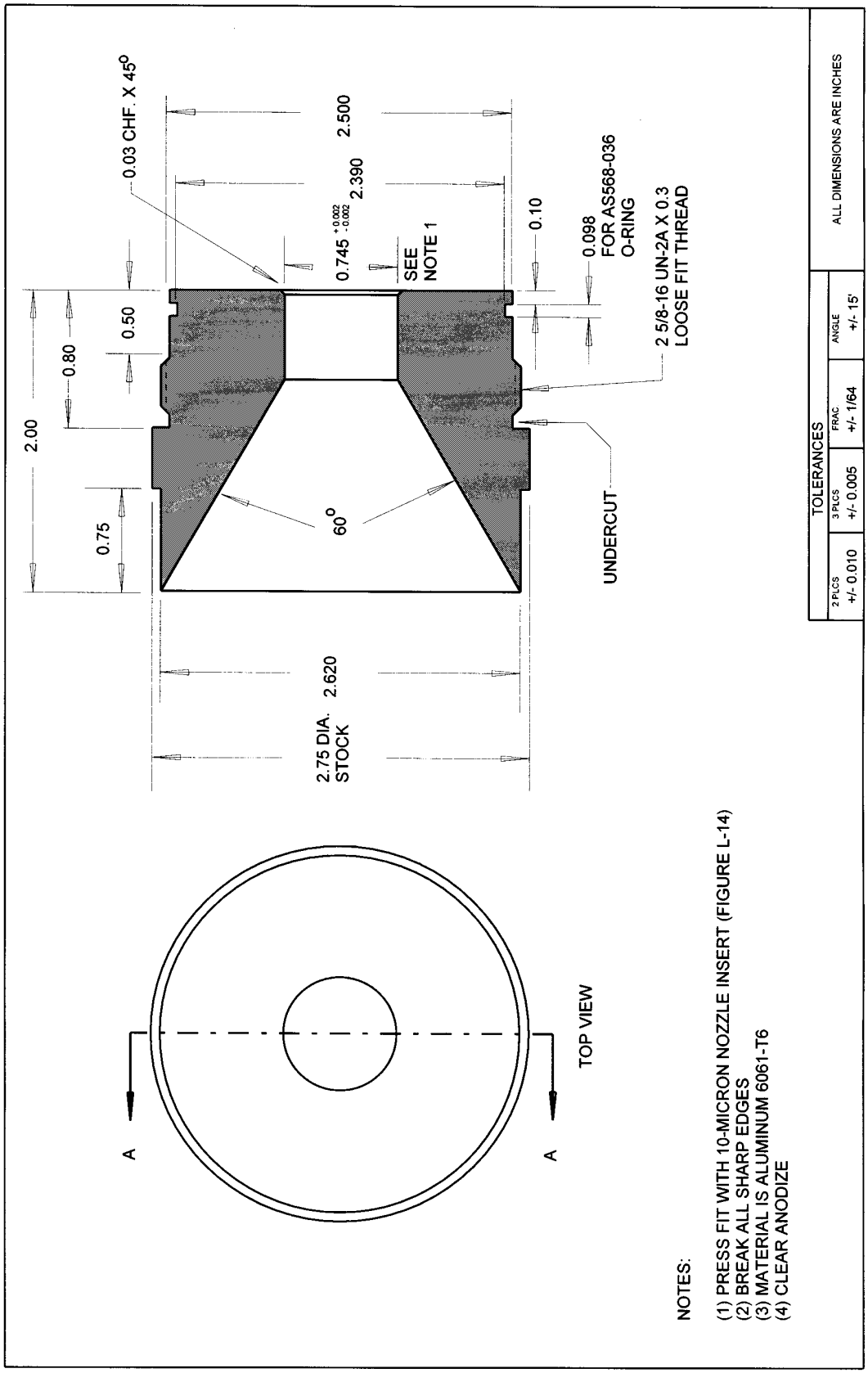


FIGURE L-14. 10-MICRON NOZZLE INSERT

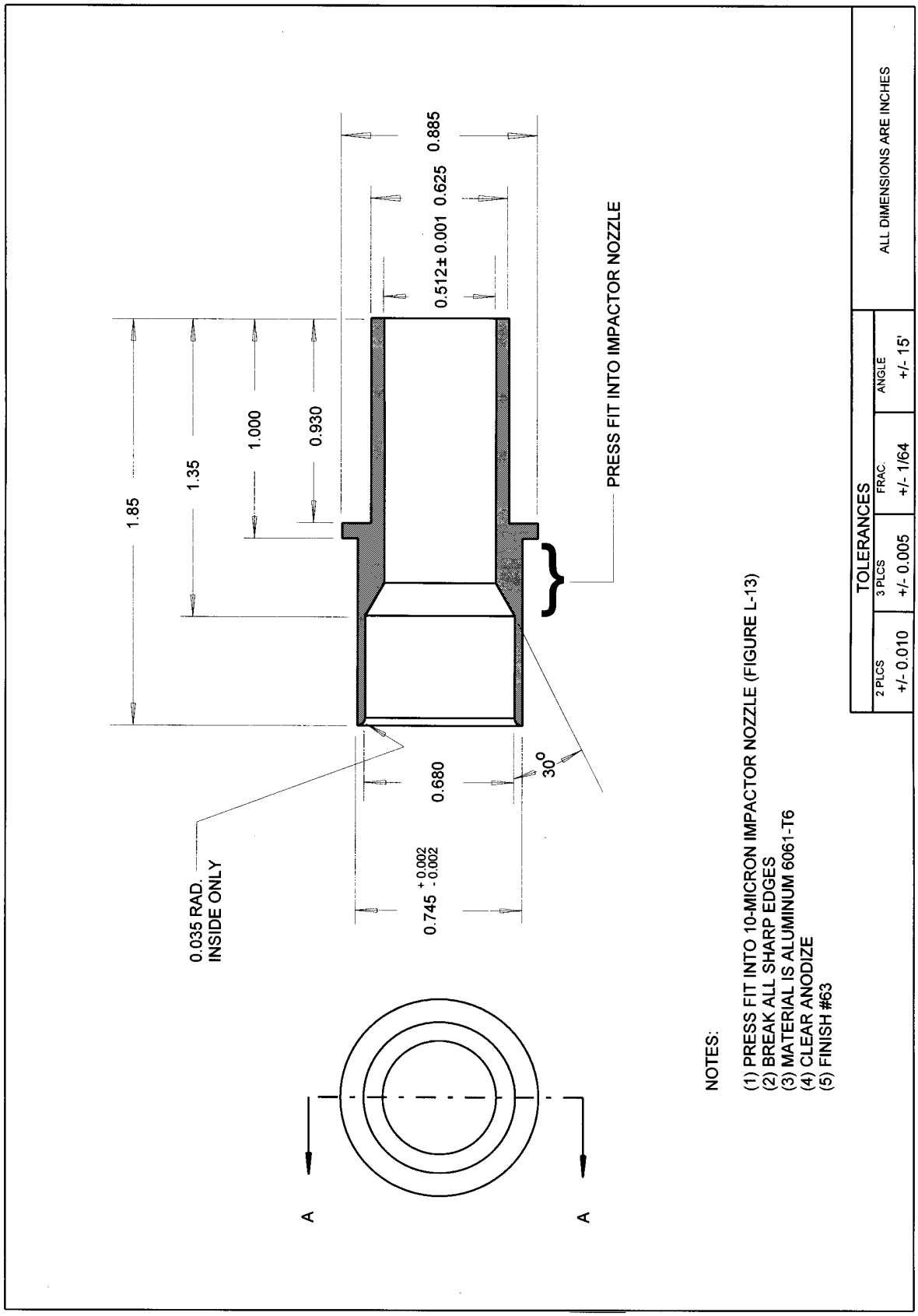


FIGURE L-15. 10-MICRON OUTER TUBE

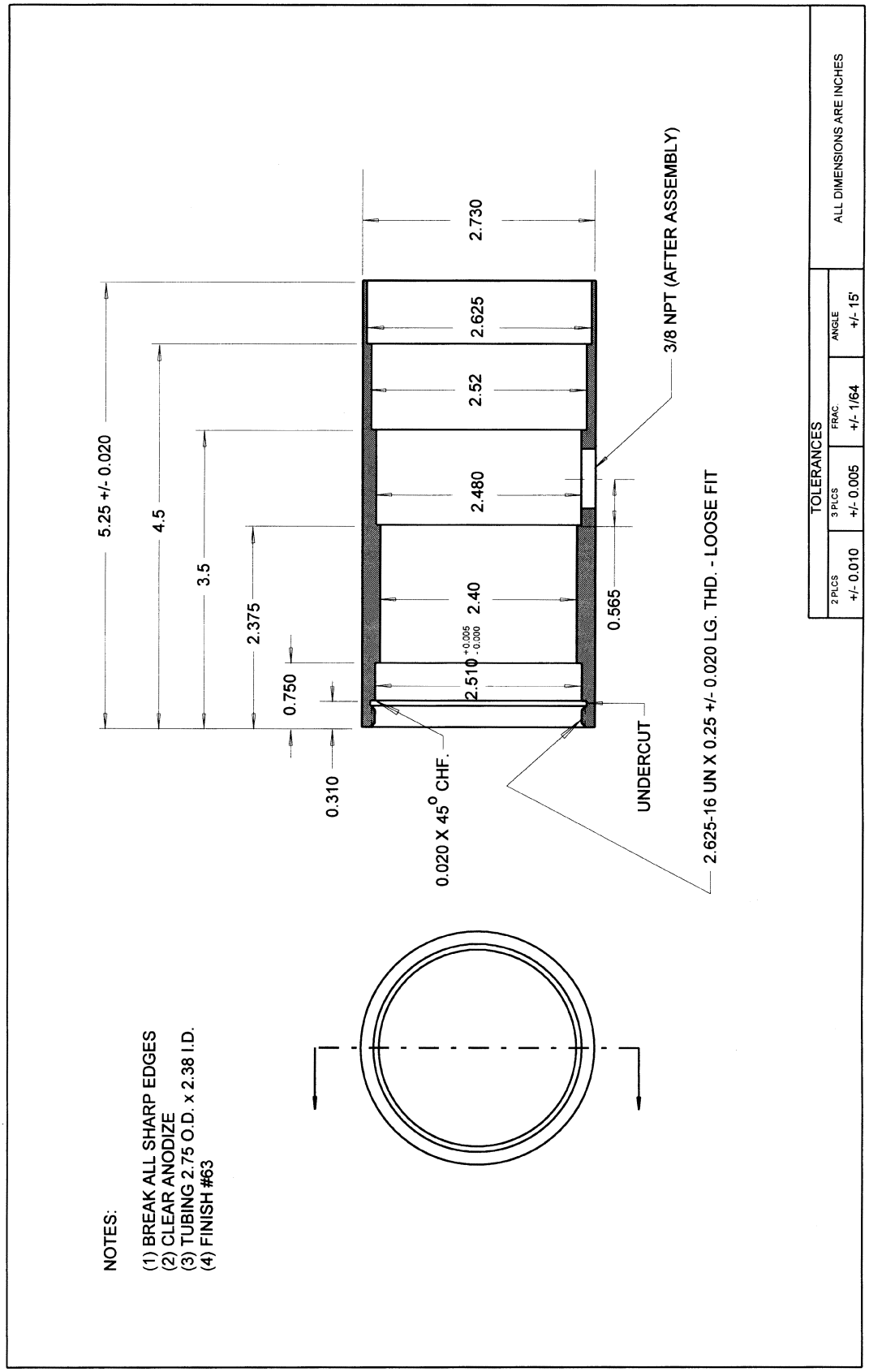


FIGURE L-16. 10-MICRON RECEIVER TUBE

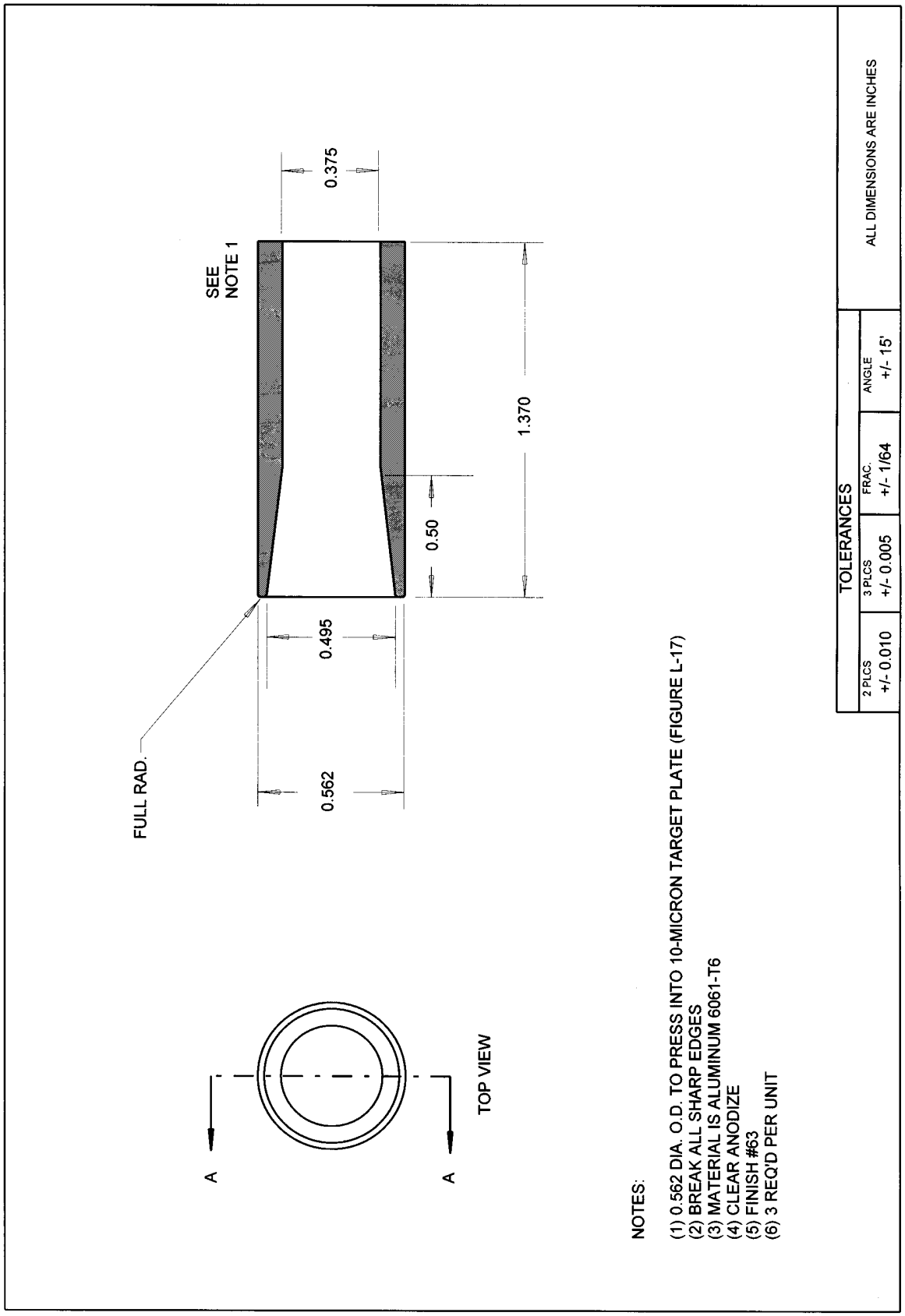


FIGURE L-17. 10-MICRON TARGET PLATE

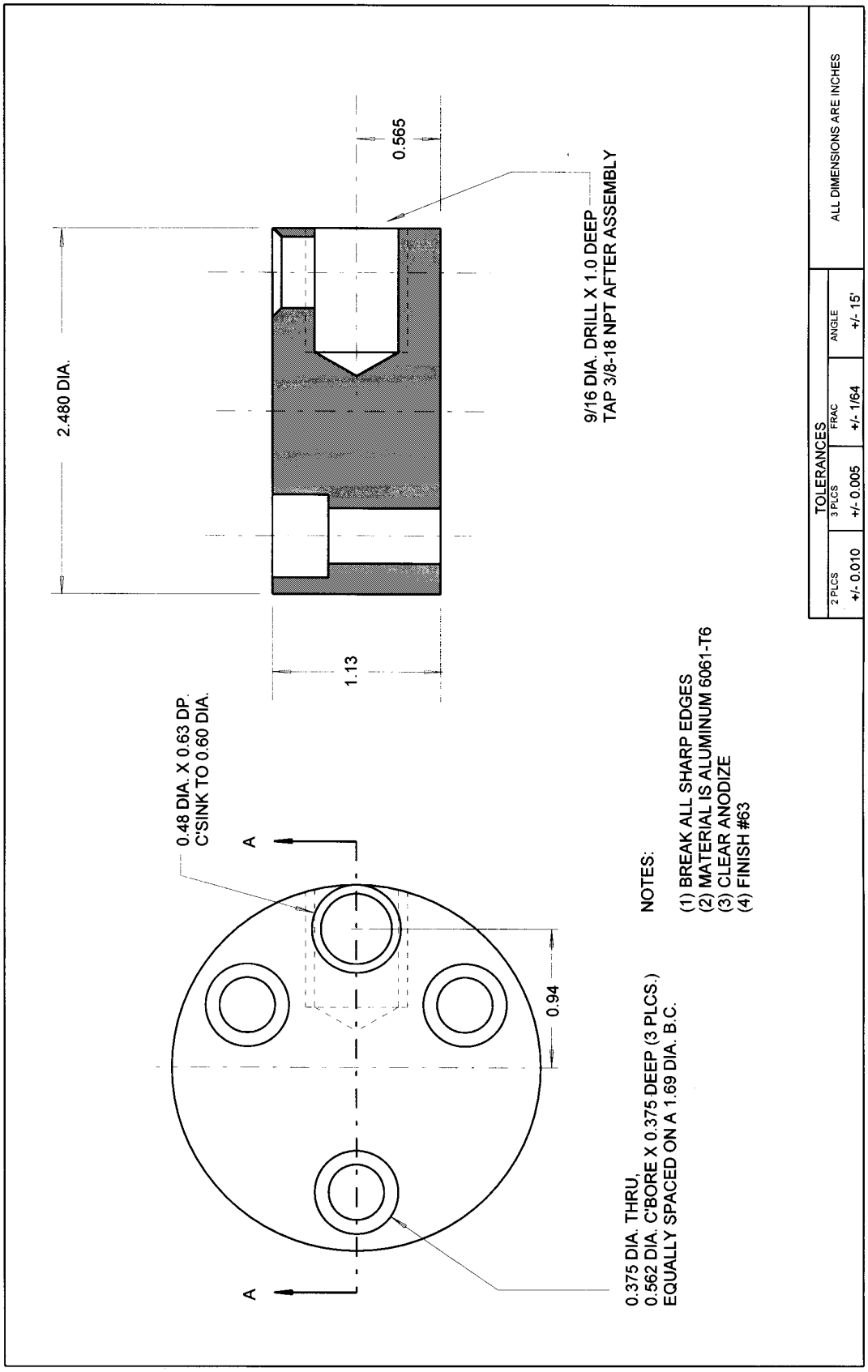


FIGURE L-18. 10-MICRON EXIT ADAPTOR

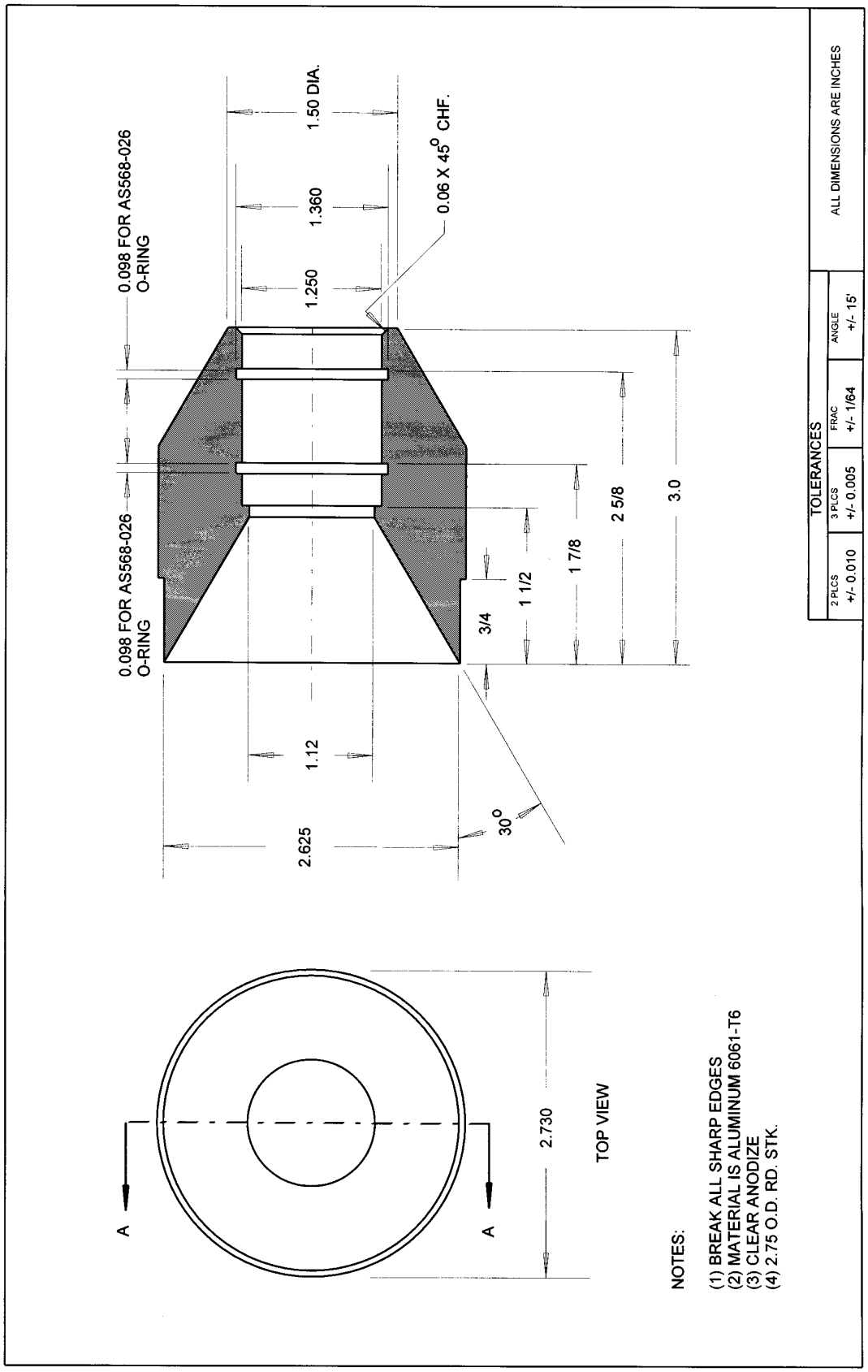


FIGURE L-19. 10-MICRON DOWN TUBE

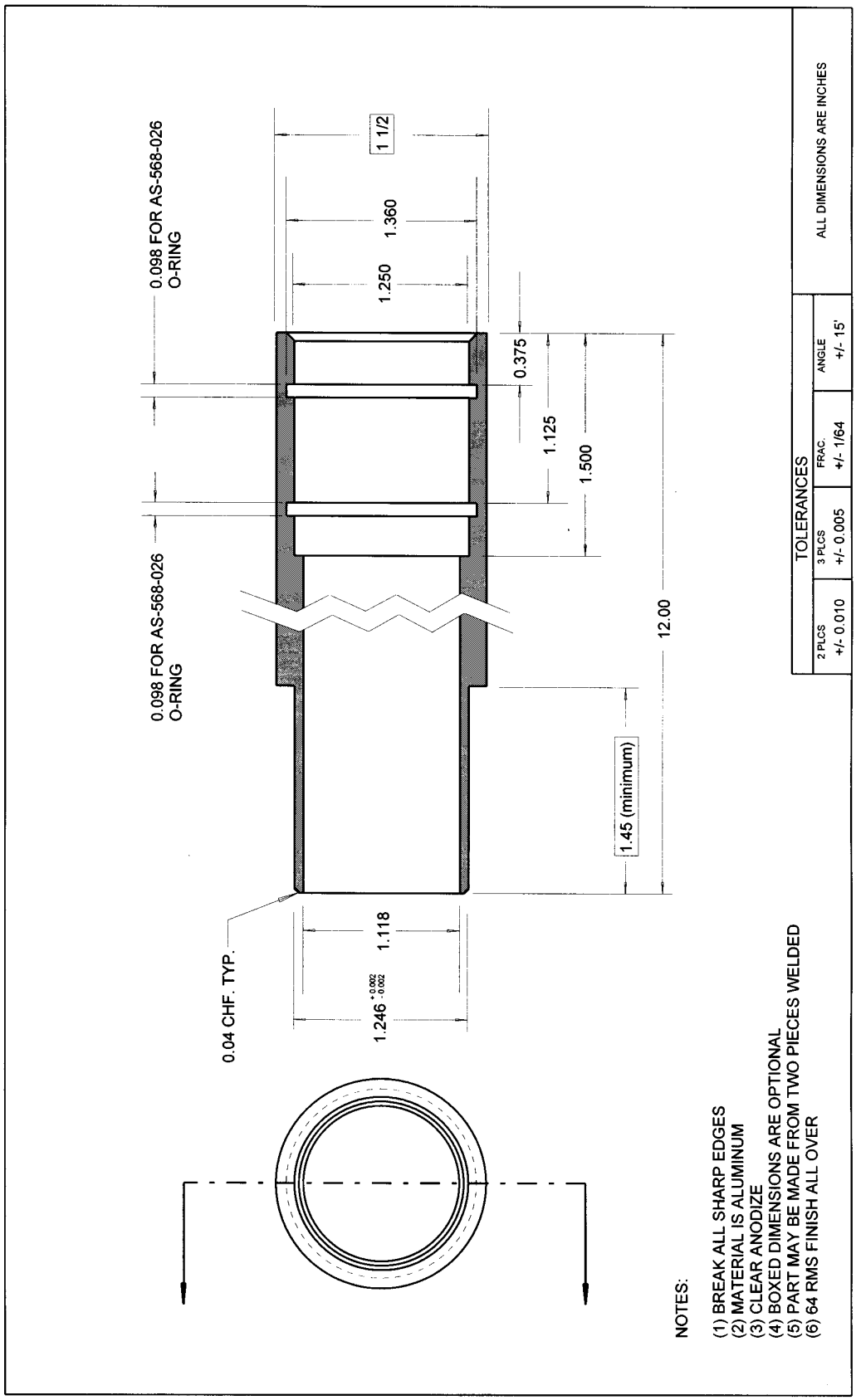
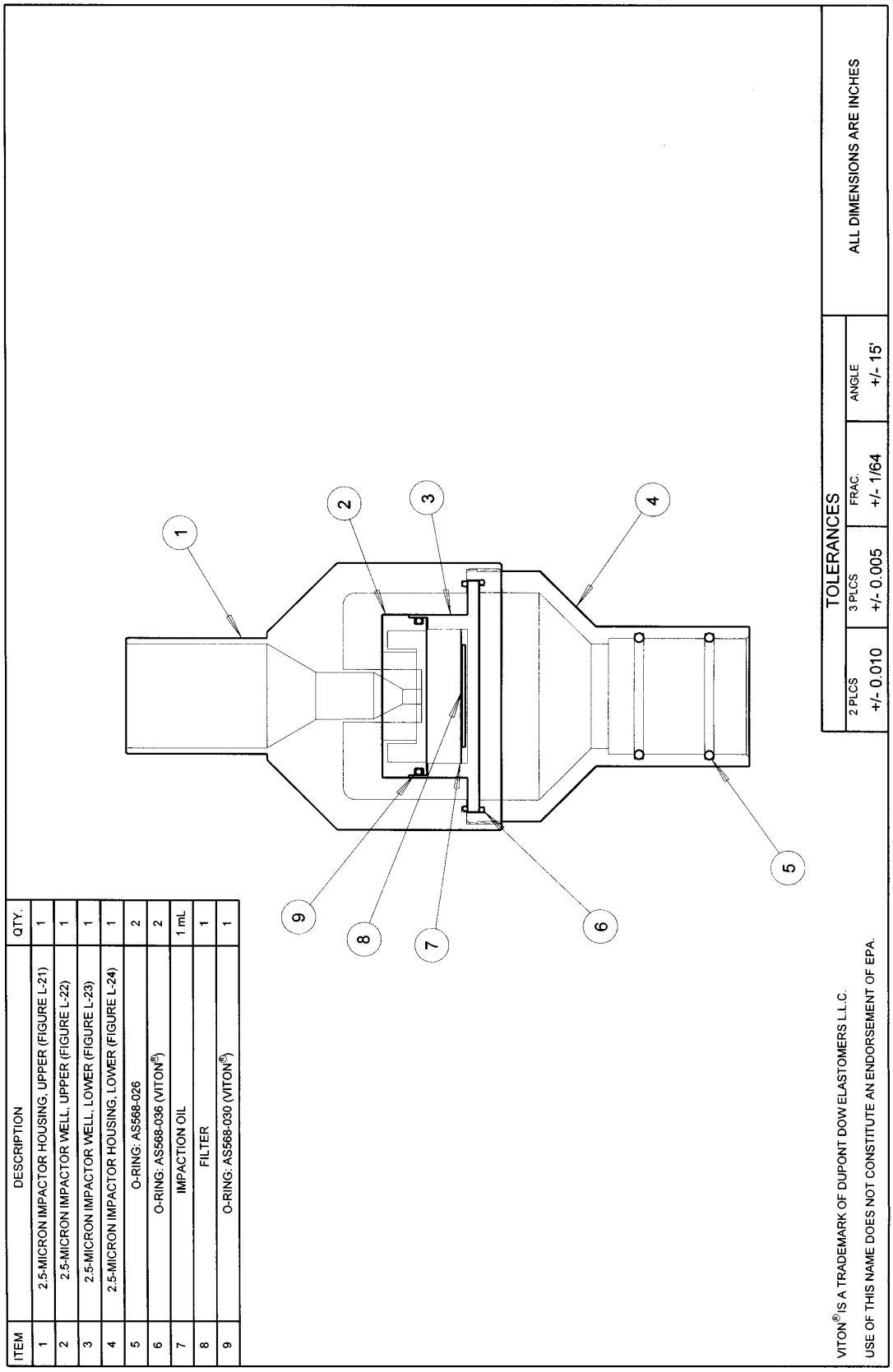


FIGURE L-20. 2.5-MICRON IMPACTOR ASSEMBLY



ITEM	DESCRIPTION	QTY.
1	2.5-MICRON IMPACTOR HOUSING, UPPER (FIGURE L-21)	1
2	2.5-MICRON IMPACTOR WELL, UPPER (FIGURE L-22)	1
3	2.5-MICRON IMPACTOR WELL, LOWER (FIGURE L-23)	1
4	2.5-MICRON IMPACTOR HOUSING, LOWER (FIGURE L-24)	1
5	O-RING: AS568-026	2
6	O-RING: AS568-036 (VITON®)	2
7	IMPACTION OIL	1 mL
8	FILTER	1
9	O-RING: AS568-030 (VITON®)	1

FIGURE L-21. 2.5-MICRON IMPACTOR HOUSING, UPPER

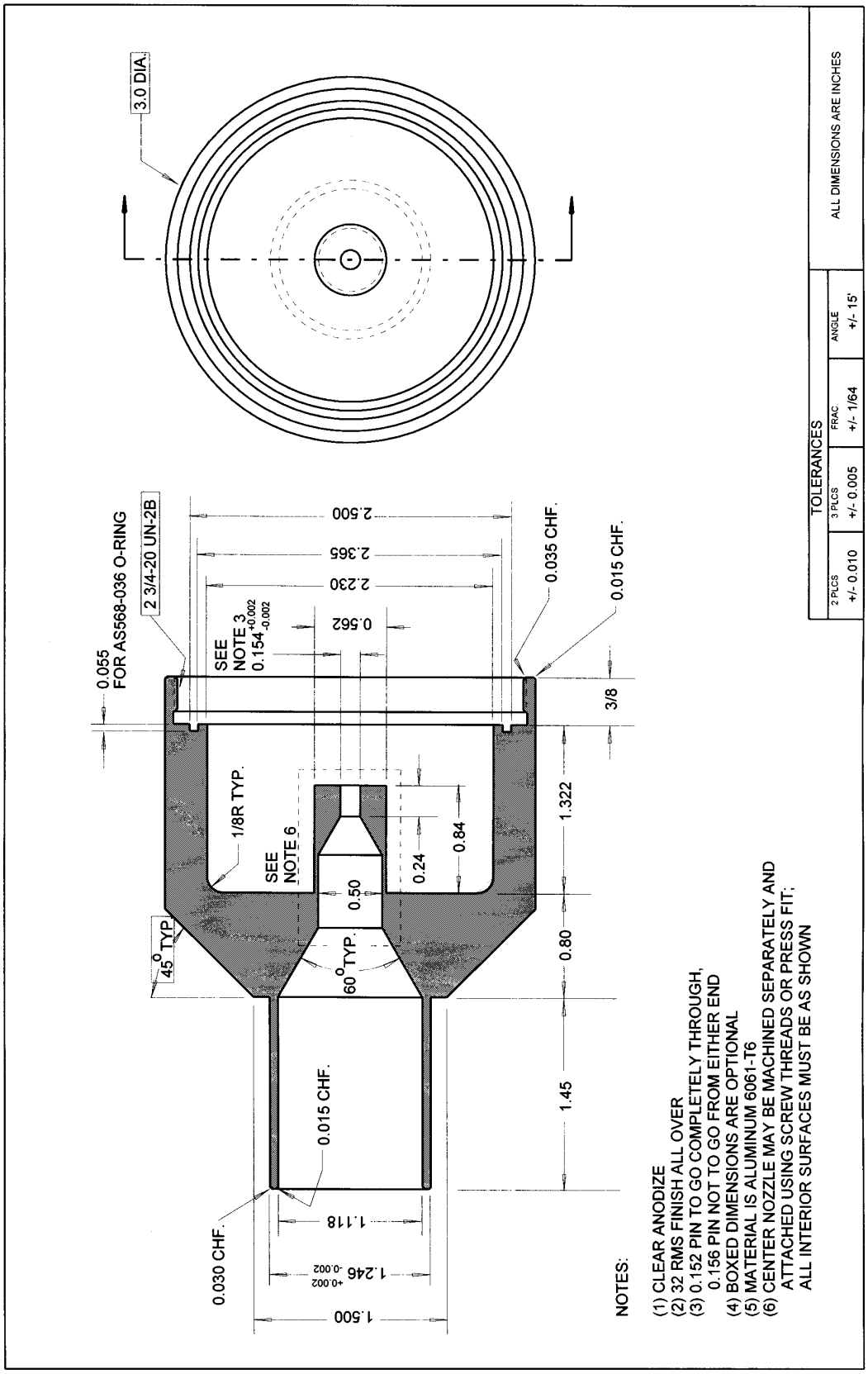


FIGURE L-22. 2.5-MICRON IMPACTOR WELL, UPPER SECTION

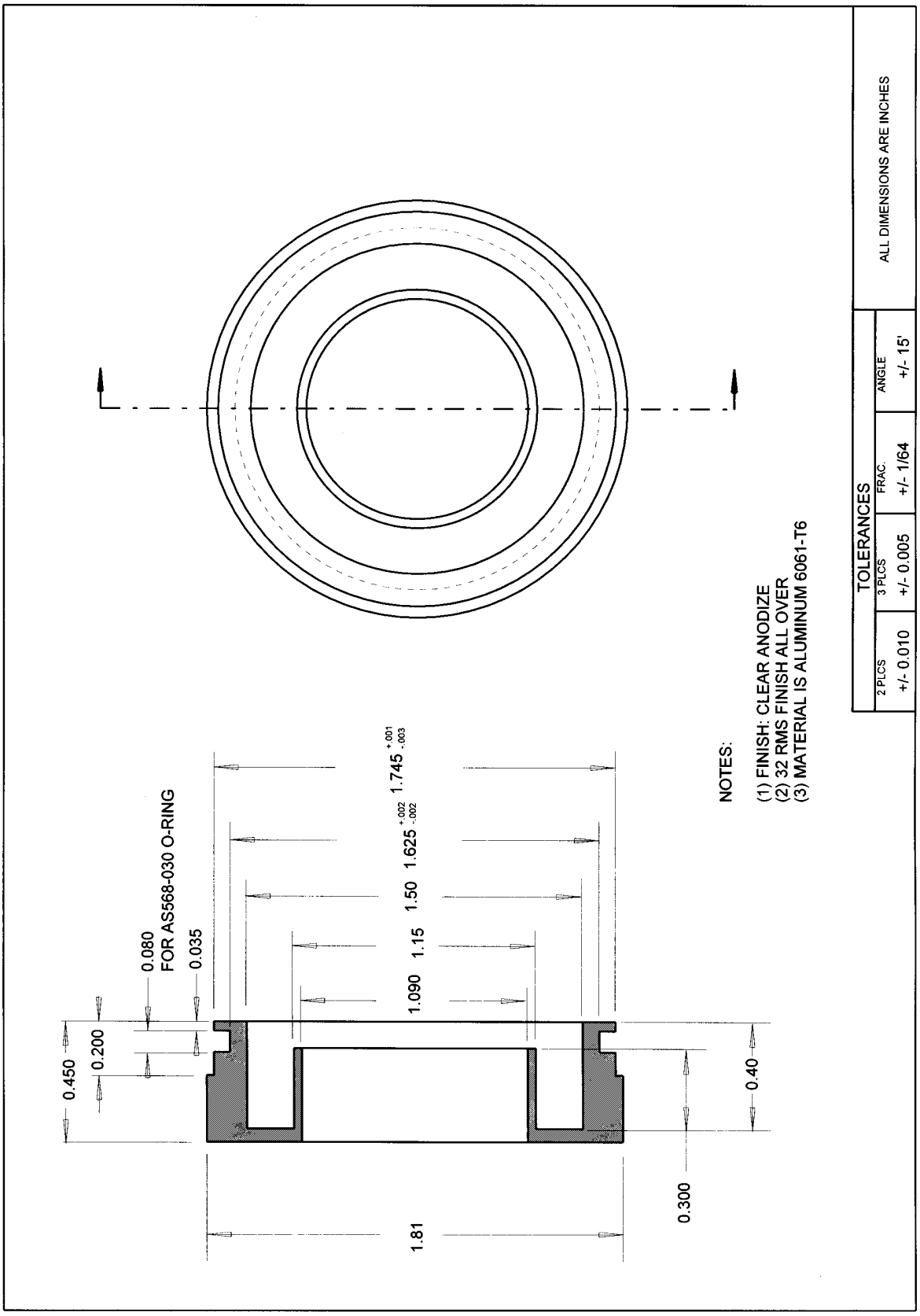


FIGURE L-23. 2.5-MICRON IMPACTOR WELL, LOWER SECTION

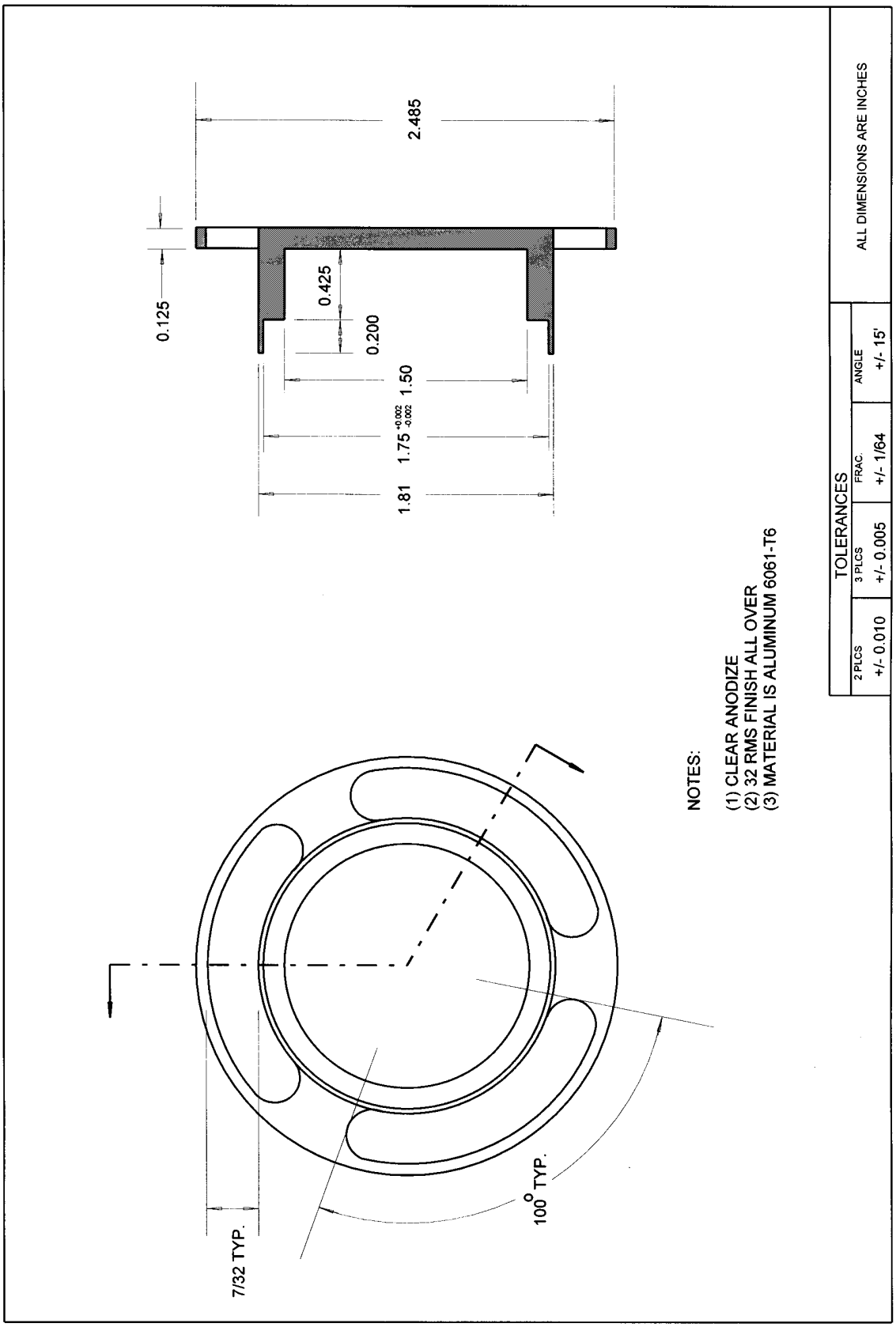


FIGURE L-24. 2.5-MICRON IMPACTOR HOUSING, LOWER

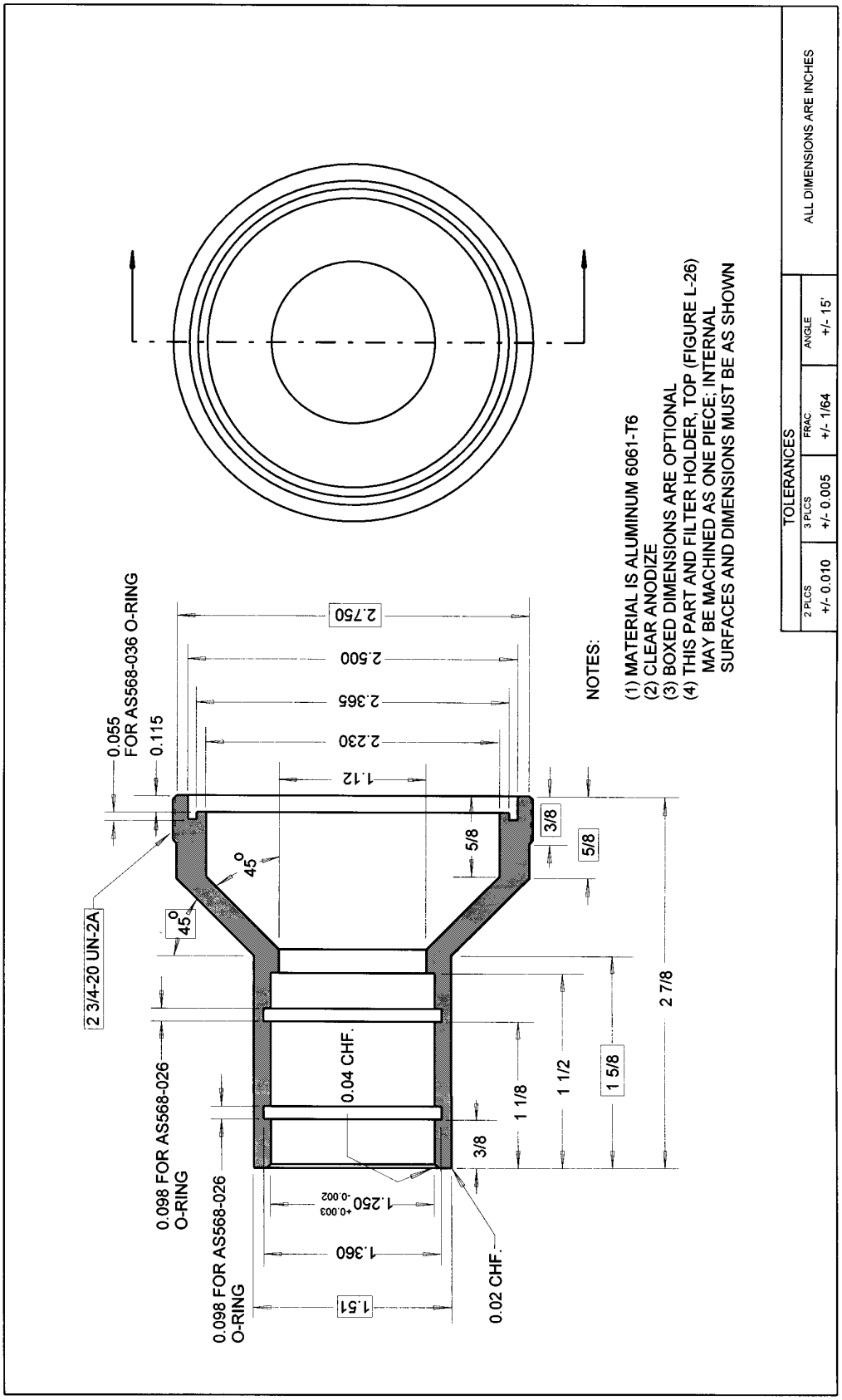


FIGURE L-25. FILTER HOLDER, ASSEMBLY

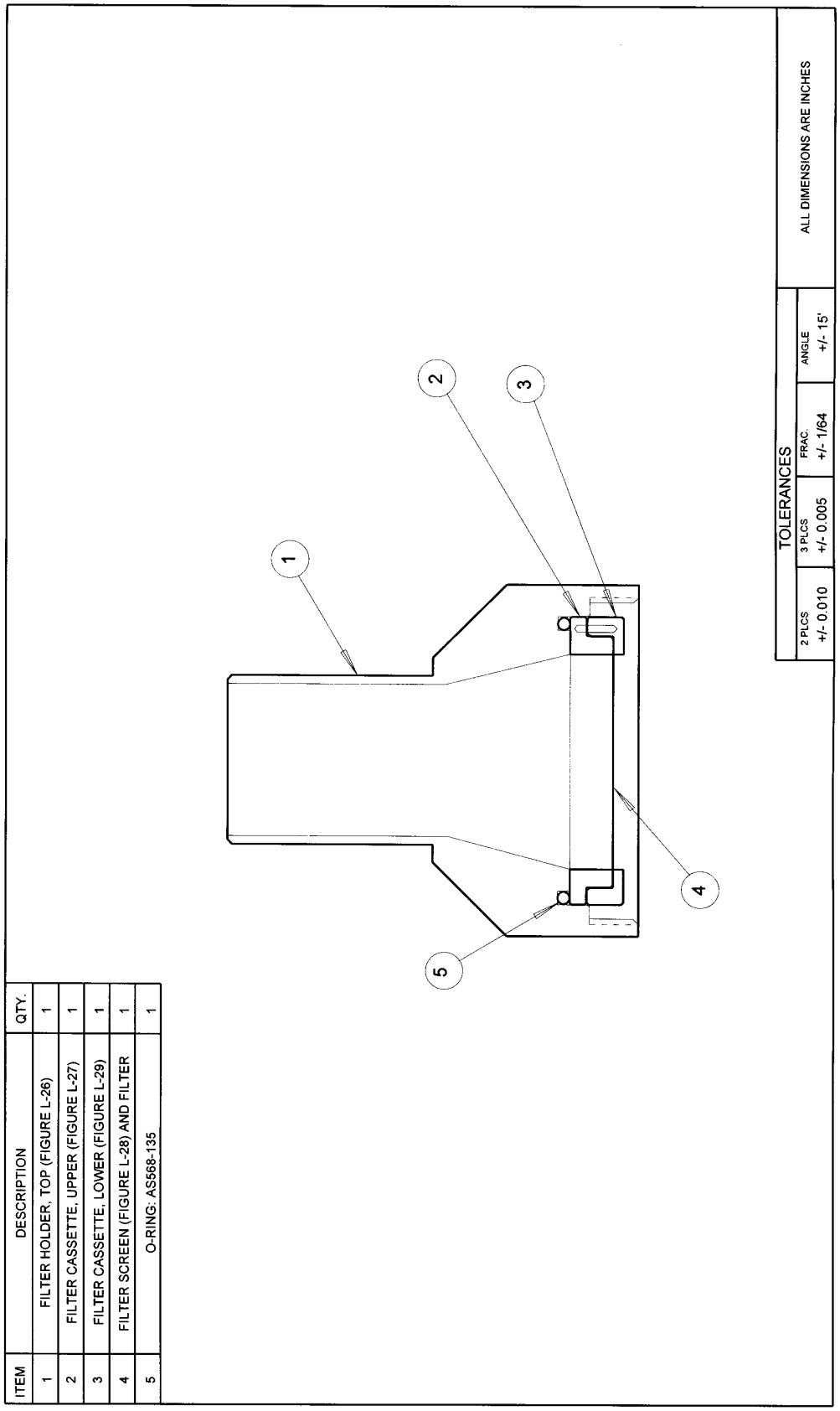


FIGURE L-26. FILTER HOLDER, TOP

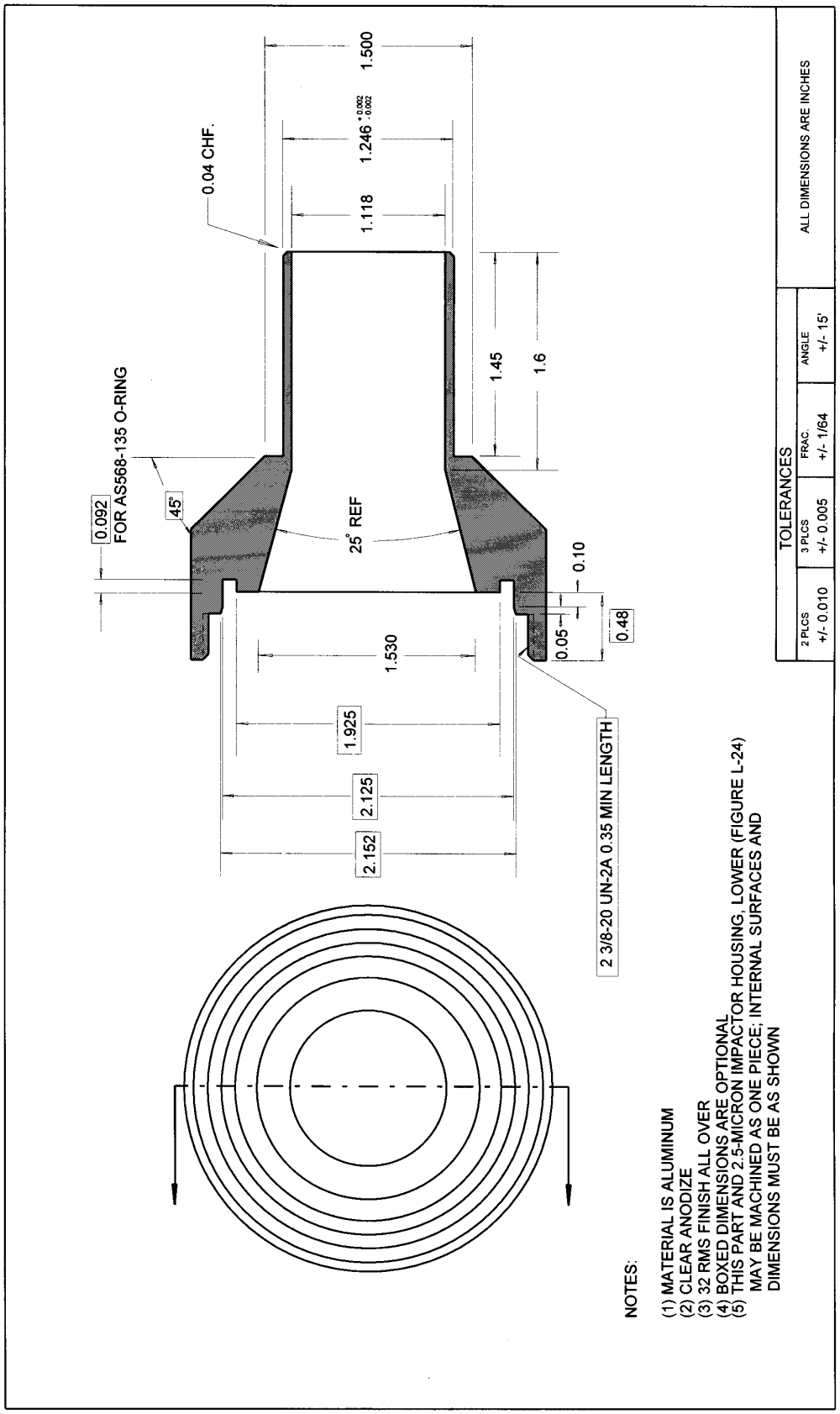


FIGURE L-27. FILTER CASSETTE, UPPER SECTION

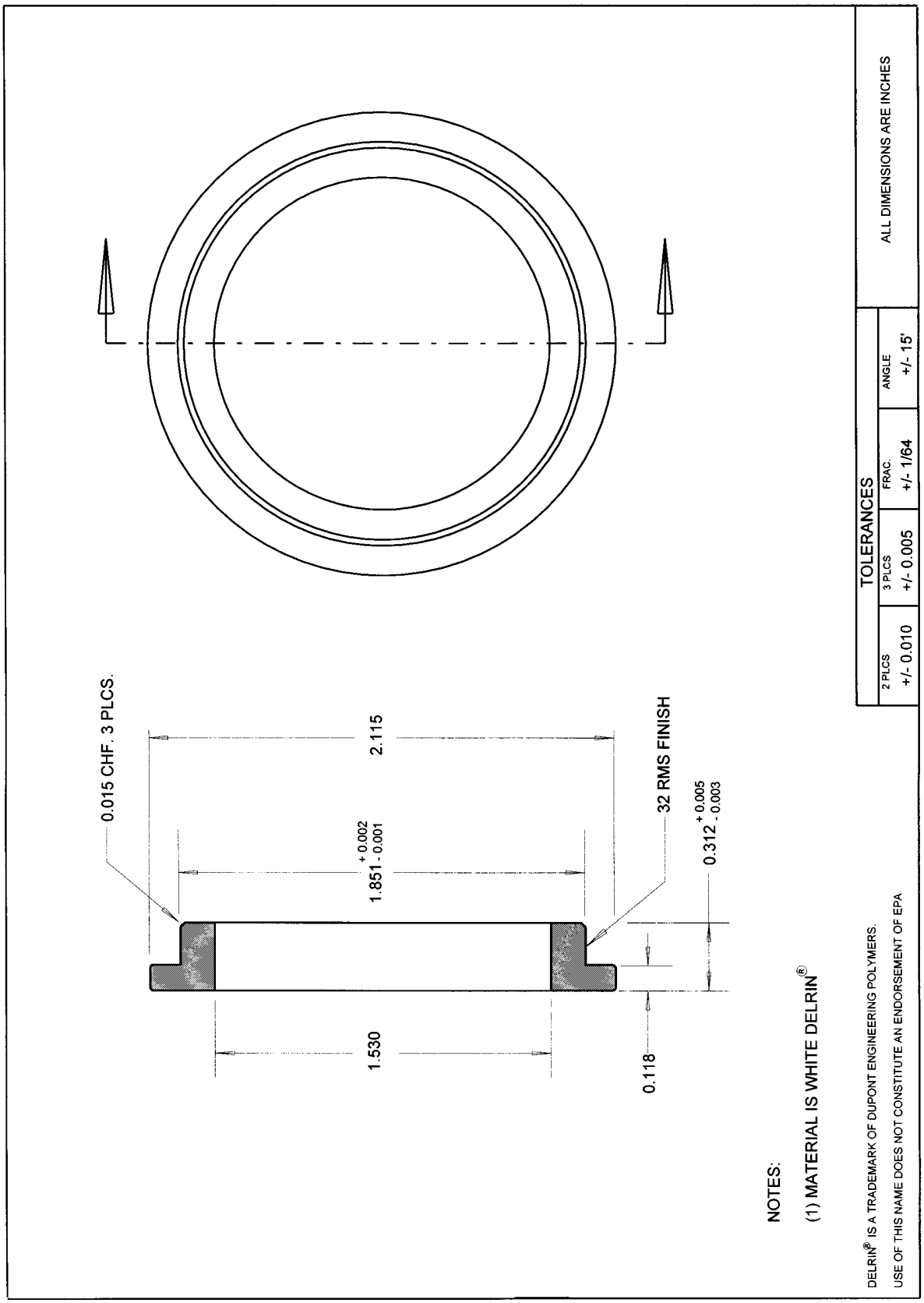


FIGURE L-28. FILTER SCREEN

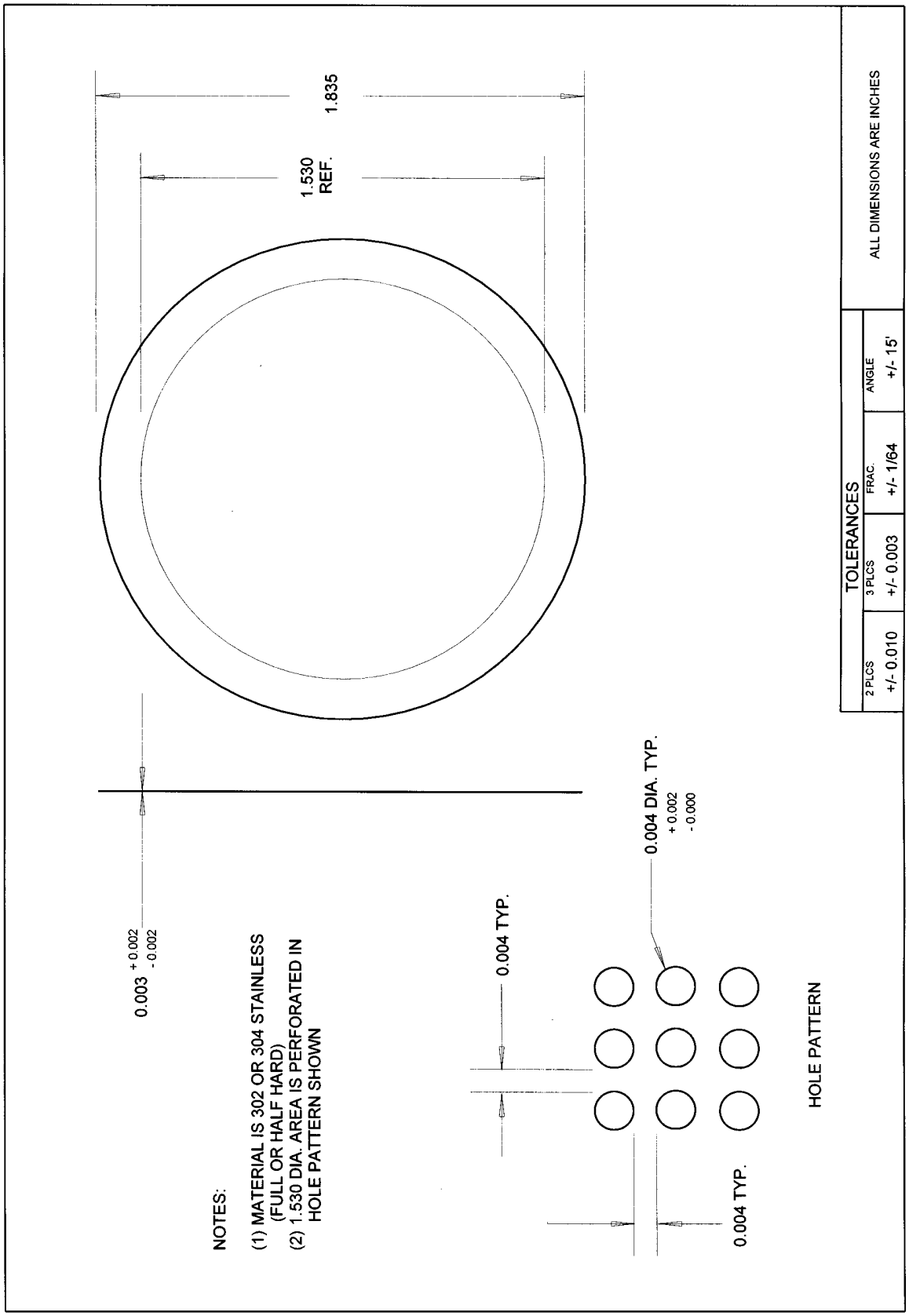


FIGURE L-29. FILTER CASSETTE, LOWER SECTION

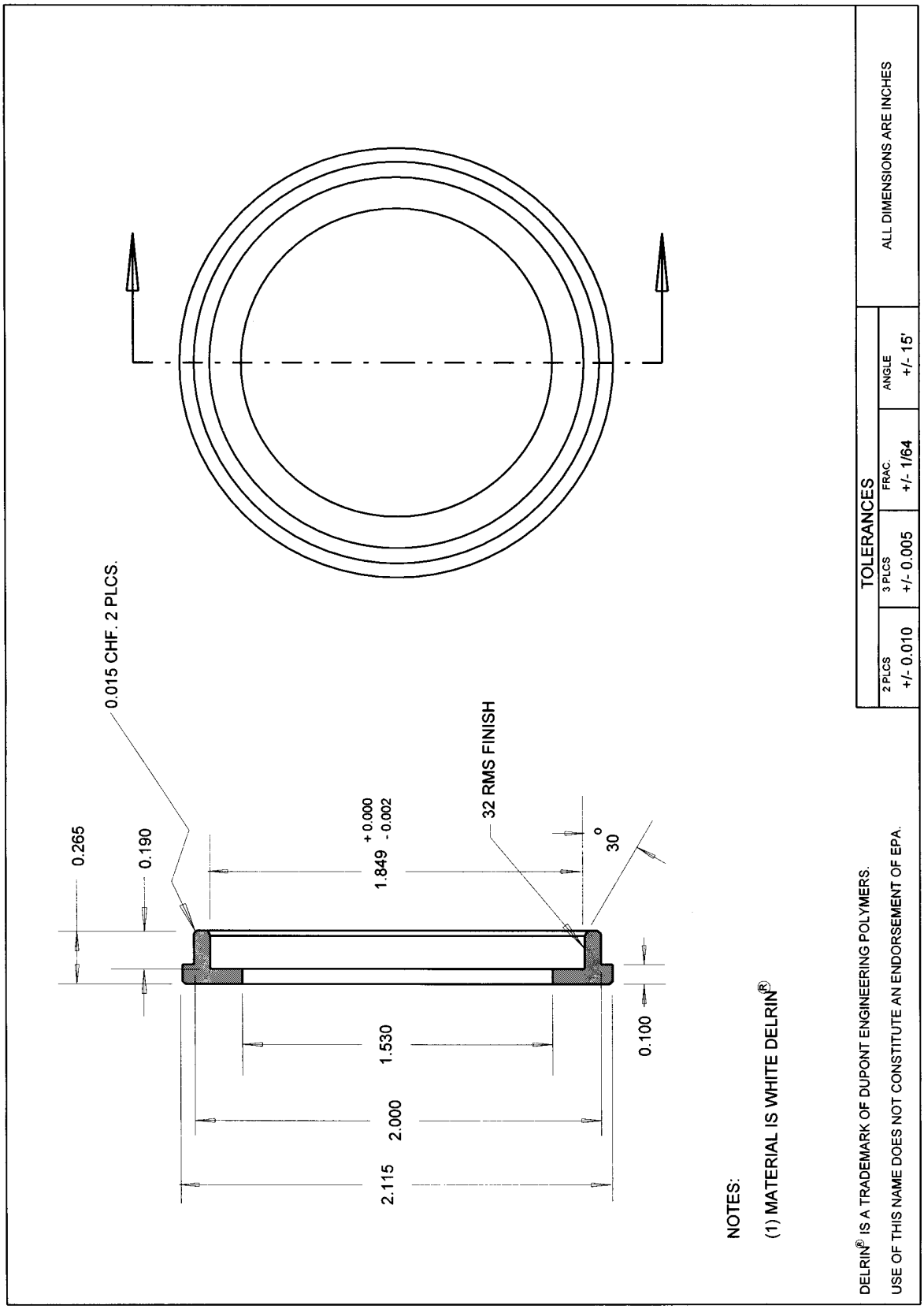
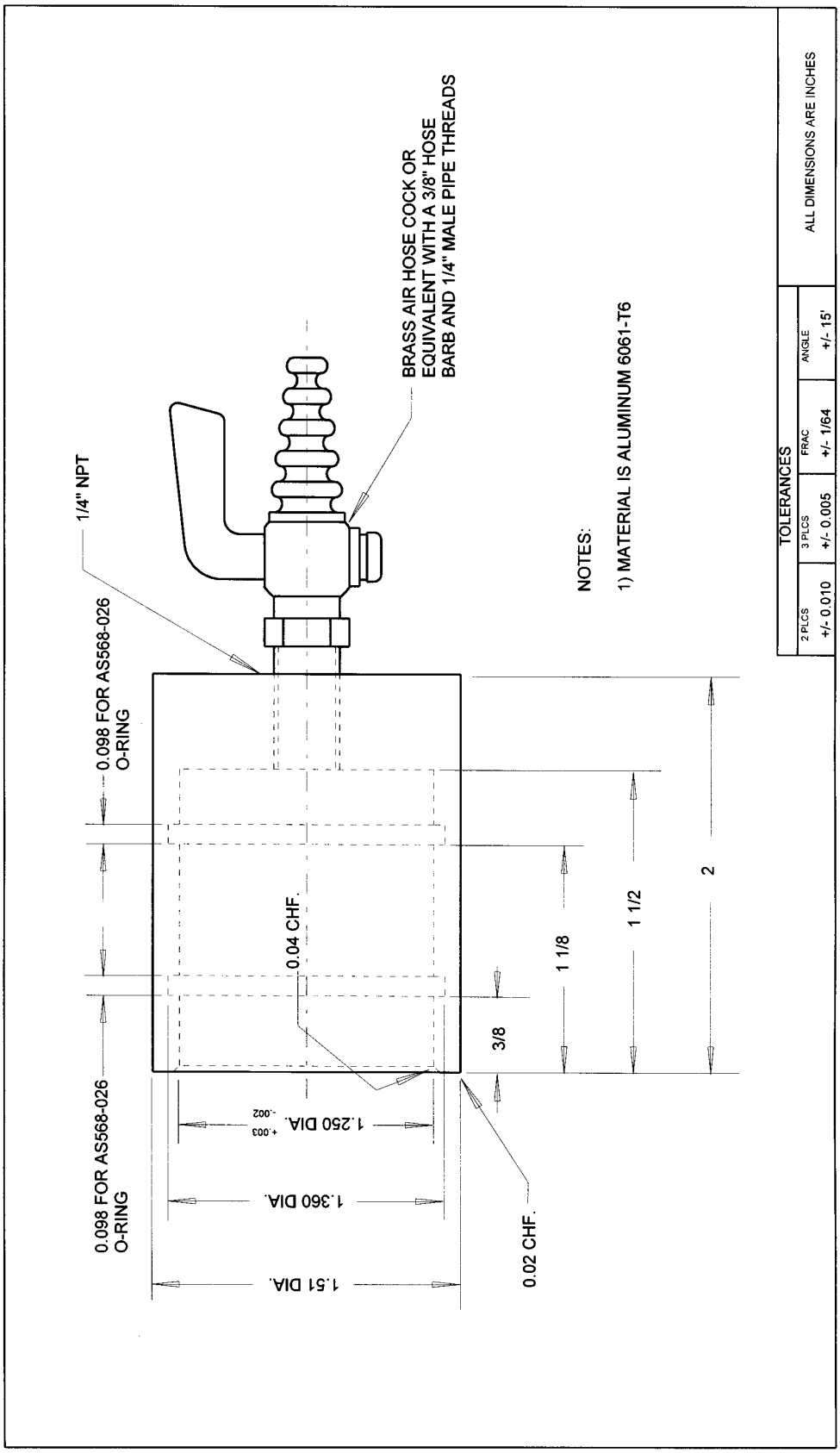


FIGURE L-30. FLOW RATE MEASUREMENT ADAPTER



7. Appendix M is added to read as follows:

Appendix M to Part 50—Reference Method for the Determination of Particulate Matter as PM_{10} in the Atmosphere

1.0 *Applicability.*

1.1 This method provides for the measurement of the mass concentration of particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM_{1O}) in ambient air over a 24-hour period for purposes of determining attainment and maintenance of the primary and secondary national ambient air quality standards for particulate matter specified in § 50.6 of this chapter. The measurement process is nondestructive, and the PM_{10} sample can be subjected to subsequent physical or chemical analyses. Quality assurance procedures and guidance are provided in part 58, Appendices A and B of this chapter and in references 1 and 2 of section 12.0 of this appendix.

2.0 *Principle.*

2.1 An air sampler draws ambient air at a constant flow rate into a specially shaped inlet where the suspended particulate matter is inertially separated into one or more size fractions within the PM_{10} size range. Each size fraction in the PM_{1O} size range is then collected on a separate filter over the specified sampling period. The particle size discrimination characteristics (sampling effectiveness and 50 percent cutpoint) of the sampler inlet are prescribed as performance specifications in part 53 of this chapter.

2.2 Each filter is weighed (after moisture equilibration) before and after use to determine the net weight (mass) gain due to collected PM_{10}. The total volume of air sampled, measured at the actual ambient temperature and pressure, is determined from the measured flow rate and the sampling time. The mass concentration of PM_{10} in the ambient air is computed as the total mass of collected particles in the PM_{10} size range divided by the volume of air sampled, and is expressed in micrograms per actual cubic meter ($\mu g/m^3$).

2.3 A method based on this principle will be considered a reference method only if the associated sampler meets the requirements specified in this appendix and the requirements in part 53 of this chapter, and the method has been designated as a reference method in accordance with part 53 of this chapter.

3.0 *Range.*

3.1 The lower limit of the mass concentration range is determined by the repeatability of filter tare weights, assuming the nominal air sample volume for the sampler. For samplers having an automatic filter-changing mechanism, there may be no upper limit. For samplers that do not have an automatic filter-changing mechanism, the upper limit is determined by the filter mass loading beyond which the sampler no longer maintains the operating flow rate within specified limits due to increased pressure drop across the loaded filter. This upper limit cannot be specified precisely because it is a complex function of the ambient particle size distribution and type, humidity, filter type, and perhaps other factors. Nevertheless, all samplers should be capable of measuring 24-hour PM_{10} mass concentrations of at least 300 $\mu g/m^3$ while maintaining the operating flow rate within the specified limits.

4.0 *Precision.*

4.1 The precision of PM_{10} samplers must be 5 $\mu g/m^3$ for PM_{10} concentrations below 80 $\mu g/m^3$ and 7 percent for PM_{10} concentrations above 80 $\mu g/m^3$, as required by part 53 of this chapter, which prescribes a test procedure that determines the variation in the PM_{10} concentration measurements of identical samplers under typical sampling conditions. Continual assessment of precision via collocated samplers is required by part 58 of this chapter for PM_{10} samplers used in certain monitoring networks.

5.0 *Accuracy.*

5.1 Because the size of the particles making up ambient particulate matter varies over a wide range and the concentration of particles varies with particle size, it is difficult to define the absolute accuracy of PM_{10} samplers. Part 53 of this chapter provides a specification for the sampling effectiveness of PM_{10} samplers. This specification requires that the expected mass concentration calculated for a candidate PM_{10} sampler, when sampling a specified particle size distribution, be within ±10 percent of that calculated for an ideal sampler whose sampling effectiveness is explicitly specified. Also, the particle size for 50 percent sampling effectiveness is required to be 10±0.5 micrometers. Other specifications related to accuracy apply to flow measurement and calibration, filter media, analytical (weighing) procedures, and artifact. The flow rate accuracy of PM_{10} samplers used in certain monitoring networks is required by part 58 of this chapter to be assessed periodically via flow rate audits.

6.0 *Potential Sources of Error.*

6.1 *Volatile Particles.* Volatile particles collected on filters are often lost during shipment and/or storage of the filters prior to the post-sampling weighing [3]. Although shipment or storage of loaded filters is sometimes unavoidable, filters should be reweighed as soon as practical to minimize these losses.

6.2 *Artifacts.* Positive errors in PM_{10} concentration measurements may result from retention of gaseous species on filters [4, 5]. Such errors include the retention of sulfur dioxide and nitric acid. Retention of sulfur dioxide on filters, followed by oxidation to sulfate, is referred to as artifact sulfate formation, a phenomenon which increases with increasing filter alkalinity [6]. Little or no artifact sulfate formation should occur using filters that meet the alkalinity specification in section 7.2.4 of this appendix, Artifact nitrate formation, resulting primarily from retention of nitric acid, occurs to varying degrees on many filter types, including glass fiber, cellulose ester, and many quartz fiber filters [5, 7, 8, 9, 10]. Loss of true atmospheric particulate nitrate during or following sampling may also occur due to dissociation or chemical reaction. This phenomenon has been observed on Teflon® filters [8] and inferred for quartz fiber filters [11, 12]. The magnitude of nitrate artifact errors in PM_{10} mass concentration measurements will vary with location and ambient temperature; however, for most sampling locations, these errors are expected to be small.

6.3 *Humidity.* The effects of ambient humidity on the sample are unavoidable. The filter equilibration procedure in section 9.0 of this appendix is designed to minimize the effects of moisture on the filter medium.

6.4 *Filter Handling.* Careful handling of filters between presampling and postsampling weighings is necessary to avoid errors due to damaged filters or loss of collected particles from the filters. Use of a filter cartridge or cassette may reduce the magnitude of these errors. Filters must also meet the integrity specification in section 7.2.3 of this appendix.

6.5 *Flow Rate Variation.* Variations in the sampler's operating flow rate may alter the particle size discrimination characteristics of the sampler inlet. The magnitude of this error will depend on the sensitivity of the inlet to variations in flow rate and on the particle distribution in the atmosphere during the sampling period. The use of a flow control device, under section 7.1.3 of this appendix, is required to minimize this error.

6.6 *Air Volume Determination.* Errors in the air volume determination may result from errors in the flow rate and/or sampling time measurements. The flow control device serves to minimize errors in the flow rate determination, and an elapsed time meter, under section 7.1.5 of this appendix, is required to minimize the error in the sampling time measurement.

7.0 *Apparatus.*

7.1 PM_{10} Sampler.

7.1.1 The sampler shall be designed to:

(a) Draw the air sample into the sampler inlet and through the particle collection filter at a uniform face velocity.

(b) Hold and seal the filter in a horizontal position so that sample air is drawn downward through the filter.

(c) Allow the filter to be installed and removed conveniently.

(d) Protect the filter and sampler from precipitation and prevent insects and other debris from being sampled.

(e) Minimize air leaks that would cause error in the measurement of the air volume passing through the filter.

(f) Discharge exhaust air at a sufficient distance from the sampler inlet to minimize the sampling of exhaust air.

(g) Minimize the collection of dust from the supporting surface.

7.1.2 The sampler shall have a sample air inlet system that, when operated within a specified flow rate range, provides particle size discrimination characteristics meeting all of the applicable performance specifications prescribed in part 53 of this chapter. The sampler inlet shall show no significant wind direction dependence. The latter requirement can generally be satisfied by an inlet shape that is circularly symmetrical about a vertical axis.

7.1.3 The sampler shall have a flow control device capable of maintaining the sampler's operating flow rate within the flow rate limits specified for the sampler inlet over normal variations in line voltage and filter pressure drop.

7.1.4 The sampler shall provide a means to measure the total flow rate during the sampling period. A continuous flow recorder is recommended but not required. The flow measurement device shall be accurate to ±2 percent.

7.1.5 A timing/control device capable of starting and stopping the sampler shall be used to obtain a sample collection period of 24 ±1 hr (1,440 ±60 min). An elapsed time meter, accurate to within ±15 minutes, shall be used to measure sampling time. This meter is optional for samplers with continuous flow recorders if the sampling time measurement obtained by means of the recorder meets the ±15 minute accuracy specification.

7.1.6 The sampler shall have an associated operation or instruction manual as required by part 53 of this chapter which includes detailed instructions on the calibration, operation, and maintenance of the sampler.

7.2 *Filters.*

7.2.1 *Filter Medium.* No commercially available filter medium is ideal in all respects for all samplers. The user's goals in sampling determine the relative importance of various filter characteristics, e.g., cost, ease of handling, physical and chemical characteristics, etc., and, consequently, determine the choice among acceptable filters. Furthermore, certain types of filters may not be suitable for use with some samplers, particularly under heavy loading conditions (high mass concentrations), because of high or rapid increase in the filter flow resistance that would exceed the capability of the sampler's flow control device. However, samplers equipped with automatic filter-changing mechanisms may allow use of these types of filters. The specifications given below are minimum requirements to ensure acceptability of the filter medium for measurement of PM_{10} mass concentrations. Other filter evaluation criteria should be considered to meet individual sampling and analysis objectives.

7.2.2 *Collection Efficiency.* ≥99 percent, as measured by the DOP test (ASTM–2986) with 0.3 µm particles at the sampler's operating face velocity.

7.2.3 *Integrity.* ±5 µg/m^3 (assuming sampler's nominal 24-hour air sample volume). Integrity is measured as the PM_{10} concentration equivalent corresponding to the average difference between the initial and the final weights of a random sample of test filters that are weighed and handled under actual or simulated sampling conditions, but have no air sample passed through them, i.e., filter blanks. As a minimum, the test procedure must include initial equilibration and weighing, installation on an inoperative sampler, removal from the sampler, and final equilibration and weighing.

7.2.4 *Alkalinity.* <25 microequivalents/gram of filter, as measured by the procedure given in reference 13 of section 12.0 of this appendix following at least two months storage in a clean environment (free from contamination by acidic gases) at room temperature and humidity.

7.3 *Flow Rate Transfer Standard.* The flow rate transfer standard must be suitable for the sampler's operating flow rate and must be calibrated against a primary flow or volume standard that is traceable to the National Institute of Standard and Technology (NIST). The flow rate transfer standard must be capable of measuring the sampler's operating flow rate with an accuracy of ±2 percent.

7.4 *Filter Conditioning Environment.*

7.4.1 *Temperature range.* 15 to 30 C.

7.4.2 *Temperature control.* ±3 C.

7.4.3 *Humidity range.* 20% to 45% RH.

7.4.4 *Humidity control.* ±5% RH.

7.5 *Analytical Balance.* The analytical balance must be suitable for weighing the type and size of filters required by the sampler. The range and sensitivity required will depend on the filter tare weights and mass loadings. Typically, an analytical balance with a sensitivity of 0.1 mg is required for high volume samplers (flow rates >0.5 m^3/min). Lower volume samplers (flow rates <0.5 m^3/min) will require a more sensitive balance.

8.0 *Calibration.*

8.1 *General Requirements.*

8.1.1 Calibration of the sampler's flow measurement device is required to establish traceability of subsequent flow measurements to a primary standard. A flow rate transfer standard calibrated against a primary flow or volume standard shall be used to calibrate or verify the accuracy of the sampler's flow measurement device.

8.1.2 Particle size discrimination by inertial separation requires that specific air velocities be maintained in the sampler's air inlet system. Therefore, the flow rate through the sampler's inlet must be maintained throughout the sampling period within the design flow rate range specified by the manufacturer. Design flow rates are specified as actual volumetric flow rates, measured at existing conditions of temperature and pressure (Q_a).

8.2 *Flow Rate Calibration Procedure.*

8.2.1 PM_{10} samplers employ various types of flow control and flow measurement devices. The specific procedure used for flow rate calibration or verification will vary depending on the type of flow controller and flow rate indicator employed. Calibration is in terms of actual volumetric flow rates (Q_a) to meet the requirements of section 8.1 of this appendix. The general procedure given here serves to illustrate the steps involved in the calibration. Consult the sampler manufacturer's instruction manual and reference 2 of section 12.0 of this appendix for specific guidance on calibration. Reference 14 of section 12.0 of this appendix provides additional information on various other measures of flow rate and their interrelationships.

8.2.2 Calibrate the flow rate transfer standard against a primary flow or volume standard traceable to NIST. Establish a calibration relationship, e.g., an equation or family of curves, such that traceability to the primary standard is accurate to within 2 percent over the expected range of ambient conditions, i.e., temperatures and pressures, under which the transfer standard will be used. Recalibrate the transfer standard periodically.

8.2.3 Following the sampler manufacturer's instruction manual, remove the sampler inlet and connect the flow rate transfer standard to the sampler such that the transfer standard accurately measures the sampler's flow rate. Make sure there are no leaks between the transfer standard and the sampler.

8.2.4 Choose a minimum of three flow rates (actual m^3/min), spaced over the acceptable flow rate range specified for the inlet, under section 7.1.2 of the appendix, that can be obtained by suitable adjustment of the sampler flow rate. In accordance with the sampler manufacturer's instruction manual, obtain or verify the calibration relationship between the flow rate (actual m^3/min) as indicated by the transfer standard and the sampler's flow indicator response. Record the ambient temperature and barometric pressure. Temperature and pressure corrections to subsequent flow indicator readings may be required for certain types of flow measurement devices. When such corrections are necessary, correction on an individual or daily basis is preferable. However, seasonal average temperature and average barometric pressure for the sampling site may be incorporated into the sampler calibration to avoid daily corrections. Consult the sampler manufacturer's instruction manual and reference 2 in section 12.0 of this appendix for additional guidance.

8.2.5 Following calibration, verify that the sampler is operating at its design flow rate (actual m^3/min) with a clean filter in place.

8.2.6 Replace the sampler inlet.

9.0 *Procedure.*

9.1 The sampler shall be operated in accordance with the specific guidance provided in the sampler manufacturer's instruction manual and in reference 2 in section 12.0 of this appendix. The general procedure given here assumes that the sampler's flow rate calibration is based on flow rates at ambient conditions (Q_a) and serves to illustrate the steps involved in the operation of a PM_{10} sampler.

9.2 Inspect each filter for pinholes, particles, and other imperfections. Establish a filter information record and assign an identification number to each filter.

9.3 Equilibrate each filter in the conditioning environment (see 7.4) for at least 24 hours.

9.4 Following equilibration, weigh each filter and record the presampling weight with the filter identification number.

9.5 Install a preweighed filter in the sampler following the instructions provided in the sampler manufacturer's instruction manual.

9.6 (a) Turn on the sampler and allow it to establish run-temperature conditions. Record the flow indicator reading and, if needed, the ambient temperature and barometric pressure. Determine the sampler flow rate (actual m^3/min) in accordance with the instructions provided in the sampler manufacturer's instruction manual.

(b) Note: No onsite temperature or pressure measurements are necessary if the sampler's flow indicator does not require temperature or pressure corrections or if seasonal average temperature and average barometric pressure for the sampling site are incorporated into

the sampler calibration, under section 8.2.4 of this appendix. If individual or daily temperature and pressure corrections are required, ambient temperature and barometric pressure can be obtained by on-site measurements or from a nearby weather station. Barometric pressure readings obtained from airports must be station pressure, not corrected to sea level, and may need to be corrected for differences in elevation between the sampling site and the airport.

9.7 If the flow rate is outside the acceptable range specified by the manufacturer, check for leaks, and if necessary, adjust the flow rate to the specified setpoint. Stop the sampler.

9.8 Set the timer to start and stop the sampler at appropriate times. Set the elapsed time meter to zero or record the initial meter reading.

9.9 Record the sample information (site location or identification number, sample date, filter identification number, and sampler model and serial number).

9.10 Sample for 24±1 hours.

9.11 Determine and record the average flow rate ($\bar{Q}_a$) in actual m^3/min for the sampling period in accordance with the instructions provided in the sampler manufacturer's instruction manual. Record the elapsed time meter final reading and, if needed, the average ambient temperature and barometric pressure for the sampling period, in note following section 9.6 of this appendix.

9.12 Carefully remove the filter from the sampler, following the sampler manufacturer's instruction manual. Touch only the outer edges of the filter.

9.13 Place the filter in a protective holder or container, e.g., petri dish, glassine envelope, or manila folder.

9.14 Record any factors such as meteorological conditions, construction activity, fires or dust storms, etc., that might be pertinent to the measurement on the filter information record.

9.15 Transport the exposed sample filter to the filter conditioning environment as soon as possible for equilibration and subsequent weighing.

9.16 Equilibrate the exposed filter in the conditioning environment for at least 24 hours under the same temperature and humidity conditions used for presampling filter equilibration (see section 9.3 of this appendix).

9.17 Immediately after equilibration, reweigh the filter and record the postsampling weight with the filter identification number.

10.0 *Sampler Maintenance.*

10.1 The PM_{10} sampler shall be maintained in strict accordance with the maintenance procedures specified in the sampler manufacturer's instruction manual.

11.0 *Calculations.*

11.1 Calculate the total volume of air sampled as:

$$V = Q_a t$$

where:

V = total air sampled, at ambient temperature and pressure, m^3;

Q_a = average sample flow rate at ambient temperature and pressure, m^3/min; and

t = sampling time, min.

11.2 (a) Calculate the PM_{10} concentration as:

$$PM_{10} = (W_f - W_i) \times 10^6 / V$$

where:

PM_{10} = mass concentration of PM_{10}, $\mu g/m^3$;

W_f, W_i = final and initial weights of filter collecting PM_{1O} particles, g; and

10^6 = conversion of g to µg.

(b) Note: If more than one size fraction in the PM_{10} size range is collected by the sampler, the sum of the net weight gain by each collection filter $[\Sigma(W_f - W_i)]$ is used to calculate the PM_{10} mass concentration.

12.0 *References.*

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8. Appendix N is added to read as follows:

Appendix N to Part 50—Interpretation of the National Ambient Air Quality Standards for Particulate Matter

1.0 *General.*

(a) This appendix explains the data handling conventions and computations necessary for determining when the annual and 24-hour primary and secondary national ambient air quality standards for PM specified in § 50.7 of this chapter are met. Particulate matter is measured in the ambient air as PM_{10} and $PM_{2.5}$ (particles with an aerodynamic diameter less than or equal to a nominal 10 and 2.5 micrometers, respectively) by a reference method based on Appendix M of this part for PM_{10} and on Appendix L of this part for $PM_{2.5}$, as applicable, and designated in accordance with part 53 of this chapter, or by an equivalent method designated in accordance with part 53 of this chapter. Data handling and computation procedures to be used in making comparisons between reported PM_{10} and $PM_{2.5}$ concentrations and the levels of the PM standards are specified in the following sections.

(b) Data resulting from uncontrollable or natural events, for example structural fires or high winds, may require special consideration. In some cases, it may be appropriate to exclude these data because they could result in inappropriate values to compare with the levels of the PM standards. In other cases, it may be more appropriate to retain the data for comparison with the level of the PM standards and then allow the EPA to formulate the appropriate regulatory response. Whether to exclude, retain, or make adjustments to the data affected by uncontrollable or natural events is subject to the approval of the appropriate Regional Administrator.

(c) The terms used in this appendix are defined as follows:

Average and *mean* refer to an arithmetic mean.

Daily value for PM refers to the 24-hour average concentration of PM calculated or measured from midnight to midnight (local time) for PM_{10} or $PM_{2.5}$.

Designated monitors are those monitoring sites designated in a State PM Monitoring Network Description for spatial averaging in areas opting for spatial averaging in accordance with part 58 of this chapter.

98th *percentile* (used for $PM_{2.5}$) means the daily value out of a year of monitoring data below which 98 percent of all values in the group fall.

99th *percentile* (used for PM_{10}) means the daily value out of a year of monitoring data below which 99 percent of all values in the group fall.

Year refers to a calendar year.

(d) Sections 2.1 and 2.5 of this appendix contain data handling instructions for the option of using a spatially averaged network of monitors for the annual standard. If spatial averaging is not considered for an area, then the spatial average is equivalent to the annual average of a single site and is treated accordingly in subsequent calculations. For example, paragraph (a)(3) of section 2.1 of this appendix could be eliminated since the spatial average would be equivalent to the annual average.

2.0 *Comparisons with the $PM_{2.5}$ Standards.*

2.1 *Annual $PM_{2.5}$ Standard.*

(a) The annual $PM_{2.5}$ standard is met when the 3-year average of the spatially averaged annual means is less than or equal to 15.0 μg/m³. The 3-year average of the spatially averaged annual means is determined by averaging quarterly means at each monitor to obtain the annual mean $PM_{2.5}$ concentrations at each monitor, then averaging across all designated monitors, and finally averaging for 3 consecutive years. The steps can be summarized as follows:

(1) Average 24-hour measurements to obtain quarterly means at each monitor.

(2) Average quarterly means to obtain annual means at each monitor.

(3) Average across designated monitoring sites to obtain an annual spatial mean for an area (this can be one site in which case the spatial mean is equal to the annual mean).

(4) Average 3 years of annual spatial means to obtain a 3-year average of spatially averaged annual means.

(b) In the case of spatial averaging, 3 years of spatial averages are required to demonstrate that the standard has been met. Designated sites with less than 3 years of data shall be included in spatial averages for those years that data completeness requirements are met. For the annual $PM_{2.5}$ standard, a year meets data completeness requirements when at least 75 percent of the scheduled sampling days for each quarter have valid data. However, years with high concentrations and more than a minimal amount of data (at least 11 samples in each quarter) shall not be ignored just because they are comprised of quarters with less than complete data. Thus, in computing annual spatially averaged means, years containing quarters with at least 11 samples but less than 75 percent data completeness shall be included in the computation if the resulting spatially averaged annual mean concentration (rounded according to the conventions of section 2.3 of this appendix) is greater than the level of the standard.

(c) Situations may arise in which there are compelling reasons to retain years containing quarters which do not meet the data completeness requirement of 75 percent or the minimum number of 11 samples. The use of less than complete data is subject to the approval of the appropriate Regional Administrator.

(d) The equations for calculating the 3-year average annual mean of the $PM_{2.5}$ standard are given in section 2.5 of this appendix.

2.2 *24-Hour $PM_{2.5}$ Standard.*

(a) The 24-hour $PM_{2.5}$ standard is met when the 3-year average of the 98th percentile values at each monitoring site is less than or equal to 65 μg/m³. This comparison shall be based on 3 consecutive, complete years of air quality data. A year meets data completeness requirements when at least 75 percent of the scheduled sampling days for each quarter have valid data. However, years with high concentrations shall not be ignored just because they are comprised of quarters with less than complete data. Thus, in computing the 3-year average 98th percentile value, years containing quarters with less than 75 percent data completeness shall be included in the computation if the annual 98th percentile value (rounded according to the conventions of section 2.3 of this appendix) is greater than the level of the standard.

(b) Situations may arise in which there are compelling reasons to retain years containing quarters which do not meet the data completeness requirement. The use of less than complete data is subject to the approval of the appropriate Regional Administrator.

(c) The equations for calculating the 3-year average of the annual 98th percentile values is given in section 2.6 of this appendix.

2.3 *Rounding Conventions.* For the purposes of comparing calculated values to the applicable level of the standard, it is necessary to round the final results of the calculations described in sections 2.5 and 2.6 of this appendix. For the annual $PM_{2.5}$ standard, the 3-year average of the spatially averaged annual means shall be rounded to the nearest 0.1 μg/m³ (decimals 0.05 and greater are rounded up to the next 0.1, and any decimal lower than 0.05 is rounded down to the nearest 0.1). For the 24-hour $PM_{2.5}$ standard, the 3-year average of the annual 98th percentile values shall be rounded to the nearest 1 μg/m³ (decimals 0.5 and greater are rounded up to nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

2.4 *Monitoring Considerations.*

(a) Section 58.13 of this chapter specifies the required minimum frequency of sampling for $PM_{2.5}$. Exceptions to the specified sampling frequencies, such as a reduced frequency during a season of expected low concentrations, are subject to the approval of the appropriate Regional Administrator. Section 58.14 of 40 CFR part 58 and section 2.8 of Appendix D of 40 CFR part 58, specify which monitors are eligible for making comparisons with the PM standards. In determining a spatial mean using two or more monitoring sites operating in a given year, the annual mean for an individual site may be included in the spatial mean if and only if the mean for that site meets the criterion specified in § 2.8 of Appendix D of 40 CFR part 58. In the event data from an otherwise eligible site is excluded from being averaged with data from other sites on the basis of this criterion, then the 3-year mean from that site shall be compared directly to the annual standard.

(b) For the annual $PM_{2.5}$ standard, when designated monitors are located at the same site and are reporting $PM_{2.5}$ values for the same time periods, and when spatial averaging has been chosen, their concentrations shall be averaged before an area-wide spatial average is calculated. Such monitors will then be considered as one monitor.

2.5 *Equations for the Annual $PM_{2.5}$ Standard.*

(a) An annual mean value for $PM_{2.5}$ is determined by first averaging the daily values of a calendar quarter:

Equation 1

$$\bar{x}_{q,y,s} = \frac{1}{n_q}\sum_{i=1}^{n_q} x_{i,q,y,s}$$

where:

$\bar{x}_{q,y,s}$ = the mean for quarter q of year y for site s;

n_q = the number of monitored values in the quarter; and

$x_{i,q,y,s}$ = the ith value in quarter q for year y for site s.

(b) The following equation is then to be used for calculation of the annual mean:

Equation 2

$$\bar{x}_{y,s} = \frac{1}{4}\sum_{q=1}^{4} \bar{x}_{q,y,s}$$

where:

$\bar{x}_{y,s}$ = the annual mean concentration for year y (y = 1, 2, or 3) and for site s; and

$\bar{x}_{q,y,s}$ = the mean for quarter q of year y for site s.

(c) (1) The spatially averaged annual mean for year y is computed by first calculating the annual mean for each site designated to be included in a spatial average, $\bar{x}_{y,s}$, and then computing the average of these values across sites:

Equation 3

$$\bar{x}_{y} = \frac{1}{n_s}\sum_{s=1}^{n_s} \bar{x}_{y,s}$$

where:

$\bar{x}_{y}$ = the spatially averaged mean for year y;

$\bar{x}_{y,s}$ = the annual mean for year y and site s; and

n_s = the number of sites designated to be averaged.

(2) In the event that an area designated for spatial averaging has two or more sites at the same location producing data for the same time periods, the sites are averaged together before using Equation 3 by:

Equation 4

$$\bar{x}_{y,s*} = \frac{1}{n_c}\sum_{s=1}^{n_c} \bar{x}_{y,s}$$

where:

$\bar{x}_{y,s*}$ = the annual mean for year y for the sites at the same location (which will now be considered one site);

n_c = the number of sites at the same location designated to be included in the spatial average; and

$\bar{x}_{y,s}$ = the annual mean for year y and site s.

(d) The 3-year average of the spatially averaged annual means is calculated by using the following equation:

Equation 5

$$\bar{x} = \frac{1}{3}\sum_{y=1}^{3} \bar{x}_y$$

where:

$\bar{x}$ = the 3-year average of the spatially averaged annual means; and

$\bar{x}_y$ = the spatially averaged annual mean for year y.

Example 1—Area Designated for Spatial Averaging That Meets the Primary Annual $PM_{2.5}$ Standard.

a. In an area designated for spatial averaging, four designated monitors recorded data in at least 1 year of a particular 3-year period. Using Equations 1 and 2, the annual means for $PM_{2.5}$ at each site are calculated for each year. The following table can be created from the results. Data completeness percentages for the quarter with the fewest number of samples are also shown.

Table 1.—Results from Equations 1 and 2

		Site #1	Site #2	Site #3	Site #4	Spatial mean
Year 1	Annual mean (μg/m³)	12.7				12.7
	% data completeness	80	0	0	0	
Year 2	Annual mean (μg/m³)	12.6	17.5	15.2		15.05
	% data completeness	90	63	38	0	
Year 3	Annual mean (μg/m³)	12.5	18.5	14.1	16.9	15.50
	% data completeness	90	80	85	50	
3-year mean						14.42

b. The data from these sites are averaged in the order described in section 2.1 of this appendix. Note that the annual mean from site #3 in year 2 and the annual mean from site #4 in year 3 do not meet the 75 percent data completeness criteria. Assuming the 38 percent data completeness represents a quarter with fewer than 11 samples, site #3 in year 2 does not meet the minimum data completeness requirement of 11 samples in each quarter. The site is therefore excluded from the calculation of the spatial mean for year 2. However, since the spatial mean for year 3 is above the level of the standard and the minimum data requirement of 11 samples in each quarter has been met, the annual mean from site #4 in year 3 is included in the calculation of the spatial mean for year 3 and in the calculation of the 3-year average. The 3-year average is rounded to 14.4 μg/m³, indicating that this area meets the annual $PM_{2.5}$ standard.

Example 2—Area With Two Monitors at the Same Location That Meets the Primary Annual $PM_{2.5}$ Standard.

a. In an area designated for spatial averaging, six designated monitors, with two monitors at the same location (#5 and #6), recorded data in a particular 3-year period. Using Equations 1 and 2, the annual means for $PM_{2.5}$ are calculated for each year. The following table can be created from the results.

Table 2.—Results From Equations 1 and 2

Annual mean (μg/m³)	Site #1	Site #2	Site #3	Site #4	Site #5	Site #6	Average of #5 and #6	Spatial mean
Year 1	12.9	9.9	12.6	11.1	14.5	14.6	14.55	12.21
Year 2	14.5	13.3	12.2	10.9	16.1	16.0	16.05	13.39
Year 3	14.4	12.4	11.5	9.7	12.3	12.1	12.20	12.04
3-Year mean								12.55

b. The annual means for sites #5 and #6 are averaged together using Equation 4 before the spatial average is calculated using Equation 3 since they are in the same location. The 3-year mean is rounded to 12.6 μg/m³, indicating that this area meets the annual $PM_{2.5}$ standard.

Example 3—Area With a Single Monitor That Meets the Primary Annual $PM_{2.5}$ Standard.

a. Given data from a single monitor in an area, the calculations are as follows. Using Equations 1 and 2, the annual means for $PM_{2.5}$ are calculated for each year. If the annual means are 10.28, 17.38, and 12.25 μg/m³, then the 3-year mean is:

$$\bar{x} = (1/3)\times(10.28+17.38+12.25) = 13.303\ \mu g/m^3.$$

b. This value is rounded to 13.3, indicating that this area meets the annual $PM_{2.5}$ standard.

2.6 *Equations for the 24-Hour $PM_{2.5}$ Standard.*

(a) When the data for a particular site and year meet the data completeness requirements in section 2.2 of this appendix, calculation of the 98th percentile is accomplished by the following steps. All the daily values from a particular site and year comprise a series of values (x_1, x_2, x_3, ..., x_n), that can be sorted into a series where each number is equal to or larger than the preceding number ($x_{[1]}$, $x_{[2]}$, $x_{[3]}$, ..., $x_{[n]}$). In this case, $x_{[1]}$ is the smallest number and $x_{[n]}$ is the largest value. The 98th percentile is found from the sorted series of daily values which is ordered from the lowest to the highest number. Compute (0.98) × (n) as the number ''i.d'', where ''i'' is the integer part of the result and ''d'' is the decimal part of the result. The 98th percentile value for year y, $P_{0.98,\ y}$, is given by Equation 6:

Equation 6

$$P_{0.98,y} = X_{[i+1]}$$

where:

$P_{0.98,y}$ = 98th percentile for year y;

$x_{[i+1]}$ = the (i+1)th number in the ordered series of numbers; and

i = the integer part of the product of 0.98 and n.

(b) The 3-year average 98th percentile is then calculated by averaging the annual 98th percentiles:

Equation 7

$$P_{0.98} = \frac{\sum_{y=1}^{3} P_{0.98,y}}{3}$$

(c) The 3-year average 98th percentile is rounded according to the conventions in section 2.3 of this appendix before a comparison with the standard is made.

Example 4—Ambient Monitoring Site With Every-Day Sampling That Meets the Primary 24-Hour $PM_{2.5}$ Standard.

a. In each year of a particular 3 year period, varying numbers of daily $PM_{2.5}$ values (e.g., 281, 304, and 296) out of a possible 365 values were recorded at a particular site with the following ranked values (in μg/m³):

Table 3.—Ordered Monitoring Data For 3 Years

Year 1		Year 2		Year 3	
j rank	X_j value	j rank	X_j value	j rank	X_j value
275	57.9	296	54.3	290	66.0
276	59.0	297	57.1	291	68.4
277	62.2	298	63.0	292	69.8

b. Using Equation 6, the 98th percentile values for each year are calculated as follows:

$$0.98 \times 281 = 275.38 \Rightarrow i+1 = 276 \Rightarrow P_{0.98,1} = X_{[276]} = 59.0 \mu g / m^3$$

$$0.98 \times 304 = 297.92 \Rightarrow i+1 = 298 \Rightarrow P_{0.98,2} = X_{[298]} = 63.0 \mu g / m^3$$

$$0.98 \times 296 = 290.07 \Rightarrow i+1 = 291 \Rightarrow P_{0.98,3} = X_{[291]} = 68.4 \mu g / m^3$$

c. 1. Using Equation 7, the 3-year average 98th percentile is calculated as follows:

$$P_{0.98} = \frac{59.0 + 63.0 + 68.4}{3} = 63.46 \mu g / m^3, \text{ which rounds to } 63 \mu g / m^3.$$

2. Therefore, this site meets the 24-hour $PM_{2.5}$ standard.

3.0 *Comparisons with the PM_{10} Standards.*

3.1 *Annual PM_{10} Standard.*

(a) The annual PM_{10} standard is met when the 3-year average of the annual mean PM_{10} concentrations at each monitoring site is less than or equal to 50 μg/m³. The 3-year average of the annual means is determined by averaging quarterly means to obtain annual mean PM_{10} concentrations for 3 consecutive, complete years at each monitoring site. The steps can be summarized as follows:

(1) Average 24-hour measurements to obtain a quarterly mean.

(2) Average quarterly means to obtain an annual mean.

(3) Average annual means to obtain a 3-year mean.

(b) For the annual PM_{10} standard, a year meets data completeness requirements when at least 75 percent of the scheduled sampling days for each quarter have valid data. However, years with high concentrations and more than a minimal amount of data (at least 11 samples in each quarter) shall not be ignored just because they are comprised of quarters with less than complete data. Thus, in computing the 3-year average annual mean concentration, years containing quarters with at least 11 samples but less than 75 percent data completeness shall be included in the computation if the annual mean concentration (rounded according to the conventions of section 2.3 of this appendix) is greater than the level of the standard.

(c) Situations may arise in which there are compelling reasons to retain years containing quarters which do not meet the data completeness requirement of 75 percent or the minimum number of 11 samples. The use of less than complete data is subject to the approval of the appropriate Regional Administrator.

(d) The equations for calculating the 3-year average annual mean of the PM_{10} standard are given in section 3.5 of this appendix.

3.2 *24-Hour PM_{10} Standard.*

(a) The 24-hour PM_{10} standard is met when the 3-year average of the annual 99th percentile values at each monitoring site is less than or equal to 150 μg/m³. This comparison shall be based on 3 consecutive, complete years of air quality data. A year meets data completeness requirements when at least 75 percent of the scheduled sampling days for each quarter have valid data. However, years with high concentrations shall not be ignored just because they are comprised of quarters with less than complete data. Thus, in computing the 3-year average of the annual 99th percentile values, years containing quarters with less than 75 percent data completeness shall be included in the computation if the annual 99th percentile value (rounded according to the conventions of section 2.3 of this appendix) is greater than the level of the standard.

(b) Situations may arise in which there are compelling reasons to retain years containing quarters which do not meet the data completeness requirement. The use of less than complete data is subject to the approval of the appropriate Regional Administrator.

(c) The equation for calculating the 3-year average of the annual 99th percentile values is given in section 2.6 of this appendix.

3.3 *Rounding Conventions.* For the annual PM_{10} standard, the 3-year average of the annual PM_{10} means shall be rounded to the nearest 1 μg/m³ (decimals 0.5 and greater are

rounded up to the next whole number, and any decimal less than 0.5 is rounded down to the nearest whole number). For the 24-hour PM_{10} standard, the 3-year average of the annual 99th percentile values of PM_{10} shall be rounded to the nearest 10 μg/m³ (155 μg/m³ and greater would be rounded to 160 μg/m³ and 154 μg/m³ and less would be rounded to 150 μg/m³).

3.4 *Monitoring Considerations.* Section 58.13 of this chapter specifies the required minimum frequency of sampling for PM_{10}. Exceptions to the specified sampling frequencies, such as a reduced frequency during a season of expected low concentrations, are subject to the approval of the appropriate Regional Administrator. For making comparisons with the PM_{10} NAAQS, all sites meeting applicable requirements in part 58 of this chapter would be used.

3.5 *Equations for the Annual PM_{10} Standard.*

(a) An annual arithmetic mean value for PM_{10} is determined by first averaging the 24-hour values of a calendar quarter using the following equation:

Equation 8

$$\bar{x}_{q,y} = \frac{1}{n_q}\sum_{i=1}^{n_q} x_{i,q,y}$$

where:

$\bar{x}_{q,y}$ = the mean for quarter q of year y;

n_q = the number of monitored values in the quarter; and

$x_{i,q,y}$ = the ith value in quarter q for year y.

(b) The following equation is then to be used for calculation of the annual mean:

Equation 9

$$\bar{x}_y = \frac{1}{4}\sum_{q=1}^{4} \bar{x}_{q,y}$$

where:

$\bar{x}_y$ = the annual mean concentration for year y, (y=1, 2, or 3); and

$x_{q,y}$ = the mean for a quarter q of year y.

(c) The 3-year average of the annual means is calculated by using the following equation:

Equation 10

$$\bar{x} = \frac{1}{3}\sum_{y=1}^{3} \bar{x}_y$$

where:

$\bar{x}$ = the 3-year average of the annual means; and

$\bar{x}_y$ = the annual mean for calendar year y.

Example 5—Ambient Monitoring Site That Does Not Meet the Annual PM_{10} Standard.

a. Given data from a PM_{10} monitor and using Equations 8 and 9, the annual means for PM_{10} are calculated for each year. If the annual means are 52.42, 82.17, and 63.23 μg/m³, then the 3-year average annual mean is:

$$\bar{x} = (1/3) \times (52.42 + 82.17 + 63.23) = 65.94, \text{ which is rounded to } 66\ \mu g/m^3.$$

b. Therefore, this site does not meet the annual PM_{10} standard.

3.6 *Equation for the 24-Hour PM_{10} Standard.*

(a) When the data for a particular site and year meet the data completeness requirements in section 3.2 of this appendix, calculation of the 99th percentile is accomplished by the following steps. All the daily values from a particular site and year comprise a series of values (x_1, x_2, x_3, ..., x_n) that can be sorted into a series where each number is equal to or larger than the preceding number ($x_{[1]}$, $x_{[2]}$, $x_{[3]}$, ..., $x_{[n]}$). In this case, $x_{[1]}$ is the smallest number and x[n] is the largest value. The 99th percentile is found from the sorted series of daily values which is ordered from the lowest to the highest number. Compute (0.99) × (n) as the number ''i.d'', where ''i'' is the integer part of the result and ''d'' is the decimal part of the result. The 99th percentile value for year y, $P_{0.99,y}$, is given by Equation 11:

Equation 11

$$P_{0.99,y} = X_{[i+1]}$$

where:

$P_{0.99,y}$ = the 99th percentile for year y;

$x_{[i+1]}$ = the $(i+1)^{th}$ number in the ordered series of numbers; and

i = the integer part of the product of 0.99 and n.

(b) The 3-year average 99th percentile value is then calculated by averaging the annual 99th percentiles:

Equation 12

$$P_{0.99} = \frac{\sum_{y=1}^{3} P_{0.99,y}}{3}$$

(c) The 3-year average 99th percentile is rounded according to the conventions in section 3.3 of this appendix before a comparison with the standard is made.

Example 6—Ambient Monitoring Site With Sampling Every Sixth Day That Meets the Primary 24-Hour PM_{10} Standard.

a. In each year of a particular 3 year period, varying numbers of PM_{10} daily values (e.g., 110, 98, and 100) out of a possible 121 daily values were recorded at a particular site with the following ranked values (in μg/m³):

Table 4.—Ordered Monitoring Data For 3 Years

Year 1		Year 2		Year 3	
j rank	X_j value	j rank	X_j value	j rank	X_j value
108	120	96	143	98	140
109	128	97	148	99	144
110	130	98	150	100	147

b. Using Equation 11, the 99th percentile values for each year are calculated as follows:

$$0.99 \times 110 = 108.9 \Rightarrow i+1 = 109 \Rightarrow P_{0.99,1} = X_{[109]} = 128\mu g/m^3$$

$$0.99 \times 98 = 97.02 \Rightarrow i+1 = 98 \Rightarrow P_{0.99,2} = X_{[98]} = 150\mu g/m^3$$

$$0.99 \times 100 = 99 \Rightarrow i + 1 = 100 \Rightarrow P_{0.99,3} = X_{[100]} = 147 \mu g / m^3$$

c. 1. Using Equation 12, the 3-year average 99th percentile is calculated as follows:

$$\frac{128 + 50 + 147}{3} = 141.7\ \mu\text{g} / \text{m}^3 \text{ rounds to } 140 \mu\text{g} / \text{m}^3.$$

2. Therefore, this site meets the 24-hour PM_{10} standard.

[FR Doc. 97–18577 Filed 7–17–97; 8:45 am]

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federal register

Friday
July 18, 1997

Part III

Environmental Protection Agency

40 CFR Part 50

National Ambient Air Quality Standards for Particulate Matter; Availability of Supplemental Information and Request for Comments; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[AD–FRL–5725–4]

National Ambient Air Quality Standards for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; availability of supplemental information and request for comments.

SUMMARY: EPA is announcing the availability of certain laboratory and field test data, and related reports associated with the development of the reference method (Appendix L of 40 CFR part 50) for measuring $PM_{2.5}$ in the ambient air. Because these data were collected, by necessity, during and after the close of the public comment period on the proposed revisions to the national ambient air quality standards for particulate matter and thus, were not available for placement in Docket No. A–95–54 until late in the rulemaking process, EPA is announcing a supplemental comment period for the limited purpose of taking comments on these field and laboratory test results only.

DATES: Written comments must be received on or before August 18, 1997.

ADDRESSES: Submit written comments (duplicate copies preferred) to: Office of Air and Radiation Docket and Information Center (6102), Attn: Docket No. A–95–54, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: John H. Haines, MD–15, Air Quality Strategies and Standards Division, Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, NC 27711, telephone: (919) 541–5533, e-mail: haines.john@epamail.epa.gov or Neil H. Frank, MD–14, Emissions, Monitoring and Analysis Division, Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, NC 27711, telephone: (919) 541–5560, e-mail: frank.neil@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Elsewhere in today's issue of the **Federal Register**, EPA is publishing the final rule (FRL–5725–2) revising the national ambient air quality standards for particulate matter. In Unit VI.B. (Appendix L—New Reference Method for $PM_{2.5}$) of the preamble to the final rule, EPA concluded that the proposed design and performance specifications for the reference sampler, with modifications described in the final rule, will achieve the design objectives set forth in the proposal. Accordingly, EPA has adopted the sampler and other method requirements specified in the revised Appendix L as the reference method for measuring $PM_{2.5}$ in the ambient air. As discussed in the preamble to the final rule, a series of field tests were performed using prototype samplers manufactured in accordance with the proposed design and performance specifications. The results of these field tests confirmed that the prototype samplers perform in accordance with design expectations. Operational experience gained through these field tests did, however, identify the need for minor modifications as discussed in the preamble to the final rule. As explained in that preamble, EPA made other modifications to the proposed design and performance specification in response to public comment. As part of this process, EPA performed laboratory tests to ensure that the modifications achieved the intended objective. While the results of the field and laboratory tests were largely confirmatory in nature and did not indicate a need to alter the basic design and performance specifications, they did identify areas that needed further refinement. Given that these tests were performed, by necessity, during and after the close of the public comment period and because the results were not available for placement in the docket until late in the rulemaking process, the preamble to the final rule announced that a supplemental comment period would be held for the limited purpose of taking comments on these field and laboratory tests results. The following documents present the results of the field and laboratory tests and associated analyses that EPA considered, as discussed in Unit VI.B. of the preamble to the final rule, in making minor modifications or other refinements to the proposed reference method for measuring $PM_{2.5}$ in the ambient air. The documents are:

1. *Adaptation of the Low-Flowrate, PM_{10}, Dichotomous Sampler Inlet to Fine Particle Collection.*
2. *Filter Temperature Specification Report.*
3. *Flow Rate Specification Report.*
4. *Laboratory and Field Evaluation of FRM Sampler Report.*
5. *Prototype $PM_{2.5}$ Federal Reference Method Field Studies Report.*

These documents have been entered into Docket No. A–95–54 and are available for inspection and copying at the Office of Air and Radiation Docket and Information Office at the address in ''ADDRESSES'' at the beginning of this document. Copies may also be obtained by contacting Neil H. Frank at the address in ''FOR FURTHER INFORMATION CONTACT.'' It is emphasized that this supplemental comment period is for the limited purpose of taking comment on the documents specified in this document only. Comments on the reference method for $PM_{2.5}$ that go beyond the scope of these specific documents will not be considered. Upon close of the supplemental comment period, EPA will consider the comments received and decide whether any further action is appropriate.

List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

(**Authority:** Secs. 108 and 109, Clean Air Act, as amended (42 U.S.C. 7408, 7409)).

Dated: July 16, 1997.

Carol M. Browner,

Administrator.

[FR Doc. 97–18578 Filed: 7–17–97; 8:45 am]

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Friday
July 18, 1997

Part IV

Environmental Protection Agency

40 CFR Parts 53 and 58

Revised Requirements for Designation of Reference and Equivalent Methods for $PM_{2.5}$ and Ambient Air Quality Surveillance for Particulate Matter; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 53 and 58

[AD–FRL–5725–6]

RIN 2060–AE66

Revised Requirements for Designation of Reference and Equivalent Methods for $PM_{2.5}$ and Ambient Air Quality Surveillance for Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule revises the 40 CFR part 58 ambient air quality surveillance regulations to include provisions for $PM_{2.5}$ (particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers), as measured by a new reference method being published in 40 CFR part 50, Appendix L, elsewhere in this issue of the **Federal Register** or by an equivalent method designed in accordance with requirements being promulgated in 40 CFR part 53. In addition, this rule also revises existing ambient air quality monitoring requirements for PM_{10} (particles with an aerodynamic diameter less than or equal to 10 micrometers). These revisions address network design and siting, quality assurance (QA) and quality control (QC), operating schedule, network completion, system modifications, data reporting, and other monitoring subjects.

EFFECTIVE DATE: This regulation is effective September 16, 1997.

ADDRESSES: All comments received relative to this rule have been placed in Docket A-96-51, located in the Air Docket (LE-131), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. The docket may be inspected between 8 a.m. and 5:30 p.m., Monday through Friday, excluding legal holidays. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For general information, contact Brenda Millar (MD-14), Monitoring and Quality Assurance Group, Emissions Monitoring, and Analysis Division, Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Telephone: (919) 541–5651, e-mail: millar.brenda@email.epa.gov. For technical information, contact Neil Frank (MD-14), Monitoring and Quality Assurance Group, Emissions, Monitoring, and Analysis Division, Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Telephone: (919) 541–5560.

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I. Authority

Section 110, 301(a), 313, and 319 of the Clean Air Act (Act) as amended 42 U.S.C. 7410, 7601(a), 7613, 7619.

II. Introduction

A. Revision to the Particulate Matter NAAQS

Elsewhere in this issue of the **Federal Register**, EPA announced revisions to the national ambient air quality standards (NAAQS) for particulate matter (PM). In that document EPA amends the current suite of PM standards by adding $PM_{2.5}$ standards and by revising the form of the current 24–hour PM_{10} standard. Specifically, EPA is adding two primary $PM_{2.5}$ standards set at 15 $\mu g/m^3$, annual mean, and 65 $\mu g/m^3$, 24–hour average. The annual $PM_{2.5}$ standard would be met when the 3–year average of the annual arithmetic mean $PM_{2.5}$ concentrations is less than or equal to 15 $\mu g/m^3$ from single or multiple community-oriented monitors in accordance with 40 CFR part 50, Appendix K and requirements set forth in this final rule. The 24–hour $PM_{2.5}$ standard would be met when the 3–year average of the 98th percentile of 24–hour $PM_{2.5}$ concentrations at each population-oriented monitor within an area is less than or equal to 65 $\mu g/m^3$.

EPA also retained the current annual PM_{10} standard at the level of 50 $\mu g/m^3$ which would be met when the 3–year average of the annual arithmetic PM_{10} concentrations at each monitor within an area is less than or equal to 50 $\mu g/m^3$. Further, EPA retained the current 24–hour PM_{10} standard at the level of 150 $\mu g/m^3$, but revised the form such that the standard would be met when the 3–year average of the 99th percentile of the monitored concentrations at the highest monitor in an area is less than or equal to 150 $\mu g/m^3$.

In the part 50 final rule published elsewhere in this issue of the **Federal Register**, EPA is also revising the current secondary standards for PM by making them identical to the suite of primary standards. The suite of $PM_{2.5}$ and PM_{10} standards, in conjunction with the establishment of a regional haze program under section 169A of the Clean Air Act (the Act), are intended to protect against PM-related welfare effects including soiling and materials damage and visibility impairment.

As discussed in the part 50 final rule for the PM NAAQS, the $PM_{2.5}$ standards are intended to protect against exposures to fine particulate pollution, while the PM_{10} standards are intended to protect against coarse fraction particles as measured by PM_{10}.

For $PM_{2.5}$, the annual standard is intended to protect against both long- and short-term exposures to fine particle pollution. Under this approach, the $PM_{2.5}$ 24–hour standard would serve as a supplement to $PM_{2.5}$ annual standard

to provide additional protection against days with high $PM_{2.5}$ concentrations, localized ''hot spots,'' and risks arising from seasonal emissions that would not be well controlled by a national annual standard.

In specifying that the calculation of the annual arithmetic mean for an area (for purposes of comparison to level of $PM_{2.5}$ annual standard) should be accomplished by comparing the annual mean from a community-oriented monitor that is representative of average community-wide exposure, or averaging the annual arithmetic means derived from multiple, community-oriented monitoring sites, EPA took into account several factors. As discussed in the part 50 final rule, many of the community-oriented epidemiologic studies examined in this review used spatial averages, when multiple monitoring sites were available, to characterize area-wide PM exposure levels and associated public health risk. In those studies that used only one monitoring location, the selected site was chosen to represent community-wide exposures, not the highest value likely to be experienced within the community. Because the annual $PM_{2.5}$ standard is intended to reduce aggregate population risk from both long- and short-term exposures by lowering the broad distribution of PM concentrations across the community, an annual standard based on monitoring data reflecting average community wide exposure would better reflect area-wide $PM_{2.5}$ exposure levels and associated health risks than would a standard based on concentrations from a single monitor with the highest measured values in the area. The concept of average community exposures is not appropriate for PM_{10} because the spatial distribution of coarse particles is different and tends to be more localized in its behavior.

Finally, under the policy approach presented in the part 50 final rule, the 24–hour $PM_{2.5}$ standard is intended to supplement an annual $PM_{2.5}$ standard by providing protection against peak 24–hour concentrations arising from situations that would not be well-controlled by an annual standard. Accordingly, the 24–hour $PM_{2.5}$ standard will be based on the single population-oriented monitoring site within a monitoring planning area with the highest measured values.

In EPA's judgment, an annual $PM_{2.5}$ standard based on monitoring data representative of community average air quality, established in conjunction with a 24–hour standard based on the population-oriented monitoring site with the highest measured values, will provide the most appropriate target for reducing area-wide population exposure to fine particle pollution and will be most consistent with the underlying epidemiological data base.

B. Air Quality Monitoring Requirements

A new Federal Reference Method (FRM) for $PM_{2.5}$ is promulgated in a new Appendix L to 40 CFR part 50. Section 319 of the Act requires that uniform criteria be followed when measuring ambient air quality. To satisfy these requirements, EPA established procedures on February 10, 1975, in 40 CFR part 53 for the determination and designation of reference or equivalent monitoring methods (40 FR 7049). Accordingly, new provisions are added to 40 CFR part 53 so that each reference method for $PM_{2.5}$, based on a particular sampler, will be formally designed as such by EPA. Similarly, samplers demonstrated as equivalent to the FRM can also be designated. Furthermore, section 110(a)(2)(C) of the Act requires ambient air quality monitoring for purposes of the State Implementation Plans (SIPs) and for reporting data quality to EPA. Uniform criteria to be followed when measuring air quality and provisions for daily air pollution index reporting are required by section 319 of the Act.[1] To satisfy these requirements, on May 10, 1979 (44 FR 27558), EPA established 40 CFR part 58 which provided detailed requirements for air quality monitoring, data reporting, and surveillance for all of the pollutants for which national ambient air quality standards have been established (criteria pollutants). Provisions were promulgated subsequently for PM measured as PM_{10} on July 1, 1987 (52 FR 24740); provisions for $PM_{2.5}$ are published in this final rule.

On December 13, 1996, these rules were proposed in the **Federal Register** as amendments to 40 CFR parts 53 and 58. The intent of the monitoring method designations and air quality surveillance requirements being promulgated today are to establish a revised particulate matter monitoring network that will produce air quality data utilizing uniform criteria for the purpose of comparison to the revised primary and secondary PM NAAQS and to facilitate implementation of a forthcoming regional haze program. The effective date of today's monitoring regulation is September 16, 1997.

[1]EPA intends to develop and propose for public comment a revised Pollutant Standards Index that will address $PM_{2.5}$ as well as PM_{10}, at a later date.

III. Discussion of Regulatory Revisions and Major Comments on 40 CFR Part 53

A. Designation of Reference and Equivalent Methods for $PM_{2.5}$

Provisions for EPA designation of reference and equivalent methods for PM_{10} and gaseous criteria pollutants have been previously established and are set forth in 40 CFR part 53. On December 13, 1996, EPA proposed to amend part 53 to add new provisions to govern designation of reference and equivalent method for $PM_{2.5}$. The December 13th notice proposed new, detailed sampler testing and other requirements that would apply to candidate reference and equivalent $PM_{2.5}$ methods and describes how EPA proposed to determine whether a candidate method should be designated as either a reference or equivalent method. The notice further solicited public comments on the proposed new provisions. Those provisions, modified somewhat based on the public comments received, are being promulgated today as amended part 53.

As for the other criteria air pollutants, reference methods for $PM_{2.5}$ are intended to provide for uniform, reproduceable measurements of $PM_{2.5}$ concentrations in ambient air to serve as a measurement standard for the primary purpose of making comparisons to the NAAQS. Equivalent methods for $PM_{2.5}$ allow for the consideration and introduction of new and innovative $PM_{2.5}$ measurement technologies for this same purpose, provided such new technologies can be shown to provide $PM_{2.5}$ measurements comparable to reference measurements under a variety of typical monitoring conditions.

B. Reference Method Designation Requirements

The new reference method for $PM_{2.5}$, described in 40 CFR part 50, Appendix L contains a combination of design and performance specifications to define the reference method $PM_{2.5}$ sampler. The performance-based specifications for the reference method sampler allow manufacturers to design and fabricate different samplers that would meet all reference method requirements. Accordingly, multiple $PM_{2.5}$ reference methods are expected to become available from several manufacturers, as is the case for reference methods for PM_{10} and most gaseous criteria pollutants. Each reference method for $PM_{2.5}$, based on a particular sampler, will be formally designated as such by EPA under the new provisions added to 40 CFR part 53.

The requirements for designation of $PM_{2.5}$ reference methods are set forth in subparts A and E of 40 CFR part 53. These requirements include specific tests to show conformance with all design and performance specifications, an operational field precision test, a comprehensive operation/instruction manual, and documentation of an adequate manufacturing and testing quality system. Subpart A, which has been amended to add provisions for $PM_{2.5}$ methods, sets forth the general requirements for both reference and equivalent methods and for the process under which applications are submitted and reference and equivalent method are designated. New subpart E, which is devoted exclusively to $PM_{2.5}$ methods, describes the test procedures and related requirements for candidate reference methods.

C. Equivalent Method Designation Requirements

The requirements for designation of equivalent methods for $PM_{2.5}$ are also set forth in amended part 53. The general requirements are set forth in subpart A. All candidate equivalent methods are subject to the field tests for operational precision and comparability to reference method measurements, which are specified in subpart C. Both subparts A and C have been amended to include the provisions for $PM_{2.5}$ methods.

To minimize the number and extent of performance tests to which candidate equivalent methods must be subjected, three classes of equivalent methods are defined.

Class I equivalent methods are based on samplers that have relatively small deviations from the specifications for reference method samplers. Therefore, in addition to the tests and other requirements applicable reference method samplers, candidate Class I equivalent samplers must be tested only to make sure that the modifications do not significantly compromise sampler performance. The additional test requirements for most Class I candidate equivalent methods are a test for possible loss of $PM_{2.5}$ in any new or modified components in the sampler inlet upstream of the sample filter, and the field testing for comparability to reference method samplers. These additional tests are described in subparts E and C, respectively.

Class II equivalent methods include all other $PM_{2.5}$ methods that are based on a 24–hour integrated filter sample that is subjected to subsequent moisture equilibration and gravimetric mass analysis. A sampler associated with a Class II equivalent method will generally have one or more substantial deviations from the design or performance specifications of the reference method, such that it cannot qualify as a Class I equivalent method. These samplers may have a different inlet, a different particle size separator, a different volumetric flow rate, a different filter or filter face velocity, or other significant differences. More extensive performance testing is required for designation of Class II candidate equivalent methods, with the specific tests required depending on the nature and extent of the differences between the candidate sampler and the specifications for reference method samplers. These tests may include a full wind tunnel evaluation, a wind tunnel inlet aspiration test, a static fractionator test, a fractionator loading test, a volatility test, and field testing against reference method samplers. The tests and their specific applicability to various types of candidate Class II equivalent method samplers are set forth in the new subpart F.

Finally, Class III equivalent methods include any candidate $PM_{2.5}$ methods that cannot qualify as either Class I or Class II. This class includes any filter-based integrated sampling method having other than a 24–hour $PM_{2.5}$ sample collection interval followed by moisture equilibration and gravimetric mass. More importantly, Class III also includes filter-based continuous or semi-continuous methods, such as beta attenuation instruments, harmonic oscillating element instruments, and other complete in situ monitor types. Non-filter-based methods such as nephelometry or other optical instruments will also fall into the Class III category.

The testing requirements for designation of Class III candidate methods are the most stringent, because quantitative comparability to the reference method will have to be shown under various potential particle size distributions and aerosol composition. However, because of the variety of measurement principles and types of methods possible for Class III candidate equivalent methods, the test requirements must be individually selected or specifically designed or adapted for each such type of method. Therefore, EPA has determined that it is not practical to attempt to develop and explicitly describe the test procedures and performance requirements for all of these potential Class III methods a priori. Rather, the specific test procedures and performance requirements applicable to each Class III candidate method will be determined by EPA on a case-by-case basis upon request, in connection with each proposed or anticipated application for a Class III equivalent method determination.

D. Proposed Reference and Equivalent Method Requirements

The proposed changes to 40 CFR part 53 to provide for designation of reference and equivalent methods for $PM_{2.5}$ consisted of revisions to subparts A and C, and new subparts E and F. The proposed revisions to subpart A included new definitions applicable to $PM_{2.5}$ methods and clarifications of existing definitions, clarifications of the reference and equivalent method designation requirements for all pollutants including the new classes of equivalent methods for $PM_{2.5}$, and requirements for $PM_{2.5}$ samplers to be manufactured in an International Organization for Standardization (ISO) 9001-registered facility (or equivalent). Additional proposed changes included clarifications of the test data and other information required to be submitted in applications for a reference or equivalent method determination, clarification of requirements for product warranty and content of operation or instruction manuals, an increased time limit for processing applications; and provisions for providing EPA with a candidate test $PM_{2.5}$ sampler or analyzer to evaluate in connection with an application for reference or equivalent method determination.

Revisions to subpart C included new procedures and specifications for comparing candidate equivalent methods for $PM_{2.5}$ to reference method samplers. The entirely new subpart E described the technical procedures for testing the physical (design) and performance characteristics of reference methods and Class I equivalent candidate methods for $PM_{2.5}$. The new subpart F described the procedures for testing the performance characteristics of Class II equivalent methods for $PM_{2.5}$.

E. Changes to the Proposed Method Designation Requirements

The tests of the design and performance characteristics of candidate samplers for designating reference methods as well as equivalent methods are intimately related to the specifications for reference methods in 40 CFR part 50, Appendix L. Many of the concerns expressed by commenters regarding the reference method for $PM_{2.5}$ in 40 CFR part 50, Appendix L also apply to some of the provisions of part 53. Other comments were more directly concerned with the provisions of 40 CFR part 53, and these comments are summarized in this unit.

Several commenters addressed the responsibilities of EPA and manufacturers in the method designation process. Specific comments included the suggestions that: (1) It would be more appropriate for EPA to conduct the necessary testing of a candidate method before designating a reference method; (2) that EPA should clarify how it will respond to possible poor sampler performance under extreme environmental conditions encountered in some areas of the United States, since the samplers are not required to meet such extreme conditions; (3) that EPA should clarify that specifications for completing sampler modifications or retrofits to work in nonstandard environments should be included as part of a sampler purchase contract; and (4) that EPA should clarify that the required method specifications must be met throughout the warranty period and that the applicant accepts responsibility and liability for ensuring conformance or resolving nonconformities, including all necessary components of the system, regardless of the original manufacturer.

The new provisions contained in the modified 40 CFR part 53 require the applicant to submit information and documentation to demonstrate that the applicant's candidate reference method sampler meets all design specifications set forth in 40 CFR part 50, Appendix L. The provisions also require the applicant to carry out specific tests to demonstrate that the candidate reference or equivalent method meets all performance specifications. The nature of these tests and the requirement that they be carried out by the applicant rather than by EPA is consistent with the previously established requirements in 40 CFR part 53 for designating reference or equivalent methods for other criteria pollutants. Section 53.9 clearly states that a sampler sold as part of a designated method must meet the applicable performance specifications for at least 1 year after delivery. Section 53.9 further requires that ISO 9001 registration of the manufacturing facility be maintained and that a Product Manufacturing Checklist signed by a certified ISO auditor be submitted annually to verify manufacturing quality control.

In response to concerns about the performance of the sampler under extreme weather conditions, EPA has established sampler specifications that are intended to cover reasonably normal environmental conditions at about 95 percent of expected monitoring sites. The performance tests in subpart E address essentially all of these operational requirements. Specification of the sampler performance for sites with extreme environmental conditions would substantially raise the cost of the sampler for users, most of whom do not require the extra capability. EPA strongly recommends that users requiring operation of samplers under extreme environmental conditions develop supplemental specifications for modified samplers to cover those specific conditions. Sampler manufacturers have indicated a commitment to respond to such special operational needs.

Documentation is required to demonstrate that samplers to be sold as reference or equivalent methods for $PM_{2.5}$ will be manufactured under an effective quality control system. Although some commenters supported the general quality assurance concepts contained in the proposed method, several questioned the inclusion of the ISO 9001-registration requirement. EPA believes that the ISO 9001-registration requirement and related provisions are the most cost-effective way to ensure that samplers are manufactured in a facility conforming to internationally recognized quality system standards.

Several comments questioned the proposed requirement that each $PM_{2.5}$ sampler model be subjected to a specific annual evaluation of performance and meet certain operating performance specifications. In response to these comments, this requirement has been deleted. However, EPA will review the performance of each $PM_{2.5}$ sampler model on an annual basis, and if compelling evidence indicates a significant bias or other operational problem, the EPA Administrator may make a preliminary finding to cancel a reference or equivalent method designation in accordance with the provisions of § 53.11 in subpart A.

Otherwise, the provisions of 40 CFR part 53 have been retained to conform with the requirements described in 40 CFR part 50, Appendix L. The proposed revisions to subparts A and C have been retained with no substantive changes. However, minor technical and editorial changes have been made to subparts A and C to clarify or simplify proposed provisions. Subpart E has undergone extensive revision and reorganization. Although these changes do not affect the objectives and nature of the tests, they are intended to make the test requirements easier to understand and the tests easier to perform. The changes were based on EPA's own experience in performing tests of prototype candidate samplers and on comments from prospective sampler manufacturers. Subpart F has also been revised to some extent. The changes to subpart F are not substantive in nature, but numerous technical and editorial changes were made to clarify the test requirements and make the tests, particularly the volatility test, more straightforward to carry out.

All testing related to an application for a $PM_{2.5}$ reference or equivalent method determination under 40 CFR part 53 must be carried out in accordance with American National Standards Institute/American Society for Quality Control (ANSI/ASQC) E4 standards. These requirements are necessary to ensure that all samplers or analyzers sold as reference or equivalent methods are manufactured and tested to the high standards required to achieve the needed data quality. These procedures are in keeping with the developing international standards for manufacturing and testing in this and other industries.

IV. Discussion of Regulatory Revisions and Major Comments on Part 58

The following discussion presents an overview of the final part 58 monitoring regulation. This is followed by a detailed discussion of the basic concepts outlined in the December 13, 1996 monitoring proposal and addresses those comments received on the proposed part 58 regulations that EPA considered to be most relevant to the changes and additions adopted in the final rule. Comments not addressed in this preamble are found in a Summary and Response to Comment document that has been placed in Docket A-96-51. Those parts of the proposed regulations which were not commented on have not been changed. The items are discussed in the order in which they appear in the regulation.

A. Overview of Part 58 Regulatory Requirements

The requirements set forth in this rule simultaneously preserve the underlying intent of the revised NAAQS and respond positively to the very substantial and reasoned comments received on the proposal. Specifically, the major monitoring requirements and principles set forth by the revised part 58 regulation include:

1. *$PM_{2.5}$ network design*. Community-oriented (core) monitors that represent community-wide average exposure, form the basis of $PM_{2.5}$ network design. This approach is consistent with the data bases used to develop the NAAQS. While all population-oriented monitoring locations are eligible for comparison to the 24–hour $PM_{2.5}$ NAAQS, only locations representative of neighborhood or larger spatial scales

are eligible for comparison to the annual NAAQS. Community monitoring zones with constrained criteria may be also used to define monitors acceptable for spatial averaging for comparison to the annual NAAQS. Monitoring for regional transport and regional background is required to assist with implementation of the air quality management program. The combination of emphasis on well-sited community-oriented monitors and the feasibility by the States to select the preferred community monitoring approach reduces complexity associated with network design and planning. The number of required core $PM_{2.5}$ State and Local Air Monitoring Stations (SLAMS), and other $PM_{2.5}$ SLAMS results in a minimum national requirement of approximately 850 $PM_{2.5}$ sites (compared to 629 proposed); the total $PM_{2.5}$ network is projected to approach 1,500 $PM_{2.5}$ sites. Exceptions to the minimum number of required samplers may be approved by the EPA Regional Administrator. As proposed, the mature network of 1,500 $PM_{2.5}$ sites would be in place within 3 years. The phase-in of the required network has been reduced from 3 to 2 years.

2. *PM_{10} monitoring networks*. Requirements for PM_{10} network design and siting are unchanged. Reductions in PM_{10} networks are encouraged in areas of low concentrations where the PM_{10} NAAQS are not expected to be violated.

3. *Sampling frequencies*. The sampling frequencies stipulated in 40 CFR 58.13 for both $PM_{2.5}$ and PM_{10}, have been modified to reflect a one in 3–day minimum requirement. Required every day sampling at certain core sites may be reduced to one in 3–day sampling after at least 3 complete years of data collection with a reference or equivalent method or when collocated with a correlated acceptable continuous (CAC) fine particulate monitor; background and regional transport may also sample once every third day. Exceptions to the minimum requirement may be approved by the EPA Regional Administrator for seasonal or year-round sampling.

4. *Chemical speciation*. A modest chemical speciation network of 50 $PM_{2.5}$ sites that provides a first order characterization of the metals, ions, and carbon constituents of $PM_{2.5}$ is a requirement of this rule. These sites will be part of the National Air Monitoring Stations (NAMS) network and will provide national consistency for trends purposes and serve as a model for other chemical speciation efforts. This required network represents a small fraction of all the chemical speciation work that EPA expects to support with Federal funds. Additional efforts may be used to enhance the required network and tailor the collection and analysis of speciated data to the needs of individual areas.

5. *Quality assurance*. The QA program is collectively based on a variety of QA tools resulting in a program which is more efficient, less costly, and relaxes the burden on State and local agencies. The key program requirements include:

a. Independent field audits with a $PM_{2.5}$ FRM are used to evaluate the bias of $PM_{2.5}$ measurements. The number of $PM_{2.5}$ audited sites compared to the proposal are reduced from all non-collocated sites to 25 percent of all SLAMS sites (including NAMS) and the audit frequency per site is reduced from 6 to 4 visits per year.

b. Flow checks will also be used to evaluate bias of $PM_{2.5}$ and PM_{10} measurements and are conducted on a quarterly basis as proposed.

c. Collocation with $PM_{2.5}$ FRM and Federal Equivalent Methods (FEM) samplers at SLAMS sites is used to judge precision. The number of collocated sites per reporting organization is 25 percent of all $PM_{2.5}$ SLAMS sites (20 percent were proposed) and approximately 20 percent of all PM_{10} SLAMS sites (which is current practice).

d. Systems audits are used to evaluate an agency's QA system and will be performed by EPA every 3 years as originally proposed.

In an effort to assist the State and local agencies in achieving the data quality objectives of the $PM_{2.5}$ monitoring program, an incentive program has been established that is based on network performance and maturity that can reduce these QA requirements.

6. *Moratorium on the use of special purpose monitor (SPM) data*. The moratorium on the use of $PM_{2.5}$ data (§ 58.14) collected by SPMs, has been changed from the first 3 calendar years following the effective date of this rule to the first 2 complete calendar years of operation of a new SPM. If such monitors produce valid data for more than 2 years, then all historical data for that site may be used for regulatory purposes.

7. *Monitoring methodology*. Appendix C has been revised to allow the use of Interagency Monitoring of Protected Visual Environments (IMPROVE) samplers at regional transport and regional background sites to satisfy the SLAMS requirements.

8. *PM monitoring network description*. The State shall submit a PM monitoring network description to the EPA Regional Administrator by July 1, 1998, which describes the PM monitoring network, its intended community monitoring approach for comparison to the annual $PM_{2.5}$ standard, use of non-population-oriented special purpose $PM_{2.5}$ monitors or alternative samplers, and proposed exceptions to EPA's requirements for minimum number of monitors or sampling frequency. The description shall be available for pubic inspection and EPA shall review and approve/disapprove the document within 60 days. A State air monitoring report with proposed network revisions, if any, shall be submitted annually.

EPA believes that the aforesaid revisions to the rule, as proposed, provide a firm basis for the uniform implementation of a national particulate monitoring network which is responsive to a revised NAAQS expressed as $PM_{2.5}$. The following is a section-by-section discussion of comments received and any resulting modifications to the proposal.

B. Section 58.1 - Definitions

EPA proposed to add several definitions applicable to PM monitoring. This consisted of revising the definition of the term traceable and definitions of the terms Consolidated Metropolitan Statistical Area (CMSA), core SLAMS, equivalent methods, Metropolitan Statistical Area (MSA), monitoring planning area (MPA), monitoring plan, $PM_{2.5}$, Primary Metropolitan Statistical Area (PMSA), population-oriented, reference method, spatial averaging zone (SAZ), SPM fine monitors, and Annual State Monitoring Report. In response to comments, EPA is modifying the proposed approach and is introducing new terminology and definitions. First, EPA is changing the definition of core SLAMS monitors to describe community-oriented monitors that are representative of neighborhood or larger spatial scales and will be key monitoring entities in the new $PM_{2.5}$ SLAMS network. As discussed later, a subset of these monitors will be required to sample everyday in the most populated metropolitan areas with the stated emphasis on community-oriented monitoring. Although very important, the background and regional transport monitors in the SLAMS network are no longer called core sites. Secondly, EPA is replacing the definition of spatial averaging zone with a definition of community monitoring zone (CMZ). This is consistent with the intent of the annual $PM_{2.5}$ standard, that is to be judged at monitoring stations that are representative of community-wide air quality. EPA is also renaming the PM monitoring plan as the PM monitoring network description. EPA's rationale for

these changes, together with a more complete description of community monitoring zones, are discussed in 40 CFR part 58, Appendix D.

In addition, several commenters addressed the definition of population-oriented monitoring, objecting to the narrowness of the definition with respect to industrial areas, and noting that if people are present in an area, the site should be considered population-oriented.

EPA assessed these comments and concluded that the definition of population-oriented monitoring or sites proposed in § 58.1 is essentially appropriate and as such will provide monitoring agencies with the flexibility to design networks that are consistent with the population-oriented approach described by the $PM_{2.5}$ standards. Therefore EPA is retaining this definition in the final rule with a minor simplifying change as follows: population-oriented monitoring (or sites) applies to residential areas, commercial areas, recreational areas, industrial areas and other areas where a substantial number of people may spend a significant fraction of their day. The definition of population-oriented monitoring will be further deliniated in future EPA guidance. As proposed, the final rule states that all population-oriented $PM_{2.5}$ monitoring locations shall be eligible for comparison to both the 24–hour PM_{10} and $PM_{2.5}$ standards. In order to make these concepts clearer for the final rule, however, several changes to the proposed language were made in the final rule regarding eligibility of monitoring sites for comparisons to the $PM_{2.5}$ NAAQS. First, the new $PM_{2.5}$ network will place emphasis on community-oriented monitoring for making comparisons to both the annual and 24–hour $PM_{2.5}$ NAAQS. Secondly, as proposed, unique population-oriented microscale and middle-scale monitoring sites shall only be used for comparisons to the 24–hour NAAQS. Furthermore, violations detected at rural background and regional transport sites are more appropriately addressed by the implementation program which EPA is developing.

C. Section 58.13 - Operating Schedule

EPA proposed that core $PM_{2.5}$ SLAMS (including NAMS and core SLAMS collocated at Photochemical Assessment Monitoring Stations (PAMS) sites) would be required to sample every day, unless an exception is approved by EPA during established seasons of low PM pollution during which time a minimum of one in 6-day sampling would be permitted. The proposal stated that non-core SLAMS sites would generally be required to sample a minimum of once every sixth day, although episodic or seasonal sampling could also be possible (e.g., in areas where significant violations of the 24–hour NAAQS are expected or at sites heavily influenced by regional transport or episodic conditions). The proposed and final rule state that special purpose monitors may sample on any sampling schedule. The proposal also recognized that although daily sampling with manual methods is labor intensive due to site visits and filter equilibration and weighing, semi-automatic sequential samplers are anticipated to be approvable as FRMs or Class I equivalent samplers (under the provisions of part 53) that will simplify the data collection process. Finally, EPA proposed that alternative $PM_{2.5}$ operating schedules that combine intermittent sampling with the use of acceptable continuous fine particulate samplers are approvable at some core sites. This alternative was intended to give the States additional flexibility in designing their $PM_{2.5}$ monitoring networks and to permit data from continuous instruments to be telemetered. This would facilitate public reporting of fine particulate concentrations, and allow air pollution alerts to be issued, and allow episodic controls to be implemented (as currently done in woodburning areas for PM_{10}). Furthermore, this alternative would permit monitoring agencies to take advantage of new and improved monitoring technologies that should become available during the first few years following the promulgation of this rule. As proposed, applicability does not apply to areas with population greater than 1 million during the first 2 years of required sampling.

Many commenters supported daily $PM_{2.5}$ sampling, citing the need to target sources, aid enforcement, and provide exposure measurements for future community health studies. Additionally, commenters supported daily $PM_{2.5}$ sampling to cover the most polluted and most populated areas and to capture all violations. Other commenters supported daily sampling but suggested limiting it to key locations or seasons (e.g., only the largest metropolitan areas or those areas with the highest $PM_{2.5}$ concentrations, only during seasons when high values are likely). Other commenters suggested allowing a reduction in sampling frequency to one in 6 days under certain conditions; for example, at sites that have demonstrated attainment, at sites with CAC analyzers, following the third year of data collection, and during the portion of the year with low $PM_{2.5}$ concentrations at a site with a district seasonal pattern.

In addition, a number of commenters suggested a delay of everyday sampling until the Class I equivalent samplers are available. It was noted that over the short-term, only designated manual samplers capable of collecting single 24–hour samples, could be available. Consequently, to meet an everyday sampling schedule, several samplers would need to be installed at each everyday sampling site to satisfy the daily schedule, and cover weekend and holiday sampling periods.

Based on its review of these comments, EPA is retaining its everyday sampling schedule for certain community-oriented (core) SLAMS (i.e., two monitoring sites in each MSA greater than 500,000 population and SLAMS collocated at PAMS for a total of 313 nationwide). The remaining SLAMS including NAMS and other core SLAMS are required to sample every third day.

Because of concerns over the potential unavailability of Class I sequential samplers, EPA is allowing a waiver of the everyday or every third day sampling schedule, when appropriate, in those situations where such sampling is not needed. This waiver would expire 1 calendar year from the time a sequential sampler has been approved by EPA. When the waiver is granted for every day sampling, one in 3-day sampling would be required. As proposed, EPA encourages the use of a supplemental CAC analyzer as a means of facilitating a reduction of the reference or equivalent method everyday sampling schedule to once in 3 days. The CAC monitoring option, however, will not be allowed in areas greater than 1 million population that have high $PM_{2.5}$ concentrations during the first 2 years of daily data collection. A minimum frequency of one in 6–day sampling is still required during periods for which exemptions to everyday or every third day sampling are allowed for $PM_{2.5}$ SLAMS.

For PM_{10}, the EPA Administrator proposed that one in 6-day sampling should be sufficient to support the proposed PM_{10} NAAQS and a less dense monitoring network would also be needed.

A number of commenters supported the typical one in 6–day sampling frequency for PM_{10}. On the other hand, a number of commenters opposed the proposed reduction in PM_{10} sampling frequency to one in 6 days, stating that one in 6–day sampling is inadequate to evaluate impacts on the 24–hour PM_{10}

standard, especially in areas with episodic events or localized hot spots, and that extreme pollutant conditions could be missed.

In response to the general concerns that sampling for PM_{10} is not sufficient and in accordance with the choice of the 99th percentile as the form of the 24–hour PM_{10} standards as discussed in 40 CFR part 50, EPA has changed the minimum required sampling frequency from one sample every 6 days to one sample in every 3 days.

The specified minimum sampling frequency of one in 3 days for $PM_{2.5}$ and PM_{10} will provide for a more statistically stable representation of actual air quality at each monitor as discussed in 40 CFR part 50. Further, increasing the sampling frequency from one in 6- to one in 3-days will ensure that the 24–hour NAAQS comparisons are not based on the highest measured values per year, and thus will significantly reduce the chances of incorrectly classifying a ''clean'' area as nonattainment, and at the same time provide enough information to confidently classify ''dirty'' areas as nonattainment without requiring those areas to sample every day.

EPA believes that once in 6–day sampling is sufficient to estimate an annual mean concentration for $PM_{2.5}$ or PM_{10}. Furthermore, every day or every third day sampling is not generally needed during periods of the lowest ambient PM concentrations. Therefore, EPA is allowing exemptions to the every day or the one in 3-day sampling requirement to individual areas with the approval of the EPA Regional Administrator, in accordance with forthcoming EPA guidance. In general, exemptions to the minimum one in 3-day sampling frequency will be approvable when existing information suggests that maximum 24–hour measurements are less than the level of the standard. In these cases, a minimum of one in 6-day sampling will be required to ensure that sufficient data are available to calculate an annual average concentration. Areas adopting less frequent sampling would be advised of the risks involved in such a choice; namely, that a single high value in 1 year could end up causing the area to be declared in violation of the 24–hour NAAQS. The guidance will also recommend that more frequent sampling be considered for those areas that are relatively close to the level of the standard. For example, areas whose $PM_{2.5}$ or PM_{10} data indicate that they meet the annual PM NAAQS, but have the potential to not meet the 24–hour PM NAAQS will be encouraged to sample everyday for $PM_{2.5}$ or PM_{10}, as appropriate, during the high PM seasons in order to better assess their status to the standards. While such an option may be more costly for individual areas, the risk of inaccurately declaring an attainment area to be nonattainment would be reduced.

D. Section 58.14 - Special Purpose Monitors

EPA proposed that special purpose monitoring (SPM) is needed in a new $PM_{2.5}$ monitoring program to help identify potential problems, to help define boundaries of problem areas, to better define temporal (e.g., diurnal) patterns, to determine the spatial scale of high concentration areas, and to help characterize the chemical composition of PM (using alternative samplers and supplemental analyzers), especially on high concentration days or during special studies. It was proposed, however, that data from SPMs would not be used for attainment/nonattainment designations if the monitor is located in an unpopulated area, if the monitoring method is not a reference or equivalent method or does not meet the requirements of section 2.4 of 40 CFR part 58, Appendix C. Moreover, in order to encourage the deployment of SPMs, EPA proposed that nonattainment designations will not be based on data produced at an SPM site with any monitoring method for a period of 3 years following the promulgation date of the NAAQS.

Numerous commenters opposed the proposed 3-year exclusion of SPM data as a basis for NAAQS violations, noting that all measured violations from all monitors should be used for nonattainment designations. Other commenters supported the exclusion, suggesting that SPM data should always be considered exploratory in nature and should remain exempt from inclusion in regulatory data bases.

EPA has revisited its position on SPMs in light of these comments. In order to encourage the deployment of SPMs, EPA has decided to continue to provide States with the flexibility to exempt SPM data from regulatory use, but limit the period of the moratorium to the first 2 complete calendar years of operation of a new SPM. Given the currently limited amount of $PM_{2.5}$ data and the complexity of the $PM_{2.5}$ air quality problem, the Agency feels that this approach still provides a significant incentive for States to engage in additional monitoring and thereby collect data that would supplement the data collected at SLAMS sites. This can be very helpful for establishing an optimum network design, for a better understanding of the impacts of specific emission sources, and for other planning purposes. If a monitoring site satisfies all applicable part 58 requirements including use of reference or equivalent methods, meeting siting criteria, and other requirements as explained in § 58.14 and it continues to collect data beyond the first 2 complete calendar years of its operation, the data from such SPM sites would then be generally eligible for comparisons to the NAAQS. One exception is when a monitoring agency intends to evaluate a special situation which is not representative of population-oriented monitoring. In this case, the data from the special purpose monitor would not be used for comparison to the $PM_{2.5}$ standards. A second exception is when the agency intends to evaluate a unique impact area that represents a small spatial scale (micro or middle). In this case, the site would only be eligible for comparison to the 24–hour NAAQS. Although SPM data will be exempt from regulatory use during the 2–year moratorium, EPA emphasizes that SPM data should nevertheless be considered in the State's PM monitoring network description and in the design of its overall SLAMS network. Moreover, SPM sites reporting values greater than the level of a NAAQS should be considered during the annual network review in accordance with § 58.25, and summary data from SPM sites must be included in the annual State Air Monitoring report described in § 58.26.

E. Section 58.15 - Designation of Monitoring Sites

The proposed monitoring regulations defined categories of sites that would be eligible for comparisons to the annual or 24–hour NAAQS. This included certain sites that could be used for comparison to both standards (B sites), to only the daily standard (D sites) and certain special purpose monitors (O sites) that potentially would not be used for comparison to any standard. Due to significant concern regarding the complexity of implementing those concepts to handle a small number of unique monitoring situations, the final rule has eliminated the coding of sites as type B, D, and O sites. Therefore, § 58.15 has been deleted in its entirety. The principal reasons also include the emphasis on community-oriented monitors, the new terminology and modified approach associated with CMZs, and more precise descriptions of SLAMS and SPMs. The final rule provides a more streamlined and simplified monitoring approach that retains the basic community average air quality exposure tenets of the $PM_{2.5}$ annual NAAQS and, as proposed,

recognizes that population-oriented hot spot monitoring may be more reflective of situations applicable to the purposes of the 24–hour $PM_{2.5}$ standard.

The changes to community monitoring and site categorization are well integrated. EPA agrees with public comment that the proposed spatial averaging approach may not have been properly communicated by suggesting that it allowed averaging of monitors across widely disparate areas not reflective of average community-oriented exposure and a homogeneous emission source mix. EPA believes that by clarifying the criteria that determine which monitors can be averaged together (i.e., monitors in areas affected by similar emission sources), along with emphasizing that well sited community-oriented monitors should be used, environmental equity concerns and related issues are effectively addressed. First, a single SLAMS or SPM that adequately represents a local area can reflect its own community monitoring area. If its annual average concentrations are more than 20 percent higher than the surrounding average $PM_{2.5}$ air quality, it would not be eligible to be averaged in with the surrounding sites of the larger geographic domain. In addition, unique population-oriented hot spot impact sites are not eligible for comparison to the annual $PM_{2.5}$ NAAQS and are only eligible for comparison to the 24–hour NAAQS. Additional details about CMZs are provided later.

F. Section 58.20 - Air Quality Surveillance: Plan Content

Although no comments were received on proposed changes to this section, the title was inadvertently stated as Plan Control; this title has been changed to Plan Content. In addition, the first sentence of paragraph (d) has been changed by deleting the words ''section 2.8 of'' and the words ''as well as the minimum requirements for networks of SLAMS stations for $PM_{2.5}$ described in section 2.8.2 of 40 CFR part 58, Appendix D.'' Since § 58.20 requires an annual review of the air quality surveillance system for all SLAMS, these changes were instituted for clarity. The reference to $PM_{2.5}$ in the third sentence of § 58.20 was retained to ensure that the review includes the unique requirements of the $PM_{2.5}$ monitoring network.

The proposal indicated that a detailed Particulate Matter Monitoring Plan (see § 58.1, as proposed) must be prepared by the affected air pollution control agency and submitted to EPA for approval. This plan was designed to comprehensively describe the Agency's $PM_{2.5}$ and PM_{10} air quality surveillance networks. Comments received noted that the term PM monitoring plan could be confused with the network description required by § 58.20. Accordingly, EPA has replaced references to the ''PM Monitoring Plan or monitoring plan'' in this final rule with references to the ''particulate matter monitoring network description or PM monitoring network description.'' The Agency notes, however, that the rule published today requires a more expanded and comprehensive network description for PM than has previously been required for other networks. Therefore, a new paragraph (f) has been added to § 58.20 to delineate the requirements for PM monitoring network descriptions. According to § 58.20(e), as amended, this network description must be submitted to the EPA Regional Administrator for approval.

To ensure opportunities for public review and inspection of the monitoring network, States must maintain information and records on such items as the station location, monitoring objectives, spatial scale of representativeness, optional CMZs, and schedule for completion of the network. Such information and records are included in a State's PM monitoring network description. The PM monitoring network description prepared by States and submitted to EPA for approval should be viewed as a long-term network of SLAMS and NAMS sites that meet the variety of monitoring objectives specified in 40 CFR part 58, Appendix D of these regulations. These objectives include determining compliance with air quality standards, developing appropriate control strategies as required, and preparing short- and long-term air quality trends. However, modifications to the network can be made without a formal SIP revision thus encouraging States to make any needed yearly (or alternate schedule as determined by the EPA Regional Administrator) changes to the SLAMS network to make it more responsive to data needs and resource constraints. In order to avoid making major modifications to the PM monitoring network description during the annual review, the detailed network, including monitoring planning areas and CMZs, should be carefully planned and designed to provide a stable base of air quality data. Since no formal SIP revision (that entails **Federal Register** proposal and public comment) is required for the PM monitoring network description revisions, EPA encourages public involvement in the review of a State's PM monitoring network description particularly when the spatial averaging monitoring approach is selected for comparisons to the annual standard.

G. Section 58.23 - Monitoring Network Completion

EPA proposed that the PM networks would be expected to be completed within 3 years of the effective date of promulgation. While new $PM_{2.5}$ networks are developed, reductions in existing PM_{10} networks would be considered. The proposal stated that during the first year, a minimum of one monitoring planning area per State would be required to have core $PM_{2.5}$ SLAMS. This area would be selected by the State according to the likelihood of observing high $PM_{2.5}$ concentrations and according to the size of the affected population. In addition, one $PM_{2.5}$ site was proposed to be collocated at one PAMS site in each of the PAMS areas. During the second year, all other core population-oriented $PM_{2.5}$ SLAMS, and all core background and transport sites, were proposed to be fully operational. During the third year, any additional required $PM_{2.5}$ (non-core) SLAMS was proposed to be fully deployed and all NAMS sites would be selected from core SLAMS and proposed to EPA for approval.

Several commenters discussed the proposed phase-in schedule. One commenter supported an accelerated phase-in schedule, while other commenters supported a longer phase-in period. Several State commenters expressed reservations about their ability to meet the proposed phase-in schedule, due to limited resources and the unavailability of monitoring equipment. One commenter felt that the phase-in should require one core monitor in each of a few geographically diverse areas per State, as this would provide more valuable information than only one per MPA.

As noted in the comments on 40 CFR part 58, Appendix D, a large number of commenters cited the immediate need for an expansive $PM_{2.5}$ monitoring network to provide adequate monitoring data to satisfy the monitoring objectives of the SLAMS network, in particular, to provide 3 years of $PM_{2.5}$ data in order to make comparisons with the NAAQS. As noted in the discussion below on resources and costs, the Agency's grant allocations for fiscal years 1997-1998 include significant resources to accelerate the implementation schedule and increase the number of monitoring sites included in today's final rule. In view of these actions, the Agency is accelerating the SLAMS monitoring

network completion schedule to require at least one core monitor in each MSA greater than 500,000 population plus one $PM_{2.5}$ site to be collocated with a PAMS site in each PAMS area and at least 2 additional SLAMS per State to be in operation by 1998; to require all other required SLAMS including required regional transport and regional background sites to be in operation by 1999; and to encourage all additional sites (to complete the network) to be in operation by 2000. In addition, the States should have at least one core SLAMS to be deployed in all areas expected to have the potential for high $PM_{2.5}$ concentrations, in accordance with EPA guidance, to be in operation by 1998 which will be supported with funding from EPA's section 105 grant program.

H. Section 58.25 - System Modification

The preamble to the proposal noted that although no changes to the regulatory language were proposed for this section, the annual monitoring system modifications review must include changes to $PM_{2.5}$ site designations (e.g., NAAQS comparison sites), and the number or boundaries of monitoring planning areas and/or spatial averaging zones, now referred to as community monitoring zones. This information is included for explanatory purposes only and does not necessitate changes to the regulatory language.

I. Section 58.26 - Annual State Monitoring Report

Under the current regulations, States are required to submit an annual SLAMS data summary report. EPA proposed that this report shall be expanded to: (1) Describe the proposed changes to the State's PM Monitoring Network Description, as defined in § 58.20; (2) include a new brief narrative report to describe the findings of the annual SLAMS network review, reflecting within the year and proposed changes to the State air quality surveillance system; and (3) provide information on PM SPMs and other PM sites noted in the PM monitoring network description regardless of whether data from the stations are submitted to EPA (including number of monitoring stations, general locations, monitoring objective, scale of measurement, and appropriate concentration statistics to characterize PM air quality such as number of measurements, averaging time, and maximum, minimum, and average concentration). The latter is for EPA to ensure that a proper mix of permanent and temporary monitoring locations are used and that populated areas throughout the Nation are monitored, and to provide needed flexibility in the State monitoring program.

In addition, the proposed changes to the PM monitoring network description included changes to existing PM networks. The proposed changes to existing PM networks included modifications to the number, size, or boundaries of MPAs or SAZ's, number and location of PM SLAMS; number or location of core $PM_{2.5}$ SLAMS; alternative sampling frequencies proposed for $PM_{2.5}$ SLAMS (including core $PM_{2.5}$ SLAMS and $PM_{2.5}$ NAMS); core $PM_{2.5}$ SLAMS to be designated $PM_{2.5}$ NAMS; and PM SLAMS to be designated PM NAMS. SPM's with measured values greater than the level of the NAAQS would become part of the SLAMS network. The proposed changes would be developed in close consultation with the appropriate EPA Regional Office and submitted to the appropriate Regional Office for approval. The portion of the document pertaining to NAMS would be submitted to the EPA Administrator (through the appropriate Regional Office).

Finally, as a continuation of current regulations, the States would be required to submit the annual SLAMS summary report and to certify to the EPA Administrator that the SLAMS data submitted are accurate and in conformance with applicable part 58 requirements. Under the proposed revisions, States would also be required to submit annual summaries of SPM data to the EPA Regional Administrator for sites included in their PM monitoring network description and to certify that such data are similarly accurate and likewise in conformance with applicable part 58 requirements or other requirements approved by the EPA Regional Administrator, if these data are intended to be used for SIP purposes. All of the proposed changes described above did not receive substantive comment and were retained in the final rule.

During the first 3 years following promulgation, the proposal stated that the State's PM monitoring description (changed to PM monitoring network description) and any modifications of it would be submitted to EPA by July 1 (starting on the year following promulgation) or by alternate annual date to be negotiated between the State and EPA Regional Administrator, with review and approval/disapproval by the EPA Regional Administrator was proposed to occur within 45 days. After the initial 3–year period or once an SAZ (now called CMZ) has been determined to be violating any $PM_{2.5}$ NAAQS, then changes to a MPA would require public review and notification to ensure that the appropriate monitoring locations and site types are included.

Several commenters addressed the requirements for the Annual State Monitoring Report. Some commenters felt that the 45-day review was too restrictive and should be extended to 60 days. Other commenters felt that the annual review requirement was reasonable in the short-term, but should be reconsidered after 3 years.

In response to these comments, the Agency is extending the Regional review period to 60 days. After the first 3 years, the required annual review can be reconsidered and its schedule revised as determined by the EPA Regional Administrator. As discussed earlier in this preamble, EPA will entertain suggestions for modifications to the published monitoring network requirements. States can request exemptions from specific required elements of the network design (e.g., required number of core SLAMS sites, other SLAMS sites, sampling frequency, etc.) through the Annual Monitoring Report.

J. Section 58.30 - NAMS Network Establishment

The preamble to the proposal called for States to submit a NAMS network description (which is to be derived from the core $PM_{2.5}$ SLAMS) of each State's SLAMS network to the EPA Administrator (through the appropriate EPA Regional Office) within 6 months of the effective date of the final rule. At the same time, a State's NAMS PM_{10} network must be reaffirmed if no changes are made to the existing network and if changed must also be fully described and documented in a submittal to the EPA Administrator (through the appropriate EPA Regional Office). The proposed § 58.34 stated that the NAMS Network completion shall be by 3 years after the effective date of the final rule. This has not been changed in this final rule. However, the proposed revisions to this section inadvertently called for the $PM_{2.5}$ network description to be submitted 3 years after the effective date of promulgation. The final rule has been changed to read July 1, 1998.

K. Section 58.31 - NAMS Network Description

The term spatial averaging zone was used in the proposed revisions to this section. In the final rule, this term has been replaced by the term community monitoring zone (CMZ).

L. Section 58.34 - NAMS Network Completion

The preamble to the proposal called for changes to the NAMS PM_{10} network to be completed by 1 year after the effective date of the final rule and to the NAMS $PM_{2.5}$ network to be completed by 3 years after the effective date of the final rule. The proposed rule incorrectly stated 6 months instead of 1 year for the PM_{10} network to be completed. The final rule has been changed to read 1 year after the effective date of these regulations for PM_{10} and 3 years after the effective date of these regulations for $PM_{2.5}$.

M. Section 58.35 - NAMS Data Submittal

The proposed revision to this section added $PM_{2.5}$ as an additional indicator of PM to the list of pollutants that must submit air quality data and associated information to the EPA Administrator as specified in the AIRS Users Guide. This section is promulgated as proposed.

N. Appendix A - Quality Assurance Requirements for SLAMS

1. *Summary of proposal*. The proposal addressed the fact that enhanced QA and QC procedures were required in the areas of sampler operation, filter handling, data quality assessment, and other operator-related aspects of the $PM_{2.5}$ measurement process. These enhanced QA/QC procedures were necessary for meeting the data quality objectives for ambient $PM_{2.5}$ monitoring.

Most operational QC aspects were specified in 40 CFR part 58, Appendix A in general terms. However, for $PM_{2.5}$, explicit, more stringent, requirements were proposed for sample filter treatment--including the moisture equilibration protocol, weighing procedures, temperature limits for collected samples, and time limits for prompt analysis of samples. Details concerning these operator-related procedures were proposed to be published as a new section 2.12 of EPA's Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II to assist monitoring personnel in maintaining high standards of data quality.

Procedures were proposed for assessing the resulting quality of the monitoring data in 40 CFR part 58, Appendix A. Perhaps the most significant new data quality assessment requirement proposed for $PM_{2.5}$ monitoring was the requirement that each $PM_{2.5}$ SLAMS monitor was to be audited at least six times per year. This was the first time a requirement had been proposed to assess the relative accuracy of the mass concentration measured by a PM SLAMS monitor. Each of these six audits would have been performed by the monitoring agency and would have consisted of concurrent operation of a collocated reference method audit sampler along with the $PM_{2.5}$ SLAMS monitor. The data from these collocated audits were proposed to have been used by EPA to assess the performance of the $PM_{2.5}$ SLAMS monitor and to identify reporting organizations or individual sites that had abnormal bias or inadequate precision for the year.

Other data assessment requirements proposed for $PM_{2.5}$ monitoring networks were patterned after the current requirements for PM_{10} networks and were intended to supplement the audit procedure. The proposal required $PM_{2.5}$ network monitors to be subject to precision and accuracy assessments for both manual and automated methods, using procedures similar or identical to the current procedures required for PM_{10} monitoring networks. Results of the field tests performed by the monitoring agencies (including the field tests) would have been sent to EPA. EPA then would have carried out the specified calculations which would have become part of the annual assessment of the quality of the monitoring data.

Although the proposed QA requirements for $PM_{2.5}$ would have resulted in an increase in quality assessment requirement for PM monitoring, the additional QA/QC checks would have incurred more cost to the monitoring agency. Some of the proposed new QA/QC assessment requirements would have somewhat overlapped the information provided by other checks, such as the periodic flow rate checks and the use of collocated samplers in monitoring networks.

A revision to 40 CFR part 58, Appendix A, was also proposed to provide for technical system audits to be performed by EPA at least every 3 years rather than every year. This change to a less frequent system audit schedule recognized the fact that for many well established agencies, an extensive system audit and rigorous inspection may not have been necessary every year. The determination of the extent and frequency of system audits at an even lower frequency than the proposed 3-year interval was being left up to the discretion of the appropriate EPA Regional Office, based on an evaluation of the Agency's data quality measures. This change would have afforded both EPA and the air monitoring agencies flexibility to manage their air monitoring resources to better address the most critical data quality issues.

2. *The $PM_{2.5}$ QA system*. Based upon public comments, the Agency has reviewed 40 CFR part 58, Appendix A and re-evaluated several aspects of the QA and QC quality control system used to assess the particulate monitoring data. The requirements associated with the PM_{10} QA system remained unchanged by these modifications. Specifically for $PM_{2.5}$, the major modifications include focusing 80 percent of the QA resources to sites with concentrations of greater than or equal to 90 percent of the annual $PM_{2.5}$ NAAQS (or 24–hour NAAQS if that is affecting the area), increasing the amount of collocated monitors to 25 percent of the total number of SLAMS monitors within a reporting organization, and changing the FRM audit procedures to an independent assessment of the bias of the $PM_{2.5}$ monitoring network. The FRM audits were reduced in number to 25 percent of the SLAMS monitors at a frequency of 4 times per year. All modifications are discussed in detail in the following paragraphs.

In response to comments that the proposed QA requirements were inadequate, and in order to clarify the intent of the quality system, EPA is incorporating the concept and definition of a quality system into section 2, Quality System Requirements. EPA defines QA as an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer. QC is defined as the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer. A quality system is defined as a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

The Agency used the data quality objective (DQO) process to specifically develop the QA system for the new $PM_{2.5}$ program. The DQO process is a systematic strategic planning tool based

on the scientific method that identifies and defines the type, quality, and quantity of data needed to satisfy a specific use. Meeting the new data quality objectives for ambient $PM_{2.5}$ monitoring requires a combination of QA and QC procedures to evaluate and control data measurement uncertainty. For this reason, EPA has developed a quality system specifically for $PM_{2.5}$ which incorporates procedures to quantify total measurement uncertainty, as it relates to total precision and total bias, within the $PM_{2.5}$ monitoring network. In order to clarify the tools used in the QA system, the Agency has included definitions in 40 CFR part 58, Appendix A. Total bias is defined as the systematic or persistent distortion of a measurement process which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value). Total precision is defined as a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions, expressed generally in terms of the standard deviation. Accuracy is defined as the degree of agreement between an observed value and an accepted reference value, accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations. The Agency will use various QA tools to quantify this measurement uncertainty; this includes collocation of monitors at various $PM_{2.5}$ sites, use of operational flow checks, and implementation of an independent FRM audit.

The measurement system represents the entire data collection activity. This activity includes the initial equilibration, weighing, and transportation of the filters to the sampler; calibration, maintenance, and proper operation of the instrument; handling/placement of the filters; proper operation of the instrument (sample collection); removal/handling/transportation of the filter from the sampler to the laboratory; weighing, storage, and archival of the sampled filter; and finally, data analysis and reporting. Additional or supplemental detailed quality assurance procedures and guidance for all operator-related aspects of the $PM_{2.5}$ monitoring process will be published as a new section 2.12 of EPA's Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Specific Methods to assist monitoring personnel in maintaining high standards of data quality.

To clarify the requirements and guidance concerning the SLAMS ambient air network, the Agency has developed Quality Assurance Division (QAD) requirements documents, which are referenced in section 2.2. For simplification, the Agency has removed the list of pertinent operational procedures from this section and has replaced the list with the updated reference. In response to comments about potential difficulties in following the requirements in ANSI E-4, EPA has instead required quality assurance and control programs to follow the requirements for quality assurance project plans contained in EPA requirements for quality assurance project plans for environmental data operations, EPA QA/R-5 an EPA QAD document.

EPA received many comments on the proposed bimonthly audits for each $PM_{2.5}$ site as proposed in section 6.0 of Appendix A. Commenters expressed concerns about the excessive burden the requirement would put on State and local air pollution control agencies, the length of time involved with the process, and the quality control, reliability, and logistical aspects of a portable audit device.

Based upon these comments, the Agency re-assessed its position concerning the number of sites and the frequency of audits that the State and local agencies perform. The Agency feels that independent FRM audits are essential to reaching the goal of the data quality objectives for $PM_{2.5}$ because these audits evaluate the total bias for each designated $PM_{2.5}$ Federal Reference and Equivalent monitoring method within the monitoring network. Therefore, the Agency has modified the proposed audit program to make it independent and also to reduce the burden on State and local agencies. Section 6.0 as proposed has been deleted, with remaining data quality assessment requirements for $PM_{2.5}$ included in section 3.5 of 40 CFR part 58, Appendix A. The resulting data will be assessed at three distinct levels--single monitor level, reporting organization level, and at a national level. Details of the assessment process will be published in EPA's Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Specific Methods.

Commenters endorsed the reduction in the frequency of systems audits from every year to every 3 years as proposed in section 2.5. Therefore, the requirement for a 3–year schedule for system audits remains unchanged.

3. *Evaluation of measurement uncertainty*. EPA received several comments on the procedures used to address the quality assurance of the data as proposed in section 3 of the Appendix. Commenters were concerned about the limited resources available to properly comply with all aspects of the proposed quality system. In the initial deployment of the SLAMS $PM_{2.5}$ network, special QA emphasis should be placed on those sites likely to be involved in possible nonattainment decisions. Once the initial attainment/nonattainment designations have been made, the Agency recommends focusing 80 percent of the QA activity (collocated monitors and FRM audits) at sites with concentrations greater than or equal to 90 percent of the mean annual $PM_{2.5}$ NAAQS (or 24–hour NAAQS if that is affecting the area); this percentage will be 100 percent if all sites have concentrations above either NAAQS. The remaining 20 percent of the QA activity would be at sites with concentrations less than 90 percent of the $PM_{2.5}$ NAAQS. If an organization has no sites at concentration ranges greater than or equal to 90 percent of the $PM_{2.5}$ NAAQS, the Agency recommends 60 percent of the QA activity be at sites among the highest 25 percent for all $PM_{2.5}$ sites in the network. The Agency understands the initial selection of sites will likely be subjective and based upon the experience of State and local organizations.

Other data assessment requirements for $PM_{2.5}$ monitoring networks are patterned after the current requirements for PM_{10} networks and are intended to quantify the monitoring network's total precision and bias. $PM_{2.5}$ network monitors will be subject to performance assessments for both manual and automated methods, using procedures similar or identical to the current procedures required for PM_{10} monitoring networks. The Agency received several comments describing incentives for acceptable performance in the QA field. In response to these concerns, EPA intends to reduce the QA burden in accordance with network monitoring and acceptable performance of the QA program. Based upon EPA's yearly data quality assessment, acceptable performance could result in a reduction in the frequencies of QA/QC requirements. Additional details for the incentive program will be provided in the Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Specific Methods.

The Agency believes that to develop a national, consistent monitoring network with quantifiable data quality, a quality system must be developed that permits maximum flexibility yet ensures that the measurement uncertainty is known and under control. For this

reason, the Agency has removed the requirement in section 3.3.5 that the paired monitors have the same FRM or equivalent sampler designation number, but now formalizes the 6-day sampling schedule for collocated monitors into the regulation; this was previously described in guidance.

With regard to the requirements for evaluating measurement uncertainty, the estimates of bias within the monitoring network will be evaluated with flow audits (section 3.5.1) and independent FRM audits (see comments concerning section 3.5.3). An audit of the operational flow rate determines bias as performed by the local operators of manual methods for $PM_{2.5}$ with each sampler each calendar quarter. Using a flow rate transfer standard, each sampler will be audited at its normal operating flow rate. The percent differences between the standard and sampler flow rates will be used to evaluate instrument-specific bias.

Specifically, for Federal Reference and Equivalent automated methods, an additional assessment of the precision will consist of a one-point precision check performed at least once every 2 weeks on each automated analyzer used to measure $PM_{2.5}$. This precision check is performed by checking the operational flow rate of the analyzer, using a procedure similar to that currently used for PM_{10} network assessments. In addition, an alternative procedure may be used where, under certain specific conditions, it is permissible to obtain the precision check flow rate data from the analyzer's internal flow meter without the use of an external flow rate transfer standard. This alternative procedure is also made applicable to PM_{10} methods.

With regard to the proposed requirements in section 3.5.2, (Measurement of precision using collocated procedures for automated and manual methods of $PM_{2.5}$) several commenters felt that invalid data or data of questionable quality should not be a part of the data base, since the general public and many end-users of the data such as consultants and modelers do not always make distinctions about data. Data reporting requirements specify that all valid monitoring data be reported to AIRS. EPA believes that the requirement contained in section 4.1 to report all QA/QC measurements including results from invalid tests is necessary to fully assess the performance of reporting organizations and to allow EPA to recommend appropriate corrective actions. Such data will be flagged so that it will not be utilized for quantitative assessments of precision, bias, and accuracy. EPA also received many comments on the use of collocated samplers to assess precision. Most of these comments advocated an increase in the number of collocated monitors as an alternative to reduce the burden of the independent audit system. Based upon these comments, EPA has reassessed its position on the number of collocated monitors and now requires 25 percent of the total number of monitors for each designated Federal Rand Equivalent Method within a reporting organization to be collocated. To further assess the total precision and bias of the monitoring network, half of the collocated monitors for each designated Federal Reference and Equivalent Method must be collocated with a Federal Reference Method (FRM) designated monitor and half must be collocated with a monitor of the same designated method type as the primary monitor. An example is shown in Table A-2 in 40 CFR part 58, Appendix A.

The Agency received numerous comments concerning the burden of the proposed FRM audit procedures for $PM_{2.5}$ (section 3.5.3), which consisted of having every site audited six times each year with a portable FRM audit sampler. In response to these comments, EPA has reduced the number of audits to 25 percent of the total number of SLAMS $PM_{2.5}$ sites to be audited 4 times each year. In addition, EPA has reduced the burden of the State and local agencies responsibility for implementing the audits by providing access to the existing EPA National Performance Audit Program (NPAP) or other comparable programs. The details concerning the assessment of the resulting data will be published in EPA's Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Specific Methods.

4. *Reporting requirements*. EPA received several comments concerning the adequacy of QA reporting requirements (section 4). The Agency has addressed these comments by strongly encouraging earlier QA data submittal in order to assist the State and local agencies in controlling and evaluating the quality of the ambient air SLAMS data.

5. *Data quality assessment*. In response to several comments concerning the adequacy of the QA data assessment procedures for the $PM_{2.5}$ program, including parts of proposed section 6.0, EPA developed a new section 5.5 to consolidate and simplify the procedures and calculations for the precision, accuracy, and bias measurements used to quantify $PM_{2.5}$ data quality. The quality assurance system has been nested in such a manner that will allow for the assessment of total measurement bias and precision, as well as portions of the measurement system (i.e. field operations, laboratory operations, etc.). Four distinct quality control checks and audits are implemented to evaluate total measurement uncertainty: (1) Determine instrument accuracy and instrument bias from flow rate audits, (2) determine precision from collocated monitors where the duplicate monitor has the same method designation, (3) determine a portion of the measurement bias from collocated monitors where the duplicate sampler is an FRM device, and (4) determine total measurement bias from FRM audits. This design will allow for early identification of data quality issues in the measurement phases (field/laboratory operations) where they may be occurring and therefore, effective implementation of corrective actions.

6. *FRM audit requirements*. The Agency received many comments concerned with the burden the proposed FRM audit system (the deleted Section 6: Annual Operational Evaluation of $PM_{2.5}$ Methods) would put upon the individual State and local air pollution agencies. Based upon the numerous comments, the Agency has re-assessed its position concerning the audit system. The Agency reduced this burden by providing the State and local agencies the flexibility to access the existing NPAP program or comparable program, additionally reducing the burden to 25 percent of the total number of SLAMS $PM_{2.5}$ sites each year, and reducing the frequency of the audits to 4 per year. EPA has removed section 6.0 from the regulations and incorporated the appropriate information into other sections within 40 CFR part 58, Appendix A. Additional information will be provided in the Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Specific Methods.

O. Appendix C - Ambient Air Quality Monitoring Methodology

EPA proposed that 40 CFR part 53, subpart C, be amended to allow the use of certain PM_{10} monitors as surrogates for $PM_{2.5}$ monitors for purposes of demonstrating compliance with the NAAQS. The proposal further stated however, following the measurement of a PM_{10} concentration higher than the 24–hour $PM_{2.5}$ standard or an annual average concentration higher than the annual average $PM_{2.5}$ standard, the PM_{10} monitor would have to be replaced with a $PM_{2.5}$ monitor. In the proposal of Appendix C, EPA also discussed the use of several types of $PM_{2.5}$ samplers at a SLAMS that are not designated as a

reference or equivalent method under 40 CFR part 53. First, EPA proposed the use of certain nonreference/nonequivalent $PM_{2.5}$ methods that could be used at a particular SLAMS site to make comparisons to the NAAQS if it met the basic requirements of the test for comparability to a reference method sampler for $PM_{2.5}$, as specified of 40 CFR part 53, subpart C in each of the four seasons of the year at the site at which it is intended to be used. A method that meets this test would then be further subjected to the operating precision and accuracy requirements specified in the proposed Appendix A to 40 CFR part 53, at twice the normal evaluation interval. A method that meets these proposed requirements would not become an equivalent method, but the method could be used at that particular SLAMS site for any regulatory purpose. Second, EPA discussed the use of CAC methods described in § 58.13(f) which are intended to supplement a reference or equivalent manual method at certain SLAMS, so that the manual method could reduce its sampling frequency from every day to once in 3 days. In addition, the proposed Appendix C clarifies that the monitoring data obtained with CAC methods would be restricted to use for the purposes of the proposed § 58.13(f) and would not be used for making comparisons to the NAAQS. Finally, the proposal also described samplers for fine particulate matter used in the IMPROVE network (hereafter termed IMPROVED samplers) and clarified that IMPROVE samplers, although not designated as equivalent methods, could be used in SLAMS for monitoring regional background concentrations of fine particulate matter.

Some commenters questioned the proposed use of PM_{10} samplers as substitutes for $PM_{2.5}$ samplers to satisfy requirements for $PM_{2.5}$ SLAMS monitoring. EPA reassessed the logic behind this proposal and agreed with commenters that substitute samplers should not be allowed. In order for a PM_{10} sampler to be a substitute $PM_{2.5}$ sampler, the annual average PM_{10} would have to be less than 15 $\mu g/m^3$ and the annual maximum 24–hour PM_{10} would have to be less than 65 $\mu g/m^3$. This situation would not be representative of community-oriented monitoring, would only exist at a few rural locations and would not even provide useful information about $PM_{2.5}$ background concentrations; therefore EPA has deleted this provision from Appendix C.

Appendix C is being amended to add a new section 2.4 continuing provisions that allow the use of a $PM_{2.5}$ method that had not been designated as a reference or equivalent method under 40 CFR part 53 at a SLAMS under special conditions. Such a method will be allowed to be used at a particular SLAMS site to make comparisons to the NAAQS if it meets the basic requirements of the test for comparability to a reference method sampler for $PM_{2.5}$, as specified in 40 CFR part 53, subpart C, in each of the four seasons of the year at the site at which it is intended to be used. A method that meets this test will then be further subjected to the operating precision and accuracy requirements specified in 40 CFR part 53, Appendix A, at twice the normal evaluation interval. A method that meets these requirements will not become an equivalent method, but can be used at that particular SLAMS site for any regulatory purpose. The method will be assigned a special method code, and data obtained with the method will be accepted into AIRS as if they had been obtained with a reference or equivalent method. This provision will allow the use of non-conventional $PM_{2.5}$ methods, such as optical or open path measurement methods, which would be difficult to test under the equivalent method test procedures proposed for 40 CFR part 53.

In addition, Appendix C is being amended to add a new section 2.5 to clarify that CAC methods for $PM_{2.5}$ approved for use in a SLAMS under new provisions in § 58.13(f) will not become de facto equivalent methods as proposed. This applies to methods that have not been designated equivalent or do not satisfy the requirements of section 2.4 previously described. In response to recommendations that IMPROVE samplers be allowed for use at core background and core transport sites, EPA is revising section 2.9 to define IMPROVE samplers for fine particulate matter and clarify that IMPROVE samplers, although not designated as equivalent methods, could be used in SLAMS for monitoring regional background and regional transport concentrations of fine particulate matter.

Finally, minor changes are being made to section 2.7.1 to update the address to which requests for approval for the use of methods under the various provisions of Appendix C should be sent, and section 5 to add additional references.

P. Appendix D - Network Design For State and Local Air Monitoring Stations (SLAMS), National Air Monitoring Stations (NAMS) and Photochemical Assessment Monitoring Stations (PAMS)

1. *Section 2.8.1 - Specific design criteria for $PM_{2.5}$.* The proposed regulation contained language regarding the implementation of spatial averaging through the design of $PM_{2.5}$ monitoring networks. MPAs and SAZs were introduced to conform to the population-oriented, spatial averaging approach taken in the proposed $PM_{2.5}$ NAAQS under 40 CFR part 50. While this proposed approach is more directly related to the epidemiological studies used as the basis for the proposed revisions to the particulate matter NAAQS, it recognized that the use of MPAs and SAZs introduced greater complexity into the network design process and the comparison of observed values to the level of the $PM_{2.5}$ annual NAAQS.

A great number of comments were received concerning the communication and complexity of spatial averaging, the selection of monitors, and the need for providing flexibility in specifying network designs and spatial averaging given that the nature and sources of fine particles vary from one area to another.

In response to concerns about the implementation and communication of spatial averaging, EPA is clarifying the requirement for SAZs by changing some terminology. EPA is also making it clear that the annual mean $PM_{2.5}$ from a single properly sited monitor that is representative of community-wide exposures or an average of annual mean $PM_{2.5}$ concentrations produced by one or more of such monitors that meet siting requirements and other constraints as set forth in this rulemaking can be compared to the $PM_{2.5}$ annual standard. Specifically, this rule indicates that comparisons to the annual $PM_{2.5}$ standard can be made through the use of individual monitors or the annual average of monitors in specific CMZs. Community-oriented monitors should be used for these comparisons. This approach will provide State and local agencies with additional flexibility in defining community-wide air quality and in designing monitoring networks. The annual average $PM_{2.5}$ concentration from one or more monitoring sites within a CMZ may be averaged to produce an alternative indicator of annual average community-wide air quality. However, the criteria for establishing CMZs have been modified (compared to the previous SAZs) so that initial monitors will be located in those

areas expected to have the highest community-oriented concentrations. It should be noted that many of the sites meeting the siting, monitoring methodology, and other monitoring requirements in 40 CFR part 58 include population-oriented SPMs and industrial monitors.

The eligible core monitors in a CMZ still must be properly sited and meet the constraints specified in section 2.8.1.6 of 40 CFR part 58, Appendix D. The term SAZ has been replaced with CMZ and zone throughout Appendix D. If the State chooses to make comparisons to the annual $PM_{2.5}$ NAAQS directly with individual monitors that use the siting requirements of section 2.8.1.6.3 of 40 CFR part 58, Appendix D then it is not required to perform the analyses needed to establish a CMZ. A State still would be expected to justify that the site meets the specified siting requirements and is representative of community-wide exposures. Then it would not be expected, apriori, to define the boundaries of zones within which the monitoring data would be averaged. This section, that was proposed as ''Monitoring Planning Areas and Spatial Averaging Zones,'' has been retitled as ''Specific Design Criteria for $PM_{2.5}$.''

2. *Section 2.8.1.3 - Core monitoring stations for $PM_{2.5}$*. The proposed regulations described requirements for the numbers of SLAMS sites including core SLAMS. To provide a minimal $PM_{2.5}$ network in all high population areas for protection of the annual and 24–hour PM NAAQS, each required MPA was proposed to have at least two core monitors. The new core monitoring locations would be an important part of the basic PM-fine SLAMS regulatory network. These sites are intended to primarily reflect community-wide air pollution in residential areas or where people spend a substantial part of the day. In addition to the population-oriented monitoring sites, core monitors would also be established for regional background and regional transport monitoring.

To permit interface with measurements of ozone precursors and related emission sources that may contribute to $PM_{2.5}$, an additional core monitor collocated at a PAMS site was proposed to be required in those MSAs where both PAMS and $PM_{2.5}$ monitoring are required. The core monitor to be collocated at a PAMS site would be considered to be part of the MPA $PM_{2.5}$ SLAMS network and would not be considered to be a part of the PAMS network as described in section 4 of 40 CFR part 58, Appendix D. Each SAZ in a required MPA was proposed to have at least one core monitor; SAZs in optional MPAs were proposed to have at least one core monitor; and SAZs were proposed to have at least one core site for every four SLAMS.

Several commenters addressed issues related to the number of core SLAMS, population-oriented SLAMS, and other SLAMS. Numerous commenters supported increasing the number of stations while few supported decreasing the number of stations. In addition, some commenters addressing the issue of spatial averaging also suggested that more monitors might be needed to address less populated areas and areas near hot spots. A few commenters suggested that large States or geographic areas might require several regional background or regional transport sites and that increased monitoring in rural or remote areas would be needed to establish naturally occurring concentrations produced by biogenic sources.

EPA agrees with commenters that more monitors are needed to address smaller communities, larger MSAs with several source categories of fine particulate emissions, to address coverage for multiple sites in optional CMZs, regional transport monitoring upwind of the major population centers in the country, and additional sites near population-oriented pollution hot spots. Accordingly, EPA has revised the regulation to increase the number of required core SLAMS and other SLAMS. These changes result in approximately 220 more required sampling sites, nationally, as compared to the number proposed (850 versus 629). At least one core SLAMS is now required in any MSA with a population greater than 200,000. EPA is requiring additional sites in all MSAs with population greater than 1 million in accordance with the following table:

Table 1.—Required Number of Core SLAMS According to MSA Population

MSA Population	Minimum Required No. of Core Sites[a]
>1 M	3
>2 M	4
>4 M	6
>6 M	8
>8 M	10

[a]Core SLAMS at PAMS are in addition to these numbers.

This section, which was proposed as section 2.8.2.1, has been renumbered as section 2.8.1.3.

As discussed in § 58.13, Operating Schedule, all $PM_{2.5}$ SLAMS are required to have a minimum operating schedule of once every 3 days, except for a subset of at least two core $PM_{2.5}$ sites per MSA with population greater than 500,000 and one site in each PAMS area that is required to conduct daily sampling as proposed.

3. *Section 2.8.1.4 - Other $PM_{2.5}$* SLAMS locations. EPA is retaining the requirement to have a minimum of one regional background and one regional transport site per State and recognizing the need for exceptions when appropriate, particularly in small States; however, these sites are no longer designated as core SLAMS. EPA also is requiring additional SLAMS monitors based upon the State population less the population in all required MSA monitoring areas (i.e., MSAs greater than 200,000), to provide population coverage throughout the State, particularly in States with fewer urbanized areas. For this remaining population there should be one additional SLAMS per 200,000 population. These additional sites may be used to satisfy any SLAMS objective anywhere in the State including population areas (large cities or small towns) or regional transport in rural areas. The requirement for the additional SLAMS is over and above the requirement for one regional background and regional transport site per State as mentioned above. This section, which was proposed as section 2.8.2.2, has been renumbered as section 2.8.1.4. For planning purposes, EPA expects that the total number of sites in a mature, fully-developed $PM_{2.5}$ network will exceed these required minimums. The projected total number is 1,500 sites, as compared to the proposed 1,200 sites. This is an increase of 25 percent compared to the number proposed and is based on the recognized need for more monitoring in smaller communities, more monitors in larger MSAs with several source categories of fine particulate emissions, the possible need for multiple sites in optional CMZs, the need to support regional transport monitoring upwind of the major population centers in the country, and the need for additional sites near pollution hot spots.

4. *Section 2.8.1.5 - Additional $PM_{2.5}$ Analysis Requirements*. EPA recognizes the need for chemical speciation of particulate matter. Such data are needed to characterize $PM_{2.5}$ composition and to better understand the sources and processes leading to elevated $PM_{2.5}$ concentrations. Because of the costs associated with conducting filter analysis on a routine basis, however the

proposal only required filters to be archived so they would be available for subsequent chemical analysis on an as needed basis. EPA recognizes that there is a need for speciation and other specialized monitoring efforts that were not specifically required by the proposed rule. Accordingly, EPA intended to give these PM monitoring efforts high priority in its section 105 grants program.

Many commenters supported the concept of chemical speciation, noting that speciation was essential for identifying all of the components of fine particles and developing control strategies. Some commenters recommended that the program be conducted under national or regional supervision to ensure consistency and reduce costs, and that routine chemical analyses are conducted in a centralized laboratory. EPA also received several comments on the proposed archival requirements. Some commenters suggested that if chemical speciation was required, the filter archival requirement could be eliminated. Other commenters noted that the long-term archival requirements placed additional resource burdens on agencies, and that possible filter degradation and/or bias could result from archiving samples prior to analysis.

Based on these comments, the Agency reassessed its position concerning chemical speciation as an optional part of the $PM_{2.5}$ monitoring program. Although speciation is resource intensive, EPA believes that its overall value in satisfying control strategy and other data needs justifies the added expense. Chemical speciation is critically important for the implementation efforts associated with air quality programs. Specific subject areas supported by chemical speciation include source attribution analysis (i.e., determining the likely mix of sources impacting a site) and emission inventory and air quality model evaluation. Emission inventory and modeling tools are used to develop sound emission reduction strategies. Speciated data are especially critical for air quality model evaluation since resolved chemical measurements provide greater assurance that acceptable model behavior results from appropriate process characterization rather than through the collective effect of compensating errors. Speciated data provide greater ability to identify the causes of poor model performance and implement corrective actions. After strategies are developed and controls are implemented, chemically resolved $PM_{2.5}$ data provide a tracking and feedback mechanism to assess the effectiveness of controls and, if necessary, provide a basis for adjustment. Chemical speciation provides an additional quality check on data consistency since a basis for comparing the sum of individual components (i.e., speciated data) with total mass measurement is available. Also, speciated data supports the forthcoming regional haze program by providing a basis for developing reliable estimates of seasonal and annual average visibility conditions. Chemically resolved data should provide more complete data for future health studies. EPA believes that speciation should be part of the final $PM_{2.5}$ monitoring program due to the collective value of speciation. However, the Agency also believes that flexibility must be provided to the States to tailor efforts to the needs of specific areas. Based on public comments, a minimum chemical speciation trends network will be required to address the needs discussed above.

Based on this requirement to collect speciated data at NAMS sites, EPA is eliminating the requirement to archive filters from NAMS. However, all other SLAMS sites will still be required to archive filters for a minimum of 1 year after collection. Access to these archived filters for chemical speciation would be helpful in cases where: (1) Exceedances or near exceedances of the standard have occurred and additional information and data are needed to determine more precisely possible sources contributing to the exceedances or high concentrations, and (2) certain sites may have shown marked differences in air quality trends at the local or national level for no apparent reason and analysis of filters from more than one site might be required to determine the reason(s) for the differences. EPA intends to assign a high priority to this program through its section 105 grant allocation program and will issue guidance describing the monitoring methods and scenarios under which speciation should be performed. The FRM described in 40 CFR part 50, Appendix L, is finalized as a single-filter based method. Therefore, supplementary monitoring equipment that, for example, permits the use of additional filter media will be needed to perform the appropriate speciation. Additional details on the monitoring methodology for performing speciation and related information on filter handling and/or storage will be addressed in forthcoming EPA guidance.

EPA is now instructing the States to initiate chemical speciation in accordance with forthcoming EPA guidance at $PM_{2.5}$ core sites collocated at approximately 25 PAMS sites and at approximately 25 other core sites for a total of approximately 50 sites nationwide. These sites would be selected as candidates for future NAMS designation. Depending on available resources, chemical speciation could be expanded to additional sites in the second and third years. The requirement to collect speciated data will be reexamined after 5 years of data collection. Based on this review, the EPA Administrator may exempt some sites from collecting speciated data. At a minimum, chemical speciation will include analysis for metals and other elemental constituents, selected anions and cations, and carbon.

EPA recognizes that advantages related to consistency, quality assurance and scales of economy would result from using centralized laboratories for conducting chemical analyses. However, EPA is concerned about the available laboratory capacity for meeting the needs of a national $PM_{2.5}$ speciation network. Several options are under consideration that include developing new central and regional laboratories and exploring the use of existing federal and State facilities. This section, which was proposed as section 2.8.2.4, has been renumbered as section 2.8.1.5.

5. *Section 3.7.6 - NAMS speciation*. Consistent with the previous discussion on speciation, the requirement to establish a subset of approximately 50 NAMS sites for routine speciation is described in a new section 3.7.6 of 40 CFR part 58, Appendix D. The approximately 50 sites will include the ones collocated at PAMS and approximately 25 other sites to be selected by the EPA Administrator, in consultation with the Regional Administrators and the States. After 5 years of data collection, the EPA Administrator may exempt some sites from collecting speciated data. The number of NAMS sites at which speciation will be performed each year and the number of samples per year will be determined in accordance with EPA guidance. The subsequent sections of section 3.7 have been renumbered accordingly.

Q. Appendix E - Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring

The proposed revisions to this Appendix consisted of relatively minor changes in the siting criteria to expand the requirements to include $PM_{2.5}$. Minor changes were made to the example monitoring location in section 8.1 of the proposed revisions to 40 CFR part 58, Appendix E, to replace ''mid-

town Manhattan in New York City'' with ''central business district of a Metropolitan area.''

R. Appendix F - Annual Summary Statistics

A new section was proposed to be added to 40 CFR part 58, Appendix F, to include annual summary statistics for $PM_{2.5}$. No changes were made to the proposed revisions.

S. Review of Network Design and Siting Requirements for PM

1. *PM_{10}*. The network design and siting requirements for the annual and 24–hour PM_{10} NAAQS will continue to emphasize identification of locations at maximum concentrations. The PM_{10} network itself, however, will be revised because the new $PM_{2.5}$ standards will likely be the controlling standards in most situations.

The new network for PM_{10} will be derived from the existing network of SLAMS, NAMS, and other monitors generically classified as SPMs which include industrial and special study monitors. Population-oriented PM_{10} NAMS will generally be maintained as will other key sampling locations in existing nonattainment areas, and in areas whose concentrations are near the levels of the revised PM_{10} NAAQS. Currently approved reference or equivalent PM_{10} samplers can continue to be utilized. The revised network will ensure that analysis of national trends in PM_{10} can be continued, that air surveillance in areas with established PM emission control programs can be maintained, and that the PM_{10} NAAQS will not be jeopardized by additional growth in PM_{10} emissions. PM_{10} sites should be collocated with new $PM_{2.5}$ sites at key community-oriented monitoring stations so that better definition of fine and coarse contributions to PM_{10} can be determined to provide a better understanding of exposure, emission controls, and atmospheric processes. PM_{10} sites not needed for trends or with maximum concentrations less than 60 percent of the NAAQS should be discontinued in a longer-term PM_{10} network.[2] The sampling frequency at all PM_{10} sites can be changed to a minimum of once in 3 days, which will be sufficient to make comparisons with the new PM_{10} standards at most locations. Locations without high 24–hour concentrations of PM_{10} (e.g., 140 $\mu g/m^3$) may be exempted from this provision, and their sampling frequency reduced to a minimum of once in 6 days.

2. *$PM_{2.5}$*. Consistency with the new $PM_{2.5}$ NAAQS demands the adoption of new perspectives for identifying and establishing monitoring stations for the $PM_{2.5}$ ambient air monitoring network. First, sites which are representative of community-wide air quality shall be the principal focus of the new $PM_{2.5}$ monitoring program; however, all eligible population-oriented $PM_{2.5}$ sites (including regional background and regional transport sites) will be used for comparisons to the new NAAQS. Second, eligible SLAMS and other eligible SPMs may be averaged within properly defined CMZs to better characterize exposure and air quality for comparison to the annual $PM_{2.5}$ NAAQS. Third, population-oriented $PM_{2.5}$ SLAMS and SPMs representative of unique microscale or middle scale impact sites would not be eligible for comparison to the annual $PM_{2.5}$ NAAQS and would only be compared to the 24–hour $PM_{2.5}$ NAAQS. The 24–hour $PM_{2.5}$ NAAQS is intended to supplement the annual $PM_{2.5}$ standard by providing additional protection at these small spatial scales. A violation of the annual $PM_{2.5}$ NAAQS at localized hot spot and other areas of a small spatial scale (i.e., less than 0.5km in diameter) are not reflective of the data used to establish the annual $PM_{2.5}$ NAAQS. It is also not indicative of a greater area-wide problem which would initiate the need for an area-wide implementation strategy. Clearly, the combination of careful network design, i.e., one that identifies the differences in monitor locations, and an implementation policy that strives to develop effective strategies optimizing regional and local efforts is required to address the intent of the $PM_{2.5}$ NAAQS.

The new network for $PM_{2.5}$ consists of a core network of community-oriented SLAMS monitors (including certain SLAMS collocated at PAMS), other SLAMS monitors (including background and regional transport sites), a NAMS network for long-term monitoring for trends purposes, and a supplementary network of SPMs. Daily sampling is required at a subset of core SLAMS located in MSAs with population greater than 500,000 and at core SLAMS collocated at PAMS sites. This will provide more accurate and complete information on population exposure. One in 3-day sampling is required at NAMS and at all other SLAMS, except when exempted by the Regional Administrator, in which case one in 6-day sampling is required. Frequent measurements are important to characterize the day-to-day variability in $PM_{2.5}$ concentrations, and to understand episodic behavior of $PM_{2.5}$. Routine chemical speciation of $PM_{2.5}$ will be required for a small subset of the core SLAMS. This is necessary to establish and track effective emission control strategies to assure protection of the NAAQS. These sites shall be part of the future $PM_{2.5}$ NAMS network. Overall, many of the new $PM_{2.5}$ sites are expected to be located at existing PM_{10} sites, that are representative of monitoring oriented exposures and would be collocated with some PAMS sites.

The concepts that address the intent of $PM_{2.5}$ network for making comparisons to the NAAQS are embodied through: (1) Monitoring planning areas; (2) specially coded sites including community-oriented (core) SLAMS, regional transport and regional background SLAMS, and other SLAMS or SPMs whose data would be used to compare to the levels of the annual and 24–hour $PM_{2.5}$ NAAQS; (3) SLAMS or SPMs representative of unique population-oriented microscale or middle scale locations that are only eligible for comparison to the 24–hour $PM_{2.5}$ NAAQS, and (4) individual community-oriented sites or CMZs to correspond to the spatial averaging approach defined by the annual $PM_{2.5}$ NAAQS.

Core sites are community-representative monitoring sites which are among the most important SLAMS for identifying areas that are in violation of the $PM_{2.5}$ NAAQS and to be used for the associated SIP planning process. Because of their generally larger spatial scales of representativeness, the core sites are the sites most likely to be eligible for spatial averaging and are also vital in order to establish the boundaries of potential areas of violation of the NAAQS that would be reflective of the areas of highest population exposure to fine particles. Core sites are neighborhood scale in their spatial dimensions. Core SLAMS and specific SPM monitoring locations which are eligible for spatial averaging must be identified in the PM monitoring network description, satisfy criteria outlined in Appendix D, and be approved by EPA. In accordance with information to be specified by the AIRS guidance, the State shall assign the appropriate monitoring site code when reporting these data to EPA.

Regional transport and regional background sites are located outside major metropolitan areas and would generally be upwind of one or more high concentration $PM_{2.5}$ impact areas. These sites are expected to be in areas

[2]Memorandum from William F. Hunt, Jr., Director, Emissions, Monitoring, and Analysis Division dated April 22, 1997, to EPA Regional Directors entitled Ambient Monitoring Reengineering (found in Docket A-96-51).

of relatively low population density or in unpopulated regions. The collection of data at these sites is encouraged because they are critical for the complete understanding of potential pollutant transport and for the development and evaluation of emission control strategies. Although violations of the NAAQS may be observed at these sites, the interpretation and use of such data observed at regional transport and regional background locations will be addressed in the PM implementation program.

SLAMS monitoring locations generally should reflect the population-oriented emphasis of the new NAAQS' population risk management approach and its data would be used for NAAQS comparisons. SPMs, on the other hand, could represent a variety of monitoring situations, some of which are not appropriate for comparison to the $PM_{2.5}$ standards. This includes monitoring at non-population-oriented hot spots or special emissions characterization sites that do not meet EPA siting criteria or required SLAMS monitoring methodology, but provide valuable planning information to support the SIP process. In addition, certain SLAMS and SPMs that represent small spatial scales (i.e., sites that are classified as microscale or middle scale, in accordance with Appendix D) would not represent average, community-oriented air quality. In general, such locations would be relatively close to a single PM emission source or a collection of small local sources. An example of such a location is a unique microscale site in a non-residential part of an urban area and which may be zoned industrial. Clearly, such a site should not be called a SLAMS. There might also be SLAMS sites in residential districts which are representative of small maximum concentration impact areas. Due to the greater spatial homogeneity of fine particles, the existence of such small scale impact locations is expected to be much less than that for coarse particles. When SLAMS or SPMs do represent small, unique population-oriented impact areas, they should be used for comparison to the 24–hour $PM_{2.5}$ standard but not for the annual standard. This is especially true when the site is dominated by a single emission source. In general, these types of small impact sites may be surrounded by broader areas of more homogeneous concentrations which are reflective of community-wide air quality. However, if the State chooses to monitor at a unique population-oriented microscale or middle scale location and the monitoring station meets all applicable 40 CFR part 58 requirements (including monitoring methodology), then the data shall be used only for comparison to the 24–hour $PM_{2.5}$ standard. This is consistent with the underlying rationale of the $PM_{2.5}$ NAAQS. Such monitors would require a special AIRS code when their data are submitted to EPA, as specified by AIRS guidance.

Exceptions to the use of micro and middle scale $PM_{2.5}$ for comparison only to the 24–hour standard may exist when micro or middle scale $PM_{2.5}$ sites represent several small areas in the monitoring domain which collectively identify a larger region of localized high concentration. For example, there may be two or more disjoint middle scale impact areas in a single residential district that are not predominantly influenced by a single $PM_{2.5}$ emission source. In this case, these small scale sites should be used for comparison to the annual NAAQS. This is because their annual average ambient air concentrations can be interpreted as if they collectively represent a larger scale. In a sense, this situation can be viewed as a neighborhood of small scale impact areas. These concepts and associated requirements are discussed in section 2.8.1 of 40 CFR part 58, Appendix D.

The new network design and siting requirements encourage the placement of $PM_{2.5}$ monitors both within and outside of population centers in order to: (1) Provide air quality data necessary to facilitate implementation of the $PM_{2.5}$ NAAQS, and (2) augment the existing visibility fine particle monitoring network. The coordination of these two monitoring objectives will facilitate implementation of a regional haze program and lead to an integrated monitoring program for fine particles.

To achieve the appropriate level of air quality surveillance in such areas, EPA believes it is important to coordinate and integrate the regional background and regional transport monitoring sites specified in this final rule with the existing IMPROVE monitors that have been in place in a number of locations around the country since the late 1980s to characterize fine particulate levels and visibility in mandatory Federal Class I areas (e.g., certain national parks and wilderness areas). The need for coordination and integration of visibility-oriented monitoring sites will increase when EPA proposes rules under section 169A of the Act to supplement the secondary NAAQS in addressing regional haze. More detailed guidance on monitoring and assessment requirements will be forthcoming to support this program. This will include details on topics such as monitor placement, monitoring methodology, duration of sampling and frequency of sampling. It is anticipated, however, that the existing IMPROVE network, together with sites established under this rule, would be an integral part of the network for determining reasonable progress under a regional haze program.

In the meantime, EPA recommends that States, in conjunction with EPA and Federal land managers, explore opportunities for expanding and managing $PM_{2.5}$ and visibility monitoring networks in the most efficient and effective ways to meet the collective goals of these programs. It is EPA's intent that monitoring conducted for purposes of the $PM_{2.5}$ primary and secondary NAAQS (including regional background and regional transport sites), and for visibility protection be undertaken as one coordinated national $PM_{2.5}$ monitoring program, rather than as a number of independent networks.

Although the major emphasis of the new $PM_{2.5}$ network is compliance monitoring in support of the NAAQS, the network is also intended to assist in reporting of data to the general public, especially during air pollution episodes and to assist in the SIP planning process. To these ends, additional monitoring and analyses are suggested concerning the location of nephelometers (or other continuous PM measuring devices) at some core monitoring sites and the collection of meteorological data at core SLAMS sites (including background and regional transport sites).

T. Resources and Cost Estimates for New PM Networks

The proposed rules contained a discussion of the costs associated with the start-up and implementation of a $PM_{2.5}$ network and the phase-down of the existing PM_{10} network.

1. *Resources and costs.* Several commenters expressed concern about the costs of the proposed monitoring and QA/QC requirements. Most commenters wanted EPA to provide the funds to meet the increased effort and costs with new monies to the agencies, noting that implementing the network in a timely manner will depend heavily on timely grant assistance from EPA.

Numerous commenters expressed concern that either not enough monitoring money was projected or that the program would be an unfunded mandate. Commenters felt that EPA should budget the funds necessary to develop an adequate $PM_{2.5}$ network that will support all SIP obligations, including support for speciation. Funds to implement a new monitoring network should include one-time funding to

procure sampling, calibration, laboratory, and audit equipment, plus annual funding to support field and laboratory operations.

Several commenters felt that EPA estimates were too low, citing underestimates for additional operational, analytical, and equipment costs including daily sampling; speciation; startup for new monitoring locations; laboratory modifications; operator training; travel; data collection and reporting; greater QA equipment and manpower needs; field testing of reference and equivalent methods; and continuous monitors. No commenter felt that EPA estimates were too high.

A few commenters addressed the suggested portions of the total monitoring program cost for speciation. Several commenters suggested that the cost of requiring speciation could be reduced by limiting the requirement to a subset of the daily monitoring sites, or offset by eliminating the requirement for daily sampling, noting that any cost savings would be overwhelmed by the greater number of $PM_{2.5}$ sites and the number of sites conducting everyday sampling.

EPA understands the complexities and resource demands required by State and local agencies in establishing and implementing the new regulations. In its review of the comments on the use of the proposed Federal reference sampler and associated quality assurance requirements, the Agency has published more cost-effective requirements with this final rule for monitoring network design, methodology, and quality assurance. Likewise, EPA recognizes the subsequent need for it to provide technical and financial assistance. In this regard, some control agencies have used FY-97 grant allocations to procure $PM_{2.5}$ prototype instruments or upgrade their filter weighing facilities. Additionally, the Agency has designated approximately $10,935,000 in section 105 grant monies for distribution to States in FY-98. EPA intends to assign a high priority to the $PM_{2.5}$ monitoring program through its section 105 grants, and additional grant dollars have been earmarked by EPA for subsequent years which should ensure successful implementation of the $PM_{2.5}$ monitoring program.

2. *Revised cost analysis*. In response to comments on cost estimation and new requirements described earlier, EPA has revised its estimates for the projected PM_{10} and $PM_{2.5}$ networks. EPA believes that it has both improved its cost estimates and more adequately addressed the needs for the PM monitoring program. The net costs associated with the final PM rules promulgated today include the start-up and implementation costs associated with the new $PM_{2.5}$ network and the cost savings associated with phase-down of the existing PM_{10} network. The estimated costs in the preamble have been revised to reflect changes to the regulations based on comments received on the proposed changes in 40 CFR parts 50, 53, and 58. In particular, $PM_{2.5}$ network costs have been revised to reflect an increase in the number of sites to 1,500, newer cost estimates for prototype samplers, equipping many sites with sequential samplers to provide for greater operational flexibility, reducing the number and frequency of audits with federal reference method samplers, and providing for additional multi-filter sampling to determine $PM_{2.5}$ constituent species. In addition, PM_{10} network costs have been revised to reflect an increase in the remaining number of PM_{10} sites to 900 and a sampling frequency of once every 3 days (instead of once every 6 days, as proposed) for those sites that previously had been sampling everyday, every 2 days, or every 6 days.

Table 2 shows the $PM_{2.5}$ network phase-in data including number of sites and samplers, costs for capital equipment, sampling and quality assurance, filter analyses, and special studies. Table 3 provides a breakdown of the costs associated with the filter analyses. Table 4 provides a breakdown of the phase-down costs for the PM_{10} network. The costs are shown for a current network of approximately 1,650 sites in 1997 and the phase-down to a future projected network of 900 sites. Table 5 shows the cost of PM monitoring according to sampling frequency and the type of PM monitor. Details of this information can be found in the Information Collection Request for these requirements. Tables 2 through 5 follow.

TABLE 2.—$PM_{2.5}$ NETWORK COSTS

[Thousands of Actual Dollars]

Year	Number of Sites	Number of Samplers [1]	Capital Cost	Sampling & QA	Filter Analysis [2]	Special Studies	Total Cost
1997	0	0	$4,500	.....	.....	.....	$4,500
1998	724	861	$8,963	$10,216	$472	$1,426	$18,225
1999	1,200	1,512	$14,877	$17,938	$2,325	$3,004	$38,143
2000	1,500	1,887	$7,155	$26,697	$3,649	.....	$37,502

[1] The $PM_{2.5}$ network includes a mature network of 332 collocated samplers for QA purposes.
[2] Three different types of filter analyses are anticipated (exceedance analyses, screening analyses, and detailed analyses).

TABLE 3.—COST FOR $PM_{2.5}$ FILTER ANALYSES

Type of Filter Analysis	Estimated Cost per Sample
Exceedance Analysis	$200
High $PM_{2.5}$ concentration events are analyzed for particle size and composition utilizing optical or electron microscopy	.....
Screening Analysis	$150
Multi-filter analyses including (1) x-ray fluorescence (XRF) for elemental composition (crustal material, sulfur, and heavy metals); (2) ion chromatography for ions such as sulfate, nitrate, and chloride; (3) thermal-optical analysis for elemental/organic/total carbon	.....
Detailed Analysis	$400
Analysis for speciated organic composition	.....

TABLE 4.—PM_{10} NETWORK COSTS

[Thousands of Actual Dollars]

Year	Number of Sites	Number of Samplers[1]	Capital Cost to Remove Sites	Operation & Maintenance Cost	Total Cost
1997	1,650	1,810	.....	$15,861	$15,861
1998	1,450	1,610	$137	$13,358	$13,495
1999	1,250	1,410	$89	$11,946	$12,035
2000	900	1,060	$159	$9,134	$9,293

[1] The PM_{10} network includes 160 collocated samplers for QA purposes.

TABLE 5.—COSTS FOR PARTICULATE MONITORING

[In 1997 Dollars]

PM Monitor and Sampling Frequency	One-Time Capital Cost	Annual Operation & Maintenance Cost
PM_{10} 1-in-6 day sampling schedule	$7,700 to $14,800	$8,000 to $8,900
PM_{10} 1-in-3 day sampling schedule	$7,700 to $19,400	$12,400
$PM_{2.5}$ 1-in-6 day sampling schedule	$9,300 to $20,700	$11,300 to $12,500
$PM_{2.5}$ 1-in-3 day sampling schedule	$12,800 to $20,700	$17,000 to $18,600
$PM_{2.5}$ every day sampling	$12,900 to $20,700	$20,700 to $22,200
Nephelometer (continuous)	$21,000	$19,700

V. References

(1) Information Collection Request, 40 CFR Part 58, Ambient Air Quality Surveillance, OMB #2060-0084, EPA ICR No. 0940.14, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, NC 27711.

VI. Regulatory Assessment Requirements

A. Regulatory Impact Analysis

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and to the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations or recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a ''significant regulatory action'' under the terms of the Executive Order 12866 and is therefore not subject to formal OMB review. However, this rule is being reviewed by OMB under Reporting and Recordkeeping Requirements.

B. Paperwork Reduction Act

The information collection requirements contained in this rule have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. An Information Collection Request document has been prepared by EPA (ICR No. 0940.14) and a copy may be obtained from Sandy Farmer, Information Policy Branch, EPA, 401 M St., SW., Mail Code 2137, Washington, DC 20460; or by calling (202) 260-2740.

1. *Need and use of the collection*. The main use for the collection of the data is to implement the air quality standards. The various parameters reported as part of this ICR are necessary to ensure that the information and data collected by State and local agencies to assess the nation's air quality are defensible, of known quality, and meet EPA's data quality goals of completeness, precision, and accuracy.

The need and authority for this information collection is contained in section 110(a)(2)(C) of the Act, that requires ambient air quality monitoring for purposes of the SIP and reporting of the data to EPA, and section 319, that requires the reporting of a daily air pollution index. The legal authority for this requirement is the Ambient Air Quality Surveillance Regulations, 40 CFR 58.20, 58.21, 58.25, 58.26, 58.28, 58.30, 58.31, 58.35, and 58.36.

EPA's Office of Air Quality Planning and Standards uses ambient air monitoring data for a wide variety of purposes, including making NAAQS attainment/nonattainment decisions; determining the effectiveness of air pollution control programs; evaluating the effects of air pollution levels on public health; tracking the progress of SIPs; providing dispersion modeling support; developing responsible, cost-effective control strategies; reconciling emission inventories; and developing air quality trends. The collection of $PM_{2.5}$ data is necessary to support the $PM_{2.5}$ NAAQS, and the information collected will have practical utility as a data analysis tool.

The State and local agencies with responsibility for reporting ambient air quality data and information as requested by these regulations will submit these data electronically to the U.S. EPA's Aerometric Information Retrieval System, Air Quality Subsystem (AIRS-AQS). Quality assurance/quality control records and monitoring network documentation are also maintained by each State/local agency, in AIRS-AQS electronic format where possible.

2. *Reporting and recordkeeping burden*. The total annual collection and reporting burden associated with this rule is estimated to be 785,430 hours. Of

this total, 778,826 hours are estimated to be for data reporting, or an average of 5,991 hours for the estimated 130 respondents. The remainder of 6,604 hours for recordkeeping burden averages 51 hours for the estimated 130 respondents. The capital operation/maintenance costs associated with this rule are estimated to be $32,463,626. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The frequency of data reporting for the NAMS and the SLAMS air quality data as well as the associated precision and accuracy data are submitted to EPA according to the schedule defined in 40 CFR part 58. This regulation currently requires that State and local air quality management agencies report their data within 90 days after the end of the quarter during which the data were collected. The annual SLAMS report is submitted by July 1 of each year for data collected from January 1 through December 31 of the previous year in accordance with 40 CFR part 58.26. This certification also implies that all SPM data to be used for regulatory purposes by the affected State or local air quality management agency have been submitted by July 1.

3. *Burden*. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15.

C. Impact on Small Entities

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the EPA Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rulemaking package does not impose any additional requirements on small entities because it applies to governments whose jurisdictions cover more than 200,000 population. Under the Regulatory Flexibility Act, governments are small entities only if they have jurisdictions of less than 50,000 people. In addition, this rule imposes no enforceable duties on small businesses.

D. Unfunded Mandates Reform Act of 1995

Under sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of $100 million or more to the private sector, or to State or local governments in the aggregate.

EPA has determined that this rule does not contain a Federal mandate that may result in an administrative burden of $100 million or more for State and local governments, in the aggregate, or the private sector in any one year. The Agency's economic analysis indicates that the total incremental administrative cost will be approximately $56,611,000 in 1997 dollars for the 3 years to phase in the network, or an average of $18,820,000 per year for the 3-year implementation period. Table 6 shows how this 3-year average was derived for the various cost elements of monitoring. While this table represents the 3-year period 1998-2000, the total cost for $PM_{2.5}$ monitoring include the initial capital costs anticipated in 1997. In addition, this rule imposes no enforceable duties on small businesses.

Table 6.—Cost Elements for PM Monitoring

Administrative Cost Based on 3-year Average (thousands of constant 1997 dollars)*					
Cost/Element	Current	Revised			Net Change
	PM_{10}	PM_{10}	$PM_{2.5}$	Totals	
Network design		$0	$1,174	$1,174	$1,174
Site installation		$0	$1,532	$1,532	$1,532
Sampling & analysis	$3,518	$2,528	$7,915	$10,443	$6,926
Maintenance	$1,658	$1,192	$2,285	$3,477	$1,818
Data management	$2,098	$1,508	$3,370	$4,878	$2,780
Quality assurance	$2,940	$2,113	$3,342	$5,455	$2,515
Supervision	$3,350	$2,408	$3,068	$5,476	$2,125
Summary	$13,564	$9,749	$22,684	$32,433	$18,820
*Totals are rounded					

List of Subjects in 40 CFR Parts 53 and 58

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: July 16, 1997.

Carol M. Browner,

Administrator.

For the reasons set forth in the preamble, title 40, chapter I, parts 53 and 58 of the Code of Federal Regulations are amended as follows:

PART 53—[AMENDED]

1. In part 53:

a. The authority citation for part 53 continues to read as follows:

Authority: Sec. 301(a) of the Clean Air Act (42 U.S.C. Sec. 1857g(a)) as amended by sec. 15(c)(2) of Pub. L. 91-604, 84 Stat. 1713, unless otherwise noted.

b. Subpart A is revised to read as follows:

Subpart A—General Provisions

Sec.
53.1 Definitions.
53.2 General requirements for a reference method determination.
53.3 General requirements for an equivalent method determination.
53.4 Applications for reference or equivalent method determinations.
53.5 Processing of applications.
53.6 Right to witness conduct of tests.
53.7 Testing of methods at the initiative of the Administrator.
53.8 Designation of reference and equivalent methods.
53.9 Conditions of designation.
53.10 Appeal from rejection of application.
53.11 Cancellation of reference or equivalent method designation.
53.12 Request for hearing on cancellation.
53.13 Hearings.
53.14 Modification of a reference or equivalent method.
53.15 Trade secrets and confidential or privileged information.
53.16 Supersession of reference methods.

Tables to Subpart A of Part 53

Table A-1.—Summary of Applicable Requirements for Reference Equivalent Methods for Air Monitoring of Criteria Pollutants

Appendix A to Subpart A of Part 53—References

Subpart A—General Provisions

§ 53.1 Definitions.

Terms used but not defined in this part shall have the meaning given them by the Act.

Act means the Clean Air Act (42 U.S.C. 1857-1857l), as amended.

Administrator means the Administrator of the Environmental Protection Agency or the Administrator's authorized representative.

Agency means the Environmental Protection Agency.

Applicant means a person or entity who submits an application for a reference or equivalent method determination under § 53.4, or a person or entity who assumes the rights and obligations of an applicant under § 53.7. Applicant may include a manufacturer, distributor, supplier, or vendor.

Automated method or analyzer means a method for measuring concentrations of an ambient air pollutant in which sample collection (if necessary), analysis, and measurement are performed automatically by an instrument.

Candidate method means a method for measuring the concentration of an air pollutant in the ambient air for which an application for a reference method determination or an equivalent method determination is submitted in accordance with § 53.4, or a method tested at the initiative of the Administrator in accordance with § 53.7.

Class I equivalent method means an equivalent method for $PM_{2.5}$ which is based on a sampler that is very similar to the sampler specified for reference methods in Appendix L of this part, with only minor deviations or modifications, as determined by EPA.

Class II equivalent method means an equivalent method for $PM_{2.5}$ that utilizes a $PM_{2.5}$ sampler in which an integrated $PM_{2.5}$ sample is obtained from the atmosphere by filtration and is subjected to a subsequent filter conditioning process followed by a gravimetric mass determination, but which is not a Class I equivalent method because of substantial deviations from the design specifications of the sampler specified for reference methods in Appendix L of part 50 of this chapter, as determined by EPA.

Class III equivalent method means an equivalent method for $PM_{2.5}$ that has been determined by EPA not to be a Class I or Class II equivalent method. This fourth type of $PM_{2.5}$ method includes alternative equivalent method samplers and continuous analyzers, based on designs and measurement principles different from those specified for reference methods (e.g., a means for estimating aerosol mass concentration other than by conventional integrated filtration followed by equilibration and gravimetric analysis. These samplers (or monitors) are those deemed to be substantially different from reference method samplers and are likely to use components and methods other than those specified for reference method samplers.

Collocated describes two or more air samplers, analyzers, or other instruments which sampler the ambient air that are operated silmultaneously while located side by side, separated by a distance that is large enough to preclude the air sampled by any of the devices from being affected by any of the other devices, but small enough so that all devices obtain identical or uniform ambient air samples that are equally representative of the general area in which the group of devices is located.

Equivalent method means a method for measuring the concentration of an air pollutant in the ambient air that has been designated as an equivalent method in accordance with this part; it does not include a method for which an equivalent method designation has been canceled in accordance with § 53.11 or § 53.16.

ISO 9001-registered facility means a manufacturing facility that is either:

(1) An International Organization for Standardization (ISO) 9001-registered manufacturing facility, registered to the ISO 9001 standard (by the Registrar Accreditation Board (RAB) of the American Society for Quality Control (ASQC) in the United States), with registration maintained continuously.

(2) A facility that can be demonstrated, on the basis of information submitted to the EPA, to be operated according to an EPA-approved and periodically audited quality system which meets, to the extent appropriate, the same general requirements as an ISO 9001-registered facility for the design and manufacture of designated reference and equivalent method samplers and monitors.

ISO-certified auditor means an auditor who is either certified by the Registrar Accreditation Board (in the United States) as being qualified to audit quality systems using the requirements of recognized standards such as ISO 9001, or who, based on information submitted to the EPA, meets the same general requirements as provided for ISO-certified auditors.

Manual method means a method for measuring concentrations of an ambient air pollutant in which sample collection, analysis, or measurement, or some combination therof, is performed manually. A method for PM_{10} or $PM_{2.5}$ which utilizes a sampler that requires manual preparation, loading, and weighing of filter samples is considered a manual method even though the sampler may be capable of

automatically collecting a series of sequential samples.

$PM_{2.5}$ sampler means a device, associated with a manual method for measuring $PM_{2.5}$, designed to collect $PM_{2.5}$ from an ambient air sample, but lacking the ability to automatically analyze or measure the collected sample to determine the mass concentrations of $PM_{2.5}$ in the sampled air.

PM_{10} sampler means a device, associated with a manual method for measuring PM_{10}, designed to collect PM_{10} from an ambient air sample, but lacking the ability to automatically analyze or measure the collected sample to determine the mass concentrations of PM_{10} in the sampled air.

Reference method means a method of sampling and analyzing the ambient air for an air pollutant that is specified as a reference method in an appendix to part 50 of this chapter, or a method that has been designated as a reference method in accordance with this part; it does not include a method for which a reference method designation has been canceled in accordance with § 53.11 or § 53.16.

Sequential samples for PM samplers means two or more PM samples for sequential (but not necessarily contiguous) time periods that are collected automatically by the same sampler without the need for intervening operator service.

Test analyzer means an analyzer subjected to testing as part of a candidate method in accordance with subparts B, C, D, E, or F of this part, as applicable. Test sampler means a PM_{10} sampler or a $PM_{2.5}$ sampler subjected to testing as part of a candidate method in accordance with subparts C, D, E, or F of this part.

Ultimate purchaser means the first person or entity who purchases a reference method or an equivalent method for purposes other than resale.

§ 53.2 General requirements for a reference method determination.

The following general requirements for a reference method determination are summarized in Table A-1 of this subpart.

(a) *Manual methods.* (1) For measuring sulfur dioxide (SO_2) and lead, Appendices A and G of part 50 of this chapter specify unique manual reference methods for those pollutants. Except as provided in § 53.16, other manual methods for SO_2 and lead will not be considered for reference method determinations under this part.

(2) A reference method for measuring PM_{10} must be a manual method that meets all requirements specified in Appendix J of part 50 of this chapter and must include a PM_{10} sampler that has been shown in accordance with this part to meet all requirements specified in subparts A and D of this part.

(3) A reference method for measuring $PM_{2.5}$ must be a manual method that meets all requirements specified in Appendix L of part 50 of this chapter and must include a $PM_{2.5}$ sampler that has been shown in accordance with this part to meet the applicable requirements specified in subparts A and E of this part. Further, reference method samplers must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51, and the Product Manufacturing Checklist set forth in subpart E of this part must be completed by an ISO-certified auditor, as defined in § 53.1, and submitted to EPA annually to retain a $PM_{2.5}$ reference method designation.

(b) *Automated methods.* An automated reference method for measuring carbon monoxide (CO), ozone (O_3), and nitrogen dioxide (NO_2) must utilize the measurement principle and calibration procedure specified in the appropriate appendix to part 50 of this chapter and must have been shown in accordance with this part to meet the requirements specified in subpart B of this part.

§ 53.3 General requirements for an equivalent method determination.

(a) *Manual methods.* A manual equivalent method must have been shown in accordance with this part to satisfy the applicable requirements specified in subpart C of this part. In addition, PM_{10} or $PM_{2.5}$ samplers associated with manual equivalent methods for PM_{10} or $PM_{2.5}$ must have been shown in accordance with this part to satisfy the following additional requirements:

(1) A PM_{10} sampler associated with a manual method for PM_{10} must satisfy the requirements of subpart D of this part.

(2) A $PM_{2.5}$ Class I equivalent method sampler must satisfy all requirements of subparts C and E of this part, which include appropriate demonstration that each and every deviation or modification from the reference method sampler specifications does not significantly alter the performance of the sampler.

(3) A $PM_{2.5}$ Class II equivalent method sampler must satisfy the applicable requirements of subparts C, E, and F of this part.

(4) Requirements for $PM_{2.5}$ Class III equivalent method samplers are not provided in this part because of the wide range of non-filter-based measurement technologies that could be applied and the likelihood that these requirements will have to be specifically adapted for each such type of technology. Specific requirements will be developed as needed and may include selected requirements from subparts C, E, or F of this part or other requirements not contained in this part.

(5) All designated equivalent methods for $PM_{2.5}$ must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51, and the Product Manufacturing Checklist set forth in subpart E of this part must be completed by an ISO-certified auditor, as defined in § 53.1, and submitted to EPA annually to retain a $PM_{2.5}$ equivalent method designation.

(b) *Automated methods.* (1) Automated equivalent methods for pollutants other than $PM_{2.5}$ or PM_{10} must have been shown in accordance with this part to satisfy the requirements specified in subparts B and C of this part.

(2) Automated equivalent methods for PM_{10} must have been shown in accordance with this part to satisfy the requirements of subparts C and D of this part.

(3) Requirements for $PM_{2.5}$ Class III automated equivalent methods for $PM_{2.5}$ are not provided in this part because of the wide range of non-filter-based measurement technologies that could be applied and the likelihood that these requirements will have to be specifically adapted for each such type of technology. Specific requirements will be developed as needed and may include selected requirements from subparts C, E, or F of this part or other requirements not contained in this part.

(4) All designated equivalent methods for $PM_{2.5}$ must be manufactured in an ISO 9001-registered facility, as set forth in subpart E of this part, and the Product Manufacturing Checklist set forth in subpart E of this part must be completed by an ISO-certified auditor and submitted to EPA annually to retain a $PM_{2.5}$ equivalent method designation.

(5) All designated equivalent methods for $PM_{2.5}$ must also meet annual requirements for network operating performance determined as set forth in section 6 of Appendix A of part 58 of this chapter.

§ 53.4 Applications for reference or equivalent method determinations.

(a) Applications for reference or equivalent method determinations shall be submitted in duplicate to: Director, National Exposure Research Laboratory, Department E (MD-77B), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

(b) Each application shall be signed by an authorized representative of the applicant, shall be marked in accordance with § 53.15 (if applicable), and shall contain the following:

(1) A clear identification of the candidate method, which will distinguish it from all other methods such that the method may be referred to unambiguously. This identification must consist of a unique series of descriptors such as title, identification number, analyte, measurement principle, manufacturer, brand, model, etc., as necessary to distinguish the method from all other methods or method variations, both within and outside the applicant's organization.

(2) A detailed description of the candidate method, including but not limited to the following: The measurement principle, manufacturer, name, model number and other forms of identification, a list of the significant components, schematic diagrams, design drawings, and a detailed description of the apparatus and measurement procedures. Drawings and descriptions pertaining to candidate methods or samplers for $PM_{2.5}$ must meet all applicable requirements in Reference 1 of Appendix A of this subpart, using appropriate graphical, nomenclature, and mathematical conventions such as those specified in References 3 and 4 of Appendix A of this subpart.

(3) A copy of a comprehensive operation or instruction manual providing a complete and detailed description of the operational, maintenance, and calibration procedures prescribed for field use of the candidate method and all instruments utilized as part of that method (under § 53.9(a)).

(i) As a minimum this manual shall include:

(A) Description of the method and associated instruments.

(B) Explanation of all indicators, information displays, and controls.

(C) Complete setup and installation instructions, including any additional materials or supplies required.

(D) Details of all initial or startup checks or acceptance tests and any auxiliary equipment required.

(E) Complete operational instructions.

(F) Calibration procedures and required calibration equipment and standards.

(G) Instructions for verification of correct or proper operation.

(H) Trouble-shooting guidance and suggested corrective actions for abnormal operation.

(I) Required or recommended routine, periodic, and preventative maintenance and maintenance schedules.

(J) Any calculations required to derive final concentration measurements.

(K) Appropriate references to Appendix L of part 50 of this chapter; Reference 6 of Appendix A of this subpart; and any other pertinent guidelines.

(ii) The manual shall also include adequate warning of potential safety hazards that may result from normal use and/or malfunction of the method and a description of necessary safety precautions. (See § 53.9(b).) However, the previous requirement shall not be interpreted to constitute or imply any warranty of safety of the method by EPA. For samplers and automated methods, the manual shall include a clear description of all procedures pertaining to installation, operation, preventive maintenance, and troubleshooting and shall also include parts identification diagrams. The manual may be used to satisfy the requirements of paragraphs (b)(1) and (b)(2) of this section to the extent that it includes information necessary to meet those requirements.

(4) A statement that the candidate method has been tested in accordance with the procedures described in subparts B, C, D, E, and/or F of this part, as applicable.

(5) Descriptions of test facilities and test configurations, test data, records, calculations, and test results as specified in subparts B, C, D, E, and/or F of this part, as applicable. Data must be sufficiently detailed to meet appropriate principles described in paragraphs 4 through 6 of Reference 2 of Appendix A of this subpart, Part b, sections 3.3.1 (paragraph 1) and 3.5.1 (paragraphs 2 and 3) and in paragraphs 1 through 3 of Reference 5 (section 4.8, Records) of Appendix A of this subpart. Salient requirements from these references include the following:

(i) The applicant shall maintain and include records of all relevant measuring equipment, including the make, type, and serial number or other identification, and most recent calibration with identification of the measurement standard or standards used and their National Institute of Standards and Technology (NIST) traceability. These records shall demonstrate the measurement capability of each item of measuring equipment used for the application and include a description and justification (if needed) of the measurement setup or configuration in which it was used for the tests. The calibration results shall be recorded and identified in sufficient detail so that the traceability of all measurements can be determined and any measurement could be reproduced under conditions close to the original conditions, if necessary, to resolve any anomalies.

(ii) Test data shall be collected according to the standards of good practice and by qualified personnel. Test anomalies or irregularities shall be documented and explained or justified. The impact and significance of the deviation on test results and conclusions shall be determined. Data collected shall correspond directly to the specified test requirement and be labeled and identified clearly so that results can be verified and evaluated against the test requirement. Calculations or data manipulations must be explained in detail so that they can be verified.

(6) A statement that the method, analyzer, or sampler tested in accordance with this part is representative of the candidate method described in the application.

(c) For candidate automated methods and candidate manual methods for PM_{10} and $PM_{2.5}$, the application shall also contain the following:

(1) A detailed description of the quality system that will be utilized, if the candidate method is designated as a reference or equivalent method, to ensure that all analyzers or samplers offered for sale under that designation will have essentially the same performance characteristics as the analyzer(s) or samplers tested in accordance with this part. In addition, the quality system requirements for candidate methods for $PM_{2.5}$ must be described in sufficient detail, based on the elements described in section 4 of Reference 1 (Quality System Requirements) of Appendix A of this subpart. Further clarification is provided in the following sections of Reference 2 of Appendix A of this subpart: Part A (Management Systems), sections 2.2 (Quality System and Description), 2.3 (Personnel Qualification and Training), 2.4 (Procurement of Items and Services), 2.5 (Documents and Records), and 2.7 (Planning); Part B (Collection and Evaluation of Environmental Data), sections 3.1 (Planning and Scoping), 3.2 (Design of Data Collection Operations), and 3.5 (Assessment and Verification of Data Usability); and Part C (Operation of Environmental Technology), sections 4.1 (Planning), 4.2 (Design of Systems), and 4.4 (Operation of Systems).

(2) A description of the durability characteristics of such analyzers or samplers (see § 53.9(c)). For methods for $PM_{2.5}$, the warranty program must

ensure that the required specifications (see Table A-1 of this subpart) will be met throughout the warranty period and that the applicant accepts responsibility and liability for ensuring this conformance or for resolving any nonconformities, including all necessary components of the system, regardless of the original manufacturer. The warranty program must be described in sufficient detail to meet appropriate provisions of the ANSI/ASQC and ISO 9001 standards (References 1 and 2 in Appendix A of this subpart) for controlling conformance and resolving nonconformance, particularly sections 4.12, 4.13, and 4.14 of Reference 1 in Appendix A of this subpart.

(i) Section 4.12 in Appendix A of this subpart requires the manufacturer to establish and maintain a system of procedures for identifying and maintaining the identification of inspection and test status throughout all phases of manufacturing to ensure that only instruments that have passed the required inspections and tests are released for sale.

(ii) Section 4.13 in Appendix A of this subpart requires documented procedures for control of nonconforming product, including review and acceptable alternatives for disposition; section 4.14 in Appendix A of this subpart requires documented procedures for implementing corrective (4.14.2) and preventive (4.14.3) action to eliminate the causes of actual or potential nonconformities. In particular, section 4.14.3 requires that potential causes of nonconformities be eliminated by using information such as service reports and customer complaints to eliminate potential causes of nonconformities.

(d) For candidate reference or equivalent methods for $PM_{2.5}$, the applicant shall provide to EPA for test purposes one sampler or analyzer that is representative of the sampler or analyzer associated with the candidate method. The sampler or analyzer shall be shipped FOB destination to Department E, (MD-77B), U.S. EPA, 79 T.W. Alexander Drive, Research Triangle Park, NC 27711, scheduled to arrive concurrent with or within 30 days of the arrival of the other application materials. This analyzer or sampler may be subjected to various tests that EPA determines to be necessary or appropriate under § 53.5(f), and such tests may include special tests not described in this part. If the instrument submitted under this paragraph malfunctions, becomes inoperative, or fails to perform as represented in the application before the necessary EPA testing is completed, the applicant shall be afforded an opportunity to repair or replace the device at no cost to EPA. Upon completion of EPA testing, the analyzer or sampler submitted under this paragraph shall be repacked by EPA for return shipment to the applicant, using the same packing materials used for shipping the instrument to EPA unless alternative packing is provided by the applicant. Arrangements for, and the cost of, return shipment shall be the responsibility of the applicant. EPA does not warrant or assume any liability for the condition of the analyzer or sampler upon return to the applicant.

§ 53.5 Processing of applications.

After receiving an application for a reference or equivalent method determination, the Administrator will publish notice of the application in the **Federal Register** and, within 120 calendar days after receipt of the application, take one or more of the following actions:

(a) Send notice to the applicant, in accordance with § 53.8, that the candidate method has been determined to be a reference or equivalent method.

(b) Send notice to the applicant that the application has been rejected, including a statement of reasons for rejection.

(c) Send notice to the applicant that additional information must be submitted before a determination can be made and specify the additional information that is needed (in such cases, the 120–day period shall commence upon receipt of the additional information).

(d) Send notice to the applicant that additional test data must be submitted and specify what tests are necessary and how the tests shall be interpreted (in such cases, the 120–day period shall commence upon receipt of the additional test data).

(e) Send notice to the applicant that the application has been found to be substantially deficient or incomplete and cannot be processed until additional information is submitted to complete the application and specify the general areas of substantial deficiency.

(f) Send notice to the applicant that additional tests will be conducted by the Administrator, specifying the nature of and reasons for the additional tests and the estimated time required (in such cases, the 120–day period shall commence 1 calendar day after the additional tests have been completed).

§ 53.6 Right to witness conduct of tests.

(a) Submission of an application for a reference or equivalent method determination shall constitute consent for the Administrator or the Administrator's authorized representative, upon presentation of appropriate credentials, to witness or observe any tests required by this part in connection with the application or in connection with any modification or intended modification of the method by the applicant.

(b) The applicant shall have the right to witness or observe any test conducted by the Administrator in connection with the application or in connection with any modification or intended modification of the method by the applicant.

(c) Any tests by either party that are to be witnessed or observed by the other party shall be conducted at a time and place mutually agreeable to both parties.

§ 53.7 Testing of methods at the initiative of the Administrator.

(a) In the absence of an application for a reference or equivalent method determination, the Administrator may conduct the tests required by this part for such a determination, may compile such other information as may be necessary in the judgment of the Administrator to make such a determination, and on the basis of the tests and information may determine that a method satisfies applicable requirements of this part.

(b) In the absence of an application requesting the Administrator to consider revising an appendix to part 50 of this chapter in accordance with § 53.16, the Administrator may conduct such tests and compile such information as may be necessary in the Administrator's judgment to make a determination under § 53.16(d) and on the basis of the tests and information make such a determination.

(c) If a method tested in accordance with this section is designated as a reference or equivalent method in accordance with § 53.8 or is specified or designated as a reference method in accordance with § 53.16, any person or entity who offers the method for sale as a reference or equivalent method thereafter shall assume the rights and obligations of an applicant for purposes of this part, with the exception of those pertaining to submission and processing of applications.

§ 53.8 Designation of reference and equivalent methods.

(a) A candidate method determined by the Administrator to satisfy the applicable requirements of this part shall be designated as a reference method or equivalent method (as applicable), and a notice of the

designation shall be submitted for publication in the **Federal Register** not later than 15 days after the determination is made.

(b) A notice indicating that the method has been determined to be a reference method or an equivalent method shall be sent to the applicant. This notice shall constitute proof of the determination until a notice of designation is published in accordance with paragraph (a) of this section.

(c) The Administrator will maintain a current list of methods designated as reference or equivalent methods in accordance with this part and will send a copy of the list to any person or group upon request. A copy of the list will be available for inspection or copying at EPA Regional Offices.

§ 53.9 Conditions of designation.

Designation of a candidate method as a reference method or equivalent method shall be conditioned to the applicant's compliance with the following requirements. Failure to comply with any of the requirements shall constitute a ground for cancellation of the designation in accordance with § 53.11.

(a) Any method offered for sale as a reference or equivalent method shall be accompanied by a copy of the manual referred to in § 53.4(b)(3) when delivered to any ultimate purchaser.

(b) Any method offered for sale as a reference or equivalent method shall generate no unreasonable hazard to operators or to the environment during normal use or when malfunctioning.

(c) Any analyzer, PM_{10} sampler, or $PM_{2.5}$ sampler offered for sale as part of a reference or equivalent method shall function within the limits of the performance specifications referred to in § 53.20(a), § 53.30(a), § 53.50, or § 53.60, as applicable, for at least 1 year after delivery and acceptance when maintained and operated in accordance with the manual referred to in § 53.4(b)(3).

(d) Any analyzer, PM_{10} sampler, or $PM_{2.5}$ sampler offered for sale as a reference or equivalent method shall bear a prominent, permanently affixed label or sticker indicating that the analyzer or sampler has been designated by EPA as a reference method or as an equivalent method (as applicable) in accordance with this part and displaying any designated method identification number that may be assigned by EPA.

(e) If an analyzer is offered for sale as a reference or equivalent method and has one or more selectable ranges, the label or sticker required by paragraph (d) of this section shall be placed in close proximity to the range selector and shall indicate clearly which range or ranges have been designated as parts of the reference or equivalent method.

(f) An applicant who offers analyzers, PM_{10} samplers, or $PM_{2.5}$ samplers for sale as reference or equivalent methods shall maintain an accurate and current list of the names and mailing addresses of all ultimate purchasers of such analyzers or samplers. For a period of 7 years after publication of the reference or equivalent method designation applicable to such an analyzer or sampler, the applicant shall notify all ultimate purchasers of the analyzer or $PM_{2.5}$ or PM_{10} sampler within 30 days if the designation has been canceled in accordance with § 53.11 or § 53.16 or if adjustment of the analyzer or sampler is necessary under § 53.11(b).

(g) If an applicant modifies an analyzer, PM_{10} sampler, or $PM_{2.5}$ sampler that has been designated as a reference or equivalent method, the applicant shall not sell the modified analyzer or sampler as a reference or equivalent method nor attach a label or sticker to the modified analyzer or sampler under paragraph (d) or (e) of this section until the applicant has received notice under § 53.14(c) that the existing designation or a new designation will apply to the modified analyzer, PM_{10} sampler, or $PM_{2.5}$ sampler or has applied for and received notice under § 53.8(b) of a new reference or equivalent method determination for the modified analyzer or sampler.

(h) An applicant who has offered $PM_{2.5}$ samplers or analyzers for sale as part of a reference or equivalent method may continue to do so only so long as the facility in which the samplers or analyzers are manufactured continues to be an ISO 9001-registered facility, as set forth in subpart E of this part. In the event that the ISO 9001 registration for the facility is withdrawn, suspended, or otherwise becomes inapplicable, either permanently or for some specified time interval, such that the facility is no longer an ISO 9001-registered facility, the applicant shall notify EPA within 30 days of the date the facility becomes other than an ISO 9001-registered facility, and upon such notification, EPA shall issue a preliminary finding and notification of possible cancellation of the reference or equivalent method designation under § 53.11.

(i) An applicant who has offered $PM_{2.5}$ samplers or analyzers for sale as part of a reference or equivalent method may continue to do so only so long as updates of the Product Manufacturing Checklist set forth in subpart E of this part are submitted annually. In the event that an annual Checklist update is not received by EPA within 12 months of the date of the last such submitted Checklist or Checklist update, EPA shall notify the applicant within 30 days that the Checklist update has not been received and shall, within 30 days from the issuance of such notification, issue a preliminary finding and notification of possible cancellation of the reference or equivalent method designation under § 53.11.

§ 53.10 Appeal from rejection of application.

Any applicant whose application for a reference or equivalent method determination has been rejected may appeal the Administrator's decision by taking one or more of the following actions:

(a) The applicant may submit new or additional information in support of the application.

(b) The applicant may request that the Administrator reconsider the data and information already submitted.

(c) The applicant may request that any test conducted by the Administrator that was a material factor in the decision to reject the application be repeated.

§ 53.11 Cancellation of reference or equivalent method designation.

(a) *Preliminary finding.* If the Administrator makes a preliminary finding on the basis of any available information that a representative sample of a method designated as a reference or equivalent method and offered for sale as such does not fully satisfy the requirements of this part or that there is any violation of the requirements set forth in § 53.9, the Administrator may initiate proceedings to cancel the designation in accordance with the following procedures.

(b) *Notification and opportunity to demonstrate or achieve compliance.* (1) After making a preliminary finding in accordance with paragraph (a) of this section, the Administrator will send notice of the preliminary finding to the applicant, together with a statement of the facts and reasons on which the preliminary finding is based, and will publish notice of the preliminary finding in the **Federal Register**.

(2) The applicant will be afforded an opportunity to demonstrate or to achieve compliance with the requirements of this part within 60 days after publication of notice in accordance with paragraph (b)(1) of this section or within such further period as the Administrator may allow, by demonstrating to the satisfaction of the Administrator that the method in question satisfies the requirements of this part, by commencing a program to

make any adjustments that are necessary to bring the method into compliance, or by taking such action as may be necessary to cure any violation of the requirements of § 53.9. If adjustments are necessary to bring the method into compliance, all such adjustments shall be made within a reasonable time as determined by the Administrator. If the applicant demonstrates or achieves compliance in accordance with this paragraph (b)(2), the Administrator will publish notice of such demonstration or achievement in the **Federal Register**.

(c) *Request for hearing.* Within 60 days after publication of a notice in accordance with paragraph (b)(1) of this section, the applicant or any interested person may request a hearing as provided in § 53.12.

(d) *Notice of cancellation*. If, at the end of the period referred to in paragraph (b)(2) of this section, the Administrator determines that the reference or equivalent method designation should be canceled, a notice of cancellation will be published in the **Federal Register** and the designation will be deleted from the list maintained under § 53.8(c). If a hearing has been requested and granted in accordance with § 53.12, action under this paragraph (d) will be taken only after completion of proceedings (including any administrative review) conducted in accordance with § 53.13 and only if the decision of the Administrator reached in such proceedings is that the designation in question should be canceled.

§ 53.12 Request for hearing on cancellation.

Within 60 days after publication of a notice in accordance with § 53.11(b)(1), the applicant or any interested person may request a hearing on the Administrator's action. If, after reviewing the request and supporting data, the Administrator finds that the request raises a substantial issue of fact, a hearing will be granted in accordance with § 53.13 with respect to such issue. The request shall be in writing, signed by an authorized representative of the applicant or interested person, and shall include a statement specifying:

(a) Any objections to the Administrator's action.

(b) Data or other information in support of such objections.

§ 53.13 Hearings.

(a)(1) After granting a request for a hearing under § 53.12, the Administrator will designate a presiding officer for the hearing.

(2) If a time and place for the hearing have not been fixed by the Administrator, the hearing will be held as soon as practicable at a time and place fixed by the presiding officer, except that the hearing shall in no case be held sooner than 30 days after publication of a notice of hearing in the **Federal Register**.

(3) For purposes of the hearing, the parties shall include EPA, the applicant or interested person(s) who requested the hearing, and any person permitted to intervene in accordance with paragraph (c) of this section.

(4) The Deputy General Counsel or the Deputy General Counsel's representative will represent EPA in any hearing under this section.

(5) Each party other than EPA may be represented by counsel or by any other duly authorized representative.

(b)(1) Upon appointment, the presiding officer will establish a hearing file. The file shall contain copies of the notices issued by the Administrator pursuant to § 53.11(b)(1), together with any accompanying material, the request for a hearing and supporting data submitted therewith, the notice of hearing published in accordance with paragraph (a)(2) of this section, and correspondence and other material data relevant to the hearing.

(2) The hearing file shall be available for inspection by the parties or their representatives at the office of the presiding officer, except to the extent that it contains information identified in accordance with § 53.15.

(c) The presiding officer may permit any interested person to intervene in the hearing upon such a showing of interest as the presiding officer may require; provided that permission to intervene may be denied in the interest of expediting the hearing where it appears that the interests of the person seeking to intervene will be adequately represented by another party (or by other parties), including EPA.

(d)(1) The presiding officer, upon the request of any party or at the officer's discretion, may arrange for a prehearing conference at a time and place specified by the officer to consider the following:

(i) Simplification of the issues.

(ii) Stipulations, admissions of fact, and the introduction of documents.

(iii) Limitation of the number of expert witnesses.

(iv) Possibility of agreement on disposing of all or any of the issues in dispute.

(v) Such other matters as may aid in the disposition of the hearing, including such additional tests as may be agreed upon by the parties.

(2) The results of the conference shall be reduced to writing by the presiding officer and made part of the record.

(e)(1) Hearings shall be conducted by the presiding officer in an informal but orderly and expeditious manner. The parties may offer oral or written evidence, subject to exclusion by the presiding officer of irrelevant, immaterial, or repetitious evidence.

(2) Witnesses shall be placed under oath.

(3) Any witness may be examined or cross-examined by the presiding officer, the parties, or their representatives. The presiding officer may, at his/her discretion, limit cross-examination to relevant and material issues.

(4) Hearings shall be reported verbatim. Copies of transcripts of proceedings may be purchased from the reporter.

(5) All written statements, charts, tabulations, and data offered in evidence at the hearing shall, upon a showing satisfactory to the presiding officer of their authenticity, relevancy, and materiality, be received in evidence and shall constitute part of the record.

(6) Oral argument shall be permitted. The presiding officer may limit oral presentations to relevant and material issues and designate the amount of time allowed for oral argument.

(f)(1) The presiding officer shall make an initial decision which shall include written findings and conclusions and the reasons therefore on all the material issues of fact, law, or discretion presented on the record. The findings, conclusions, and written decision shall be provided to the parties and made part of the record. The initial decision shall become the decision of the Administrator without further proceedings unless there is an appeal to, or review on motion of, the Administrator within 30 calendar days after the initial decision is filed.

(2) On appeal from or review of the initial decision, the Administrator will have all the powers consistent with making the initial decision, including the discretion to require or allow briefs, oral argument, the taking of additional evidence or the remanding to the presiding officer for additional proceedings. The decision by the Administrator will include written findings and conclusions and the reasons or basis therefore on all the material issues of fact, law, or discretion presented on the appeal or considered in the review.

§ 53.14 Modification of a reference or equivalent method.

(a) An applicant who offers a method for sale as a reference or equivalent method shall report to the EPA Administrator prior to implementation any intended modification of the

method, including but not limited to modifications of design or construction or of operational and maintenance procedures specified in the operation manual (see § 53.9(g)). The report shall be signed by an authorized representative of the applicant, marked in accordance with § 53.15 (if applicable), and addressed as specified in § 53.4(a).

(b) A report submitted under paragraph (a) of this section shall include:

(1) A description, in such detail as may be appropriate, of the intended modification.

(2) A brief statement of the applicant's belief that the modification will, will not, or may affect the performance characteristics of the method.

(3) A brief statement of the probable effect if the applicant believes the modification will or may affect the performance characteristics of the method.

(4) Such further information, including test data, as may be necessary to explain and support any statement required by paragraphs (b)(2) and (b)(3) of this section.

(c) Within 30 calendar days after receiving a report under paragraph (a) of this section, the Administrator will take one or more of the following actions:

(1) Notify the applicant that the designation will continue to apply to the method if the modification is implemented.

(2) Send notice to the applicant that a new designation will apply to the method (as modified) if the modification is implemented, submit notice of the determination for publication in the **Federal Register**, and revise or supplement the list referred to in § 53.8(c) to reflect the determination.

(3) Send notice to the applicant that the designation will not apply to the method (as modified) if the modification is implemented and submit notice of the determination for publication in the **Federal Register**.

(4) Send notice to the applicant that additional information must be submitted before a determination can be made and specify the additional information that is needed (in such cases, the 30–day period shall commence upon receipt of the additional information).

(5) Send notice to the applicant that additional tests are necessary and specify what tests are necessary and how they shall be interpreted (in such cases, the 30–day period shall commence upon receipt of the additional test data).

(6) Send notice to the applicant that additional tests will be conducted by the Administrator and specify the reasons for and the nature of the additional tests (in such cases, the 30–day period shall commence 1 calendar day after the additional tests are completed).

(d) An applicant who has received a notice under paragraph (c)(3) of this section may appeal the Administrator's action as follows:

(1) The applicant may submit new or additional information pertinent to the intended modification.

(2) The applicant may request the Administrator to reconsider data and information already submitted.

(3) The applicant may request that the Administrator repeat any test conducted that was a material factor in the Administrator's determination. A representative of the applicant may be present during the performance of any such retest.

§ 53.15 Trade secrets and confidential or privileged information.

Any information submitted under this part that is claimed to be a trade secret or confidential or privileged information shall be marked or otherwise clearly identified as such in the submittal. Information so identified will be treated in accordance with part 2 of this chapter (concerning public information).

§ 53.16 Supersession of reference methods.

(a) This section prescribes procedures and criteria applicable to requests that the Administrator specify a new reference method, or a new measurement principle and calibration procedure on which reference methods shall be based, by revision of the appropriate appendix to part 50 of this chapter. Such action will ordinarily be taken only if the Administrator determines that a candidate method or a variation thereof is substantially superior to the existing reference method(s).

(b) In exercising discretion under this section, the Administrator will consider:

(1) The benefits, in terms of the requirements and purposes of the Act, that would result from specifying a new reference method or a new measurement principle and calibration procedure.

(2) The potential economic consequences of such action for State and local control agencies.

(3) Any disruption of State and local air quality monitoring programs that might result from such action.

(c) An applicant who wishes the Administrator to consider revising an appendix to part 50 of this chapter on the ground that the applicant's candidate method is substantially superior to the existing reference method(s) shall submit an application for a reference or equivalent method determination in accordance with § 53.4 and shall indicate therein that such consideration is desired. The application shall include, in addition to the information required by § 53.4, data and any other information supporting the applicant's claim that the candidate method is substantially superior to the existing reference method(s).

(d) After receiving an application under paragraph (c) of this section, the Administrator will publish notice of its receipt in the **Federal Register** and, within 120 calendar days after receipt of the application, take one of the following actions:

(1) Determine that it is appropriate to propose a revision of the appendix to part 50 of this chapter in question and send notice of the determination to the applicant.

(2) Determine that it is inappropriate to propose a revision of the appendix to part 50 of this chapter in question, determine whether the candidate method is a reference or equivalent method, and send notice of the determinations, including a statement of reasons for the determination not to propose a revision, to the applicant.

(3) Send notice to the applicant that additional information must be submitted before a determination can be made and specify the additional information that is needed (in such cases, the 120–day period shall commence upon receipt of the additional information).

(4) Send notice to the applicant that additional tests are necessary, specifying what tests are necessary and how the test shall be interpreted (in such cases, the 120–day period shall commence upon receipt of the additional test data).

(5) Send notice to the applicant that additional tests will be conducted by the Administrator, specifying the nature of and reasons for the additional tests and the estimated time required (in such cases, the 120–day period shall commence 1 calendar day after the additional tests have been completed).

(e)(1)(i) After making a determination under paragraph (d)(1) of this section, the Administrator will publish a notice of proposed rulemaking in the **Federal Register**. The notice of proposed rulemaking will indicate that the Administrator proposes:

(A) To revise the appendix to part 50 of this chapter in question.

(B) Where the appendix specifies a measurement principle and calibration procedure, to cancel reference method designations based on the appendix.

(C) To cancel equivalent method designations based on the existing reference method(s).

(ii) The notice of proposed rulemaking will include the terms or substance of the proposed revision, will indicate what period(s) of time the Administrator proposes to allow for replacement of existing methods under section 2.3 of Appendix C to part 58 of this chapter, and will solicit public comments on the proposal with particular reference to the considerations set forth in paragraphs (a) and (b) of this section.

(2)(i) If, after consideration of comments received, the Administrator determines that the appendix to part 50 in question should be revised, the Administrator will, by publication in the **Federal Register**:

(A) Promulgate the proposed revision, with such modifications as may be appropriate in view of comments received.

(B) Where the appendix to part 50 (prior to revision) specifies a measurement principle and calibration procedure, cancel reference method designations based on the appendix.

(C) Cancel equivalent method designations based on the existing reference method(s).

(D) Specify the period(s) that will be allowed for replacement of existing methods under section 2.3 of Appendix C to part 58 of this chapter, with such modifications from the proposed period(s) as may be appropriate in view of comments received.

(3) Canceled designations will be deleted from the list maintained under § 53.8(c). The requirements and procedures for cancellation set forth in § 53.11 shall be inapplicable to cancellation of reference or equivalent method designations under this section.

(4) If the appendix to part 50 of this chapter in question is revised to specify a new measurement principle and calibration procedure on which the applicant's candidate method is based, the Administrator will take appropriate action under § 53.5 to determine whether the candidate method is a reference method.

(5) Upon taking action under paragraph (e)(2) of this section, the Administrator will send notice of the action to all applicants for whose methods reference and equivalent method designations are canceled by such action.

(f) An applicant who has received notice of a determination under paragraph (d)(2) of this section may appeal the determination by taking one or more of the following actions:

(1) The applicant may submit new or additional information in support of the application.

(2) The applicant may request that the Administrator reconsider the data and information already submitted.

(3) The applicant may request that any test conducted by the Administrator that was a material factor in making the determination be repeated.

Tables to Subpart A of Part 53

TABLE A–1.—SUMMARY OF APPLICABLE REQUIREMENTS FOR REFERENCE AND EQUIVALENT METHODS FOR AIR MONITORING OF CRITERIA POLLUTANTS

Pollutant	Ref. or Equivalent	Manual or Automated	Applicable part 50 Appendix	Applicable Subparts of part 53					
				A	B	C	D	E	F
SO_2	Reference	Manual	A						
		Manual		✔		✔			
	Equivalent	Automated		✔	✔	✔			
CO	Reference	Automated	C	✔	✔				
		Manual		✔		✔			
	Equivalent	Automated		✔	✔	✔			
O_3	Reference	Automated	D	✔	✔				
		Manual		✔		✔			
	Equivalent	Automated		✔	✔	✔			
NO_2	Reference	Automated	F	✔	✔				
		Manual		✔		✔			
	Equivalent	Automated		✔	✔	✔			
Pb	Reference	Manual	G						
	Equivalent	Manual		✔		✔			
PM_{10}	Reference	Manual	J	✔			✔		
		Manual		✔		✔	✔		
	Equivalent	Automated		✔		✔	✔		
$PM_{2.5}$	Reference	Manual	L	✔				✔	
	Equivalent Class I	Manual	L	✔		✔		✔	
	Equivalent Class II	Manual	L	✔		✔		✔	✔
	Equivalent Class III	Manual or Automated		✔		✔[1]		✔[1]	✔[1]

[1] Note: Because of the wide variety of potential devices possible, the specific requirements applicable to a Class III candidate equivalent method for $PM_{2.5}$ are not specified explicitly in this part but, instead, shall be determined on a case-by-case basis for each such candidiate method.

Appendix A to Subpart A of Part 53—References

(1) American National Standard Quality Systems-Model for Quality Assurance in Design, Development, Production, Installation, and Servicing, ANSI/ISO/ASQC Q9001-1994. Available from American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, WI 53202.

(2) American National Standard—Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, ANSI/ASQC E41994. Available from American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, WI 53202.

(3) Dimensioning and Tolerancing, ASME Y14.5M-1994. Available from the American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017.

(4) Mathematical Definition of Dimensioning and Tolerancing Principles, ASME Y14.5.1M-1994. Available from the American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017.

(5) ISO 10012, Quality Assurance Requirements for Measuring Equipment-Part 1: Meteorological confirmation system for measuring equipment):1992(E). Available from American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, WI 53202.

(6) Copies of section 2.12 of the Quality Assurance Handbook for Air Pollution

Measurement Systems, Volume II, Ambient Air Specific Methods, EPA/600/R-94/038b, are available from Department E (MD-77B), U.S. EPA, Research Triangle Park, NC 27711.

c. Subpart C is revised to read as follows:

Subpart C—Procedures for Determining Comparability Between Candidate Methods and Reference Methods

Sec.

53.30 General provisions.
53.31 Test conditions.
53.32 Test procedures for methods for SO_2, CO, O_3, and NO_2.
53.33 Test procedure for methods for lead.
53.34 Test procedure for methods for PM_{10} and $PM_{2.5}$.

Tables to Subpart C of Part 53

Table C-1.—Test Concentration Ranges, Number of Measurements Required, and Maximum Discrepancy Specification
Table C-2.—Sequence of Test Measurements
Table C-3.—Test Specifications for Lead Methods
Table C-4.—Test Specifications for PM_{10} and $PM_{2.5}$ Methods

Figures to Subpart C of Part 53

Figure C-1.—Suggested Format for Reporting Test Results

Appendix A to Subpart C of Part 53—References

Subpart C—Procedures for Determining Comparability Between Candidate Methods and Reference Methods

§ 53.30 General provisions.

(a) *Determination of comparability.* The test procedures prescribed in this subpart shall be used to determine if a candidate method is comparable to a reference method when both methods measure pollutant concentrations in ambient air.

(1) Comparability is shown for SO_2, CO, O_3, and NO_2 methods when the differences between:

(i) Measurements made by a candidate manual method or by a test analyzer representative of a candidate automated method.

(ii) Measurements made simultaneously by a reference method, are less than or equal to the values specified in the last column of Table C-1 of this subpart.

(2) Comparability is shown for lead methods when the differences between:

(i) Measurements made by a candidate method.

(ii) Measurements made by the reference method on simultaneously collected lead samples (or the same sample, if applicable), are less than or equal to the value specified in Table C-3 of this subpart.

(3) Comparability is shown for PM_{10} and $PM_{2.5}$ methods when the relationship between:

(i) Measurements made by a candidate method.

(ii) Measurements made by a reference method on simultaneously collected samples (or the same sample, if applicable) at each of two test sites, is such that the linear regression parameters (slope, intercept, and correlation coefficient) describing the relationship meet the values specified in Table C-4 of this subpart.

(b) *Selection of test sites*—(1) *All methods.* Each test site shall be in a predominately urban area which can be shown to have at least moderate concentrations of various pollutants. The site shall be clearly identified and shall be justified as an appropriate test site with suitable supporting evidence such as maps, population density data, vehicular traffic data, emission inventories, pollutant measurements from previous years, concurrent pollutant measurements, and meteorological data. If approval of a proposed test site is desired prior to conducting the tests, a written request for approval of the test site or sites must be submitted prior to conducting the tests and must include the supporting and justification information required. The Administrator may exercise discretion in selecting a different site (or sites) for any additional tests the Administrator decides to conduct.

(2) *Methods for* SO_2, CO, O_3, and NO_2. All test measurements are to be made at the same test site. If necessary, the concentration of pollutant in the sampled ambient air may be augmented with artificially generated pollutant to facilitate measurements in the specified ranges described under paragraph (d)(2) of this section.

(3) *Methods for Pb.* Test measurements may be made at any number of test sites. Augmentation of pollutant concentrations is not permitted, hence an appropriate test site or sites must be selected to provide lead concentrations in the specified range.

(4) *Methods for* PM_{10}. Test measurements must be made, or derived from particulate samples collected, at not less than two test sites, each of which must be located in a geographical area characterized by ambient particulate matter that is significantly different in nature and composition from that at the other test site(s). Augmentation of pollutant concentrations is not permitted, hence appropriate test sites must be selected to provide PM_{10} concentrations in the specified range. The tests at the two sites may be conducted in different calendar seasons, if appropriate, to provide PM_{10} concentrations in the specified ranges.

(5) *Methods for* $PM_{2.5}$. Augmentation of pollutant concentrations is not permitted, hence appropriate test sites must be selected to provide $PM_{2.5}$ concentrations and $PM_{2.5}/PM_{10}$ ratios (if applicable) in the specified ranges.

(i) Where only one test site is required, as specified in Table C-4 of this subpart, the site need only meet the $PM_{2.5}$ ambient concentration levels required by § 53.34(c)(3).

(ii) Where two sites are required, as specified in Table C-4 of this subpart, each site must be selected to provide the ambient concentration levels required by § 53.34(c)(3). In addition, one site must be selected such that all acceptable test sample sets, as defined in § 53.34(c)(3), have a $PM_{2.5}/PM_{10}$ ratio of more than 0.75; the other site must be selected such that all acceptable test sample sets, as defined in § 53.34(c)(3), have a $PM_{2.5}/PM_{10}$ ratio of less than 0.40. At least two reference method PM_{10} samplers shall be collocated with the candidate and reference method $PM_{2.5}$ samplers and operated simultaneously with the other samplers at each test site to measure concurrent ambient concentrations of PM_{10} to determine the $PM_{2.5}/PM_{10}$ ratio for each sample set. The $PM_{2.5}/PM_{10}$ ratio for each sample set shall be the average of the $PM_{2.5}$ concentration, as determined in § 53.34(c)(1), divided by the average PM_{10} concentration, as measured by the PM_{10} samplers. The tests at the two sites may be conducted in different calendar seasons, if appropriate, to provide $PM_{2.5}$ concentrations and $PM_{2.5}/PM_{10}$ ratios in the specified ranges.

(c) *Test atmosphere.* Ambient air sampled at an appropriate test site or sites shall be used for these tests. Simultaneous concentration measurements shall be made in each of the concentration ranges specified in Tables C-1, C-3, or C-4 of this subpart, as appropriate.

(d) *Sample collection*—(1) *All methods.* All test concentration measurements or samples shall be taken in such a way that both the candidate method and the reference method receive air samples that are homogenous or as nearly identical as practical.

(2) *Methods for* SO_2, CO, O_3, and NO_2. Ambient air shall be sampled from a common intake and distribution manifold designed to deliver homogenous air samples to both methods. Precautions shall be taken in the design and construction of this manifold to minimize the removal of particulates and trace gases, and to ensure that identical samples reach the two methods. If necessary, the concentration of pollutant in the sampled ambient air may be augmented

with artificially-generated pollutant. However, at all times the air sample measured by the candidate and reference methods under test shall consist of not less than 80 percent ambient air by volume. Schematic drawings, physical illustrations, descriptions, and complete details of the manifold system and the augmentation system (if used) shall be submitted.

(3) *Methods for Pb, PM_{10}* and $PM_{2.5}$. The ambient air intake points of all the candidate and reference method collocated samplers for lead, PM_{10} or $PM_{2.5}$ shall be positioned at the same height above the ground level, and between 2 and 4 meters apart. The samplers shall be oriented in a manner that will minimize spatial and wind directional effects on sample collection.

(4) *PM_{10} methods employing the same sampling procedure as the reference method but a different analytical method.* Candidate methods for PM_{10} which employ a sampler and sample collection procedure that are identical to the sampler and sample collection procedure specified in the reference method, but use a different analytical procedure, may be tested by analyzing common samples. The common samples shall be collected according to the sample collection procedure specified by the reference method and shall be analyzed in accordance with the analytical procedures of both the candidate method and the reference method.

(e) *Submission of test data and other information.* All recorder charts, calibration data, records, test results, procedural descriptions and details, and other documentation obtained from (or pertinent to) these tests shall be identified, dated, signed by the analyst performing the test, and submitted. For candidate methods for $PM_{2.5}$, all submitted information must meet the requirements of the ANSI/ASQC E4 Standard, sections 3.3.1, paragraphs 1 and 2 (Reference 1 of Appendix A of this subpart).

§ 53.31 Test conditions.

(a) *All methods.* All test measurements made or test samples collected by means of a sample manifold as specified in § 53.30(d)(2) shall be at a room temperature between 20 °C and 30 °C, and at a line voltage between 105 and 125 volts. All methods shall be calibrated as specified in paragraph (c) of this section prior to initiation of the tests.

(b) *Samplers and automated methods.* (1) Setup and start-up of the test analyzer, test sampler(s), and reference method (if applicable) shall be in strict accordance with the applicable operation manual(s). If the test analyzer does not have an integral strip chart or digital data recorder, connect the analyzer output to a suitable strip chart or digital data recorder. This recorder shall have a chart width of at least 25 centimeters, a response time of 1 second or less, a deadband of not more than 0.25 percent of full scale, and capability of either reading measurements at least 5 percent below zero or offsetting the zero by at least 5 percent. Digital data shall be recorded at appropriate time intervals such that trend plots similar to a strip chart recording may be constructed with a similar or suitable level of detail.

(2) Other data acquisition components may be used along with the chart recorder during the conduct of these tests. Use of the chart recorder is intended only to facilitate visual evaluation of data submitted.

(3) Allow adequate warmup or stabilization time as indicated in the applicable operation manual(s) before beginning the tests.

(c) *Calibration.* The reference method shall be calibrated according to the appropriate appendix to part 50 of this chapter (if it is a manual method) or according to the applicable operation manual(s) (if it is an automated method). A candidate manual method (or portion thereof) shall be calibrated, according to the applicable operation manual(s), if such calibration is a part of the method.

(d) *Range.* (1) Except as provided in paragraph (d)(2) of this section, each method shall be operated in the range specified for the reference method in the appropriate appendix to part 50 of this chapter (for manual reference methods), or specified in Table B-1 of subpart B of this part (for automated reference methods).

(2) For a candidate method having more than one selectable range, one range must be that specified in Table B-1 of subpart B of this part and a test analyzer representative of the method must pass the tests required by this subpart while operated on that range. The tests may be repeated for a broader range (i.e., one extending to higher concentrations) than the one specified in Table B-1 of subpart B of this part, provided that the range does not extend to concentrations more than two times the upper range limit specified in Table B-1 of subpart B of this part and that the test analyzer has passed the tests required by subpart B of this part (if applicable) for the broader range. If the tests required by this subpart are conducted or passed only for the range specified in Table B-1 of subpart B of this part, any equivalent method determination with respect to the method will be limited to that range. If the tests are passed for both the specified range and a broader range (or ranges), any such determination will include the broader range(s) as well as the specified range. Appropriate test data shall be submitted for each range sought to be included in such a determination.

(e) *Operation of automated methods.* (1) Once the test analyzer has been set up and calibrated and tests started, manual adjustment or normal periodic maintenance as specified in the manual referred to in § 53.4(b)(3) is permitted only every 3 days. Automatic adjustments which the test analyzer performs by itself are permitted at any time. The submitted records shall show clearly when manual adjustments were made and describe the operations performed.

(2) All test measurements shall be made with the same test analyzer; use of multiple test analyzers is not permitted. The test analyzer shall be operated continuously during the entire series of test measurements.

(3) If a test analyzer should malfunction during any of these tests, the entire set of measurements shall be repeated, and a detailed explanation of the malfunction, remedial action taken, and whether recalibration was necessary (along with all pertinent records and charts) shall be submitted.

§ 53.32 Test procedures for methods for SO_2, CO, O_3, and NO_2.

(a) Conduct the first set of simultaneous measurements with the candidate and reference methods:

(1) Table C-1 of this subpart specifies the type (1- or 24–hour) and number of measurements to be made in each of the three test concentration ranges.

(2) The pollutant concentration must fall within the specified range as measured by the reference method.

(3) The measurements shall be made in the sequence specified in Table C-2 of this subpart, except for the 1-hour SO_2 measurements, which are all in the high range.

(b) For each pair of measurements, determine the difference (discrepancy) between the candidate method measurement and reference method measurement. A discrepancy which exceeds the discrepancy specified in Table C-1 of this subpart constitutes a failure. Figure C-1 of this subpart contains a suggested format for reporting the test results.

(c) The results of the first set of measurements shall be interpreted as follows:

(1) Zero failures. The candidate method passes the test for comparability.

(2) Three or more failures. The candidate method fails the test for comparability.

(3) One or two failures. Conduct a second set of simultaneous measurements as specified in Table C-1 of this subpart. The results of the combined total of first-set and second-set measurements shall be interpreted as follows:

(i) One or two failures. The candidate method passes the test for comparability.

(ii) Three or more failures. The candidate method fails the test for comparability.

(4) For SO_2, the 1-hour and 24–hour measurements shall be interpreted separately, and the candidate method must pass the tests for both 1- and 24–hour measurements to pass the test for comparability.

(d) A 1-hour measurement consists of the integral of the instantaneous concentration over a 60-minute continuous period divided by the time period. Integration of the instantaneous concentration may be performed by any appropriate means such as chemical, electronic, mechanical, visual judgment, or by calculating the mean of not less than 12 equally spaced instantaneous readings. Appropriate allowances or corrections shall be made in cases where significant errors could occur due to characteristic lag time or rise/fall time differences between the candidate and reference methods. Details of the means of integration and any corrections shall be submitted.

(e) A 24–hour measurement consists of the integral of the instantaneous concentration over a 24–hour continuous period divided by the time period. This integration may be performed by any appropriate means such as chemical, electronic, mechanical, or by calculating the mean of 24 sequential 1-hour measurements.

(f) For ozone and carbon monoxide, no more than six 1-hour measurements shall be made per day. For sulfur dioxide, no more than four 1-hour measurements or one 24–hour measurement shall be made per day. One-hour measurements may be made concurrently with 24–hour measurements if appropriate.

(g) For applicable methods, control or calibration checks may be performed once per day without adjusting the test analyzer or method. These checks may be used as a basis for a linear interpolation-type correction to be applied to the measurements to correct for drift. If such a correction is used, it shall be applied to all measurements made with the method, and the correction procedure shall become a part of the method.

§ 53.33 Test procedure for methods for lead.

(a) *Sample collection*. Collect simultaneous 24–hour samples (filters) of lead at the test site or sites with both the reference and candidate methods until at least 10 filter pairs have been obtained. If the conditions of § 53.30(d)(4) apply, collect at least 10 common samples (filters) in accordance with § 53.30(d)(4) and divide each to form the filter pairs.

(b) *Audit samples*. Three audit samples must be obtained from the address given in § 53.4(a). The audit samples are 3/4 x 8-inch glass fiber strips containing known amounts of lead at the following nominal levels: 100 μg/strip; 300 μg/strip; 750 μg/strip. The true amount of lead, in total μg/strip, will be provided with each audit sample.

(c) *Filter analysis*. (1) For both the reference method samples and the audit samples, analyze each filter extract three times in accordance with the reference method analytical procedure. The analysis of replicates should not be performed sequentially, i.e., a single sample should not be analyzed three times in sequence. Calculate the indicated lead concentrations for the reference method samples in μg/m³ for each analysis of each filter. Calculate the indicated total lead amount for the audit samples in μg/strip for each analysis of each strip. Label these test results as R_{1A}, R_{1B}, R_{1C}, R_{2A}, R_{2B}, ..., Q_{1A}, Q_{1B}, Q_{1C}, ..., where R denotes results from the reference method samples; Q denotes results from the audit samples; 1, 2, 3 indicate the filter number, and A, B, C indicate the first, second, and third analysis of each filter, respectively.

(2) For the candidate method samples, analyze each sample filter or filter extract three times and calculate, in accordance with the candidate method, the indicated lead concentrates in μg/m³ for each analysis of each filter. Label these test results as C_{1A}, C_{1B}, C_{2C}, ..., where C denotes results from the candidate method. For candidate methods which provide a direct measurement of lead concentrations without a separable procedure, $C_{1A}=C_{1B}=C_{1C}$, $C_{2A}=C_{2B}=C_{2C}$, etc.

(d) *Average lead concentration*. For the reference method, calculate the average lead concentration for each filter by averaging the concentrations calculated from the three analyses:

Equation 1

$$R_{i\ ave} = \frac{R_{iA} + R_{iB} + R_{iC}}{3}$$

where:
i is the filter number.

(e) *Acceptable filter pairs*. Disregard all filter pairs for which the lead concentration as determined in the previous paragraph (d) of this section by the average of the three reference method determinations, falls outside the range of 0.5 to 4.0 μg/m³. All remaining filter pairs must be subjected to both of the following tests for precision and comparability. At least five filter pairs must be within the 0.5 to 4.0 μg/m³ range for the tests to be valid.

(f) *Test for precision*. (1) Calculate the precision (P) of the analysis (in percent) for each filter and for each method, as the maximum minus the minimum divided by the average of the three concentration values, as follows:

Equation 2

$$P_{Ri} = \frac{R_{i\ max} - R_{i\ min}}{R_{i\ ave}} \times 100\%$$

or

Equation 3

$$P_{Ci} = \frac{C_{i\ max} - C_{i\ min}}{C_{i\ ave}} \times 100\%$$

where:
i indicates the filter number.

(2) If any reference method precision value (P_{Ri}) exceeds 15 percent, the precision of the reference method analytical procedure is out of control. Corrective action must be taken to determine the source(s) of imprecision and the reference method determinations must be repeated according to paragraph (c) of this section, or the entire test procedure (starting with paragraph (a) of this section) must be repeated.

(3) If any candidate method precision value (P_{Ci}) exceeds 15 percent, the candidate method fails the precision test.

(4) The candidate method passes this test if all precision values (i.e., all P_{Ri}'s and all P_{Ci}'s) are less than 15 percent.

(g) *Test for accuracy*. (1)(i) For the audit samples calculate the average lead concentration for each strip by averaging the concentrations calculated from the three analyses:

Equation 4

$$Q_{i\ ave} = \frac{Q_{iA} + Q_{iB} + Q_{iC}}{3}$$

where:
i is audit sample number.

(ii) Calculate the percent difference (D_q) between the indicated lead concentration for each audit sample and the true lead concentration (T_q) as follows:

Equation 5

$$D_{qi} = \frac{Q_{i\,ave} - T_{qi}}{T_{qi}} \times 100\%$$

(2) If any difference value (D_{qi}) exceeds ±5 percent, the accuracy of the reference method analytical procedure is out of control. Corrective action must be taken to determine the source of the error(s) (e.g., calibration standard discrepancies, extraction problems, etc.) and the reference method and audit sample determinations must be repeated according to paragraph (c) of this section, or the entire test procedure (starting with paragraph (a) of this section) must be repeated.

(h) *Test for comparability*. (1) For each filter pair, calculate all nine possible percent differences (D) between the reference and candidate methods, using all nine possible combinations of the three determinations (A, B, and C) for each method, as:

Equation 6

$$D_{in} = \frac{C_{ij} - R_{ik}}{R_{ik}} \times 100\%$$

where:
i is the filter number, and n numbers from 1 to 9 for the nine possible difference combinations for the three determinations for each method (j= A, B, C, candidate; k= A, B, C, reference).

(2) If none of the percent differences (D) exceeds ± 20 percent, the candidate method passes the test for comparability.

(3) If one or more of the percent differences (D) exceeds ± 20 percent, the candidate method fails the test for comparability.

(i) The candidate method must pass both the precision test (paragraph (f) of this section) and the comparability test (paragraph (h) of this section) to qualify for designation as an equivalent method.

§ 53.34 Test procedure for methods for PM_{10} and $PM_{2.5}$.

(a) *Collocated measurements*. Set up three reference method samplers collocated with three candidate method samplers or analyzers at each of the number of test sites specified in Table C-4 of this subpart. At each site, obtain as many sets of simultaneous PM_{10} or $PM_{2.5}$ measurements as necessary (see paragraph (c)(3) of this section), each set consisting of three reference method and three candidate method measurements, all obtained simultaneously. For $PM_{2.5}$ candidate Class II equivalent methods, at least two collocated PM_{10} reference method samplers are also required to obtain $PM_{2.5}/PM_{10}$ ratios for each sample set. Candidate PM_{10} method measurements shall be 24–hour integrated measurements; $PM_{2.5}$ measurements may be either 24- or 48–hour integrated measurements. All collocated measurements in a sample set must cover the same 24- or 48–hour time period. For samplers, retrieve the samples promptly after sample collection and analyze each sample according to the reference method or candidate method, as appropriate, and determine the PM_{10} or $PM_{2.5}$ concentration in $\mu g/m^3$. If the conditions of § 53.30(d)(4) apply, collect sample sets only with the three reference method samplers. Guidance for quality assurance procedures for $PM_{2.5}$ methods is found in section 2.12 of the Quality Assurance Handbook (Reference 6 of Appendix A to subpart A of this part).

(b) *Sequential samplers*. For sequential samplers, the sampler shall be configured for the maximum number of sequential samples and shall be set for automatic collection of all samples sequentially such that the test samples are collected equally, to the extent possible, among all available sequential channels or utilizing the full available sequential capability.

(c) *Test for comparability and precision*. (1) For each of the measurement sets, calculate the average PM_{10} or $PM_{2.5}$ concentration obtained with the reference method samplers:

Equation 7

$$\overline{R}_j = \frac{\sum_{i=1}^{3} R_{ij}}{3}$$

where:
R denotes results from the reference method;
i is the sampler number; and
j is the set.

(2)(i)(A) For each of the measurement sets, calculate the precision of the reference method PM_{10} or $PM_{2.5}$ measurements as:

Equation 8

$$P_j = \sqrt{\frac{\sum_{i=1}^{3} R_{ij}^2 - \frac{1}{3}\left(\sum_{i=1}^{3} R_{ij}\right)^2}{2}}$$

(B) If the corresponding j is below:

80 $\mu g/m^3$ for PM_{10} methods.

40 $\mu g/m^3$ for 24–hour $PM_{2.5}$ at single test sites for Class I candidate methods.

40 $\mu g/m^3$ for 24–hour $PM_{2.5}$ at sites having $PM_{2.5}/PM_{10}$ ratios >0.75.

30 $\mu g/m^3$ for 48–hour $PM_{2.5}$ at single test sites for Class I candidate methods.

30 $\mu g/m^3$ for 48–hour $PM_{2.5}$ at sites having $PM_{2.5}/PM_{10}$ ratios >0.75.

30 $\mu g/m^3$ for 24–hour $PM_{2.5}$ at sites having $PM_{2.5}/PM_{10}$ ratios <0.40.

20 $\mu g/m^3$ for 48–hour $PM_{2.5}$ at sites having $PM_{2.5}/PM_{10}$ ratios >0.75.

(ii) Otherwise, calculate the precision of the reference method PM_{10} or $PM_{2.5}$ measurements as:

Equation 9

$$RP_j = \frac{1}{\overline{R}_j}\sqrt{\frac{\sum_{i=1}^{3} R_{ij}^2 - \frac{1}{3}\left(\sum_{i=1}^{3} R_{ij}\right)^2}{2}} \times 100\%$$

(3) If j falls outside the acceptable concentration range specified in Table C-4 of this subpart for any set, or if Pj or RPj, as applicable, exceeds the value specified in Table C-4 of this subpart for any set, that set of measurements shall be discarded. For each site, Table C-4 of this subpart specifies the minimum number of sample sets required for various conditions, and § 53.30(b)(5) specifies the $PM_{2.5}/PM_{10}$ ratio requirements applicable to Class II candidate equivalent methods. Additional measurement sets shall be collected and analyzed, as necessary, to provide a minimum of 10 acceptable measurement sets for each test site. If more than 10 measurement sets are collected that meet the above criteria, all such measurement sets shall be used to demonstrate comparability.

(4) For each of the acceptable measurement sets, calculate the average PM_{10} or $PM_{2.5}$ concentration obtained with the candidate method samplers:

Equation 10

$$\overline{C}_j = \frac{\sum_{i=1}^{3} C_{ij}}{3}$$

where:
C denotes results from the candidate method;
i is the sampler number; and
j is the set.

(5) For each site, plot the average PM_{10} or $PM_{2.5}$ measurements obtained with the candidate method (C_j) against the corresponding average PM_{10} or $PM_{2.5}$ measurements obtained with the reference method (R_j). For each site, calculate and record the linear regression slope and intercept, and the correlation coefficient.

(6) If the linear regression parameters calculated under paragraph (c)(5) of this section meet the values specified in Table C-4 of this subpart for all test sites, the candidate method passes the test for comparability.

Tables to Subpart C of Part 53

TABLE C–1.—TEST CONCENTRATION RANGES, NUMBER OF MEASUREMENTS REQUIRED, AND MAXIMUM DISCREPANCY SPECIFICATION

Pollutant	Concentration Range Parts per Million	Simultaneous Measurements Required				Maximum Discrepancy Specification, Parts per Million
		1–hr		24–hr		
		First Set	Second Set	First Set	Second Set	
Ozone	Low 0.06 to 0.10	5	6			0.02
	Med 0.15 to 0.25	5	6			.03
	High 0.35 to 0.45	4	6			.04
	Total	14	18			
Carbon Monoxide	Low 7 to 11	5	6			1.5
	Med 20 to 30	5	6			2.0
	High 35 to 45	4	6			3.0
	Total	14	18			
Sulfur Dioxide	Low 0.02 to 0.05			3	3	0.02
	Med 0.10 to 0.15			2	3	.03
	High 0.30 to 0.50	7	8	2	2	.04
	Total	7	8	7	8	
Nitrogen Dioxide	Low 0.02 to 0.08			3	3	0.02
	Med 0.10 to 0.20			2	3	.03
	High 0.25 to 0.35			2	2	.03
	Total			7	8	

TABLE C–2.—SEQUENCE OF TEST MEASUREMENTS

Measurement	Concentration Range	
	First Set	Second Set
1	Low	Medium
2	High	High
3	Medium	Low
4	High	High
5	Low	Medium
6	Medium	Low
7	Low	Medium
8	Medium	Low
9	High	High

TABLE C–2.—SEQUENCE OF TEST MEASUREMENTS—Continued

Measurement	Concentration Range	
	First Set	Second Set
10	Medium	Low
11	High	Medium
12	Low	High
13	Medium	Medium
14	Low	High
15		Low
16		Medium
17		Low
18		High

TABLE C–3.—TEST SPECIFICATIONS FOR LEAD METHODS

Concentration range, μg/m³	0.5–4.0
Minimum number of 24-hr measurements	5
Maximum analytical precision, percent	5
Maximum analytical accuracy, percent	±5
Maximum difference, percent of reference method	±20

TABLE C–4.—TEST SPECIFICATIONS FOR PM_{10} AND $PM_{2.5}$ METHODS

Specification	PM_{10}	$PM_{2.5}$	
		Class I	Class II
Acceptable concentration range (R_j), μg/m³	30–300	10–200	10–200
Minimum number of test sites	2	1	2
Number of candidate method samplers per site	3	3	3
Number of reference method samplers per site	3	3	3
Minimum number of acceptable sample sets per site for PM_{10}:			
R_j < 80 μg/m³	3		
R_j > 80 μg/m³	3		
Total	10		
Minimum number of acceptable sample sets per site for $PM_{2.5}$:			
Single test site for Class I candidate equivalent methods:			
R_j < 40 μg/m³ for 24-hr or R_j < 30 μg/m³ for 48-hr samples		3	
R_j > 40 μg/m³ for 24-hr or R_j > 30 μg/m³ for 48-hr samples		3	
Sites at which the $PM_{2.5}/PM_{10}$ ratio must be > 0.75:			
R_j < 40 μg/m³ for 24-hr or R_j < 30 μg/m³ for 48-hr samples			3
R_j > 40 μg/m³ for 24-hr or R_j > 30 μg/m³ for 48-hr samples			3
Sites at which the $PM_{2.5}/PM_{10}$ ratio must be < 0.40:			
R_j < 30 μg/m³ for 24-hr or R_j < 20 μg/m³ for 48-hr samples			3

TABLE C–4.—TEST SPECIFICATIONS FOR PM_{10} AND $PM_{2.5}$ METHODS—Continued

Specification	PM_{10}	$PM_{2.5}$	
		Class I	Class II
R_j > 30 μg/m³ for 24-hr or R_j > 20 μg/m³ for 48-hr samples			3
Total, each site		10	10
Precision of replicate reference method measurements, P_j or RP_j respectively, maximum.	5 μg/m³ or 7%	2 μg/m³ or 5%	2 μg/m³ or 5%
Slope of regression relationship	1±0.1	1±0.05	1±0.05
Intercept of regression relationship, μg/m³	0±5	0±1	0±1
Correlation of reference method and candidate method measurements	≥0.97	≥0.97	≥0.97

Figures to Subpart C of Part 53

Figure C-1.—Suggested Format for Reporting Test Results

Candidate Method———————————————————————————

Reference Method———————————————————————————

Applicant———————————————————————————————

☐ First Set ☐ Second Set ☐ Type ☐ 1 Hour ☐ 24 Hour

Concentration Range		Date	Time	Concentration, ppm		Difference	Table C-1 Spec.	Pass or Fail
				Candidate	Reference			
Low ——— ppm to ——— ppm	1							
	2							
	3							
	4							
	5							
	6							
Medium ——— ppm to ——— ppm	1							
	2							
	3							
	4							
	5							
	6							
High ——— ppm to ——— ppm	1							
	2							
	3							
	4							
	5							
	6							
	7							
	8							
							Total Failures:	

Appendix A to Subpart C of Part 53--References

(1) American National Standard--Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, ANSI/ASQC E4-1994. Available from American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, WI 53202.

d. Subpart E is added to read as follows:

Subpart E—Procedures for Testing Physical (Design) and Performance Characteristics of Reference Methods and Class I Equivalent Methods for $PM_{2.5}$

Sec.
53.50 General provisions.
53.51 Demonstration of compliance with design specifications and manufacturing and test requirements.
53.52 Leak check test.
53.53 Test for flow rate accuracy, regulation, measurement accuracy, and cut-off.
53.54 Test for proper sampler operation following power interruptions.
53.55 Test for effect of variations in power line voltage and ambient temperature.
53.56 Test for effect of variations in ambient pressure.
53.57 Test for filter temperature control during sampling and post-sampling periods.
53.58 Operational field precision and blank test.
53.59 Aerosol transport test for Class I equivalent method samplers.

Tables to Subpart E of Part 53

Table E-1.—Summary of Test Requirements for Reference and Class I Equivalent Methods for $PM_{2.5}$.
Table E-2.—Spectral Energy Distribution and Permitted Tolerance for Conducting Radiative Tests.

Figures to Subpart E of Part 53

Figure E-1—Designation Testing Checklist
Figure E-2—Product Manufacturing Checklist

Appendix A to Subpart E of Part 53—References

Subpart E—Procedures for Testing Physical (Design) and Performance Characteristics of Reference Methods and Class I Equivalent Methods for $PM_{2.5}$

§ 53.50 General provisions.

(a) This subpart sets forth the specific tests that must be carried out and the test results, evidence, documentation, and other materials that must be provided to EPA to demonstrate that a $PM_{2.5}$ sampler associated with a candidate reference method or Class I equivalent method meets all design and performance specifications set forth in 40 CFR part 50, Appendix L, as well as additional requirements specified in this subpart E. Some of these tests may also be applicable to portions of a candidate Class II equivalent method sampler, as determined under subpart F of this part. Some or all of these tests may also be applicable to a candidate Class III equivalent method sampler, as may be determined under § 53.3(a)(4) or § 53.3(b)(3).

(b) Samplers associated with candidate reference methods for $PM_{2.5}$ shall be subject to the provisions, specifications, and test procedures prescribed in §§ 53.51 through 53.58. Samplers associated with candidate Class I equivalent methods for $PM_{2.5}$ shall be subject to the provisions, specifications, and test procedures prescribed in all sections of this subpart. Samplers associated with candidate Class II equivalent methods for $PM_{2.5}$ shall be subject to the provisions, specifications, and test procedures prescribed in all applicable sections of this subpart, as specified in subpart F of this part.

(c) The provisions of § 53.51 pertain to test results and documentation required to demonstrate compliance of a candidate method sampler with the design specifications set forth in 40 CFR part 50, Appendix L. The test procedures prescribed in §§ 53.52 through 53.59 pertain to performance tests required to demonstrate compliance of a candidate method sampler with the performance specifications set forth in 40 CFR part 50, Appendix L, as well as additional requirements specified in this subpart E. These latter test procedures shall be used to test the performance of candidate samplers against the performance specifications and requirements specified in each procedure and summarized in Table E-1 of this subpart.

(d) Test procedures prescribed in § 53.59 do not apply to candidate reference method samplers. These procedures apply primarily to candidate Class I equivalent method samplers for $PM_{2.5}$ which have a sample air flow path configuration upstream of the sample filter that is modified with respect to that specified for the reference method sampler, as set forth in 40 CFR part 50, Appendix L, Figures L-1 to L-29, such as might be necessary to provide for sequential sample capability. The additional tests determine the adequacy of aerosol transport through any altered components or supplemental devices that are used in a candidate sampler upstream of the sample filter. In addition to the other test procedures in this subpart, these test procedures shall be used to further test the performance of such an equivalent method sampler against the performance specifications given in the procedure and summarized in Table E-1 of this subpart.

(e) A 10–day operational field test of measurement precision is required under § 53.58 for both candidate reference and equivalent method samplers. This test requires collocated operation of three candidate method samplers at a field test site. For candidate equivalent method samplers, this test may be combined and carried out concurrently with the test for comparability to the reference method specified under § 53.34, which requires collocated operation of three reference method samplers and three candidate equivalent method samplers.

(f) All tests and collection of test data shall be performed in accordance with the requirements of Reference 1, section 4.10.5 (ISO 9001) and Reference 2, Part B, section 3.3.1, paragraphs 1 and 2 and Part C, section 4.6 (ANSI/ASQC E4) in Appendix A of this subpart. All test data and other documentation obtained specifically from or pertinent to these tests shall be identified, dated, signed by the analyst performing the test, and submitted to EPA in accordance with subpart A of this part.

§ 53.51 Demonstration of compliance with design specifications and manufacturing and test requirements.

(a) *Overview*. (1) The subsequent paragraphs of this section specify certain documentation that must be submitted and tests that are required to demonstrate that samplers associated with a designated reference or equivalent method for $PM_{2.5}$ are properly manufactured to meet all applicable design and performance specifications and have been properly tested according to all applicable test requirements for such designation. Documentation is required to show that instruments and components of a $PM_{2.5}$ sampler are manufactured in an ISO 9001-registered facility under a quality system that meets ISO-9001 requirements for manufacturing quality control and testing.

(2) In addition, specific tests are required to verify that two critical features of reference method samplers impactor jet diameter and the surface finish of surfaces specified to be anodized meet the specifications of 40 CFR part 50, Appendix L. A checklist is required to provide certification by an ISO-certified auditor that all performance and other required tests have been properly and appropriately conducted, based on a reasonable and appropriate sample of the actual operations or their documented records. Following designation of the method, another checklist is required, initially

and annually, to provide an ISO-certified auditor's certification that the sampler manufacturing process is being implemented under an adequate and appropriate quality system.

(3) For the purposes of this section, the definitions of ISO 9001-registered facility and ISO-certified auditor are found in § 53.1. An exception to the reliance by EPA on ISO affiliate audits is the requirement for the submission of the operation or instruction manual associated with the candidate method to EPA as part of the application. This manual is required under § 53.4(b)(3). EPA has determined that acceptable technical judgment for review of this manual may not be assured by ISO affiliates, and approval of this manual will therefore be performed by EPA.

(b) *ISO registration of manufacturing facility.* (1) The applicant must submit documentation verifying that the samplers identified and sold as part of a designated $PM_{2.5}$ reference or equivalent method will be manufactured in an ISO 9001-registered facility and that the manufacturing facility is maintained in compliance with all applicable ISO 9001 requirements (Reference 1 in Appendix A of this subpart). The documentation shall indicate the date of the original ISO 9001 registration for the facility and shall include a copy of the most recent certification of continued ISO 9001 facility registration. If the manufacturer does not wish to initiate or complete ISO 9001 registration for the manufacturing facility, documentation must be included in the application to EPA describing an alternative method to demonstrate that the facility meets the same general requirements as required for registration to ISO-9001. In this case, the applicant must provide documentation in the application to demonstrate, by required ISO-certified auditor's inspections, that a quality system is in place which is adequate to document and monitor that the sampler system components and final assembled samplers all conform to the design, performance and other requirements specified in this part and in 40 CFR part 50, Appendix L.

(2) Phase-in period. For a period of 1 year following the effective date of this subpart, a candidate reference or equivalent method for $PM_{2.5}$ that utilizes a sampler manufactured in a facility that is not ISO 9001-registered or otherwise approved by EPA under paragraph (b)(1) of this section may be conditionally designated as a reference or equivalent method under this part. Such conditional designation will be considered on the basis of evidence submitted in association with the candidate method application showing that appropriate efforts are currently underway to seek ISO 9001 registration or alternative approval of the facility's quality system under paragraph (b)(1) of this section within the next 12 months. Such conditional designation shall expire 1 year after the date of the **Federal Register** notice of the conditional designation unless documentation verifying successful ISO 9001 registration for the facility or other EPA-acceptable quality system review and approval process of the production facility that will manufacture the samplers is submitted at least 30 days prior to the expiration date.

(c) *Sampler manufacturing quality control.* The manufacturer must ensure that all components used in the manufacture of $PM_{2.5}$ samplers to be sold as part of a reference or equivalent method and that are specified by design in 40 CFR part 50, Appendix L, are fabricated or manufactured exactly as specified. If the manufacturer's quality records show that its quality control (QC) and quality assurance (QA) system of standard process control inspections (of a set number and frequency of testing that is less than 100 percent) complies with the applicable QA provisions of section 4 of Reference 4 in Appendix A of this subpart and prevents nonconformances, 100 percent testing shall not be required until that conclusion is disproved by customer return or other independent manufacturer or customer test records. If problems are uncovered, inspection to verify conformance to the drawings, specifications, and tolerances shall be performed. Refer also to paragraph (e) of this section--final assembly and inspection requirements.

(d) *Specific tests and supporting documentation required to verify conformance to critical component specifications.*—(1) *Verification of* $PM_{2.5}$ impactor jet diameter. The diameter of the jet of each impactor manufactured for a $PM_{2.5}$ sampler under the impactor design specifications set forth in 40 CFR part 50, Appendix L, shall be verified against the tolerance specified on the drawing, using standard, NIST-traceable ZZ go/no go plug gages. This test shall be a final check of the jet diameter following all fabrication operations, and a record shall be kept of this final check. The manufacturer shall submit evidence that this procedure is incorporated into the manufacturing procedure, that the test is or will be routinely implemented, and that an appropriate procedure is in place for the disposition of units that fail this tolerance test.

(2) *Verification of surface finish.* The anodization process used to treat surfaces specified to be anodized shall be verified by testing treated specimen surfaces for weight and corrosion resistance to ensure that the coating obtained conforms to the coating specification. The specimen surfaces shall be finished in accordance with military standard specification 8625F, Type II, Class I (Reference 4 in Appendix A of this subpart) in the same way the sampler surfaces are finished, and tested, prior to sealing, as specified in section 4.5.2 of Reference 4 in Appendix A of this subpart.

(e) *Final assembly and inspection requirements.* Each sampler shall be tested after manufacture and before delivery to the final user. Each manufacturer shall document its post-manufacturing test procedures. As a minimum, each test shall consist of the following: Tests of the overall integrity of the sampler, including leak tests; calibration or verification of the calibration of the flow measurement device, barometric pressure sensor, and temperature sensors; and operation of the sampler with a filter in place over a period of at least 48 hours. The results of each test shall be suitably documented and shall be subject to review by an ISO-certified auditor.

(f) *Manufacturer's audit checklists.* Manufacturers shall require an ISO-certified auditor to sign and date a statement indicating that the auditor is aware of the appropriate manufacturing specifications contained in 40 CFR part 50, Appendix L, and the test or verification requirements in this subpart. Manufacturers shall also require an ISO-certified auditor to complete the checklists, shown in Figures E-1 and E-2 of this subpart, which describe the manufacturer's ability to meet the requirements of the standard for both designation testing and product manufacture.

(1) *Designation testing checklist.* The completed statement and checklist as shown in Figure E-1 of this subpart shall be submitted with the application for reference or equivalent method determination.

(2) *Product manufacturing checklist.* Manufacturers shall require an ISO-certified auditor to complete a Product Manufacturing Checklist (Figure E-2 of this subpart), which evaluates the manufacturer on its ability to meet the requirements of the standard in maintaining quality control in the production of reference or equivalent devices. The initial completed checklist shall be submitted with the application for reference or equivalent method determination. Also, this checklist (Figure E-2 of this subpart) must be completed and submitted annually to

retain a reference or equivalent method designation for a $PM_{2.5}$ method.

(3) *Phase-in period*. If the conditions of paragraph (b)(2) of this section apply, a candidate reference or equivalent method for $PM_{2.5}$ may be conditionally designated as a reference or equivalent method under this part 53 without the submission of the checklists described in paragraphs (f)(1) and (f)(2) of this section. Such conditional designation shall expire 1 year after the date of the **Federal Register** notice of the conditional designation unless the checklists are submitted at least 30 days prior to the expiration date.

§ 53.52 Leak check test.

(a) *Overview*. In section 7.4.6 of 40 CFR part 50, Appendix L, the sampler is required to include the facility, including components, instruments, operator controls, a written procedure, and other capabilities as necessary, to allow the operator to carry out a leak test of the sampler at a field monitoring site without additional equipment. This test procedure is intended to test the adequacy and effectiveness of the sampler's leak check facility. Because of the variety of potential sampler configurations and leak check procedures possible, some adaptation of this procedure may be necessary to accommodate the specific sampler under test. The test conditions and performance specifications associated with this test are summarized in Table E-1 of this subpart. The candidate test sampler must meet all test parameters and test specifications to successfully pass this test.

(b) *Technical definitions*. (1) External leakage includes the total flow rate of external ambient air which enters the sampler other than through the sampler inlet and which passes through any one or more of the impactor, filter, or flow rate measurement components.

(2) Internal leakage is the total sample air flow rate that passes through the filter holder assembly without passing through the sample filter.

(c) *Required test equipment*. (1) Flow rate measurement device, range 70 mL/min to 130 mL/min, 2 percent certified accuracy, NIST-traceable.

(2) Flow rate measurement adaptor (40 CFR part 50, Appendix L, Figure L-30) or equivalent adaptor to facilitate measurement of sampler flow rate at the top of the downtube.

(3) Impermeable membrane or disk, 47 mm nominal diameter.

(4) Means, such as a micro-valve, of providing a simulated leak flow rate through the sampler of approximately 80 mL/min under the conditions specified for the leak check in the sampler's leak check procedure.

(5) Teflon sample filter, as specified in section 6 of 40 CFR part 50, Appendix L.

(d) *Calibration of test measurement instruments*. Submit documentation showing evidence of appropriately recent calibration, certification of calibration accuracy, and NIST-traceability (if required) of all measurement instruments used in the tests. The accuracy of flow rate meters shall be verified at the highest and lowest pressures and temperatures used in the tests and shall be checked at zero and one or more non-zero flow rates within 7 days of use for this test.

(e) *Test setup*. (1) The test sampler shall be set up for testing as described in the sampler's operation or instruction manual referred to in § 53.4(b)(3). The sampler shall be installed upright and set up in its normal configuration for collecting $PM_{2.5}$ samples, except that the sample air inlet shall be removed and the flow rate measurement adaptor shall be installed on the sampler's downtube.

(2) The flow rate control device shall be set up to provide a constant, controlled flow rate of 80 mL/min into the sampler downtube under the conditions specified for the leak check in the sampler's leak check procedure.

(3) The flow rate measurement device shall be set up to measure the controlled flow rate of 80 mL/min into the sampler downtube under the conditions specified for the leak check in the sampler's leak check procedure.

(f) *Procedure*. (1) Install the impermeable membrane in a filter cassette and install the cassette into the sampler. Carry out the internal leak check procedure as described in the sampler's operation/instruction manual and verify that the leak check acceptance criterion specified in Table E-1 of this subpart is met.

(2) Replace the impermeable membrane with a Teflon filter and install the cassette in the sampler. Remove the inlet from the sampler and install the flow measurement adaptor on the sampler's downtube. Close the valve of the adaptor to seal the flow system. Conduct the external leak check procedure as described in the sampler's operation/instruction manual and verify that the leak check acceptance criteria specified in Table E-1 of this subpart are met.

(3) Arrange the flow control device, flow rate measurement device, and other apparatus as necessary to provide a simulated leak flow rate of 80 mL/min into the test sampler through the downtube during the specified external leak check procedure. Carry out the external leak check procedure as described in the sampler's operation/instruction manual but with the simulated leak of 80 mL/min.

(g) *Test results*. The requirements for successful passage of this test are:

(1) That the leak check procedure indicates no significant external or internal leaks in the test sampler when no simulated leaks are introduced.

(2) That the leak check procedure properly identifies the occurrence of the simulated external leak of 80 mL/min.

§ 53.53 Test for flow rate accuracy, regulation, measurement accuracy, and cut-off.

(a) *Overview*. This test procedure is designed to evaluate a candidate sampler's flow rate accuracy with respect to the design flow rate, flow rate regulation, flow rate measurement accuracy, coefficient of variability measurement accuracy, and the flow rate cut-off function. The tests for the first four parameters shall be conducted over a 6–hour time period during which reference flow measurements are made at intervals not to exceed 5 minutes. The flow rate cut-off test, conducted separately, is intended to verify that the sampler carries out the required automatic sample flow rate cut-off function properly in the event of a low-flow condition. The test conditions and performance specifications associated with this test are summarized in Table E-1 of this subpart. The candidate test sampler must meet all test parameters and test specifications to successfully pass this test.

(b) *Technical definitions*. (1) Sample flow rate means the quantitative volumetric flow rate of the air stream caused by the sampler to enter the sampler inlet and pass through the sample filter, measured in actual volume units at the temperature and pressure of the air as it enters the inlet.

(2) The flow rate cut-off function requires the sampler to automatically stop sample flow and terminate the current sample collection if the sample flow rate deviates by more than the variation limits specified in Table E-1 of this subpart (±10 percent from the nominal sample flow rate) for more than 60 seconds during a sample collection period. The sampler is also required to properly notify the operator with a flag warning indication of the out-of-specification flow rate condition and if the flow rate cut-off results in an elapsed sample collection time of less than 23 hours.

(c) *Required test equipment*. (1) Flow rate meter, suitable for measuring and recording the actual volumetric sample flow rate at the sampler downtube, with

a minimum range of 10 to 25 L/min, 2 percent certified, NIST-traceable accuracy. Optional capability for continuous (analog) recording capability or digital recording at intervals not to exceed 30 seconds is recommended. While a flow meter which provides a direct indication of volumetric flow rate is preferred for this test, an alternative certified flow measurement device may be used as long as appropriate volumetric flow rate corrections are made based on measurements of actual ambient temperature and pressure conditions.

(2) Ambient air temperature sensor, with a resolution of 0.1 °C and certified to be accurate to within 0.5 °C (if needed). If the certified flow meter does not provide direct volumetric flow rate readings, ambient air temperature measurements must be made using continuous (analog) recording capability or digital recording at intervals not to exceed 5 minutes.

(3) Barometer, range 600 mm Hg to 800 mm Hg, certified accurate to 2 mm Hg (if needed). If the certified flow meter does not provide direct volumetric flow rate readings, ambient pressure measurements must be made using continuous (analog) recording capability or digital recording at intervals not to exceed 5 minutes.

(4) Flow measurement adaptor (40 CFR part 50, Appendix L, Figure L-30) or equivalent adaptor to facilitate measurement of sample flow rate at the sampler downtube.

(5) Valve or other means to restrict or reduce the sample flow rate to a value at least 10 percent below the design flow rate (16.67 L/min). If appropriate, the valve of the flow measurement adaptor may be used for this purpose.

(6) Means for creating an additional pressure drop of 55 mm Hg in the sampler to simulate a heavily loaded filter, such as an orifice or flow restrictive plate installed in the filter holder or a valve or other flow restrictor temporarily installed in the flow path near the filter.

(7) Teflon sample filter, as specified in section 6 of 40 CFR part 50, Appendix L (if required).

(d) *Calibration of test measurement instruments*. Submit documentation showing evidence of appropriately recent calibration, certification of calibration accuracy, and NIST-traceability (if required) of all measurement instruments used in the tests. The accuracy of flow-rate meters shall be verified at the highest and lowest pressures and temperatures used in the tests and shall be checked at zero and at least one flow rate within ±3 percent of 16.7 L/min within 7 days prior to use for this test. Where an instrument's measurements are to be recorded with an analog recording device, the accuracy of the entire instrument-recorder system shall be calibrated or verified.

(e) *Test setup*. (1) Setup of the sampler shall be as required in this paragraph (e) and otherwise as described in the sampler's operation or instruction manual referred to in § 53.4(b)(3). The sampler shall be installed upright and set up in its normal configuration for collecting $PM_{2.5}$ samples. A sample filter and (or) the device for creating an additional 55 mm Hg pressure drop shall be installed for the duration of these tests. The sampler's ambient temperature, ambient pressure, and flow rate measurement systems shall all be calibrated per the sampler's operation or instruction manual within 7 days prior to this test.

(2) The inlet of the candidate sampler shall be removed and the flow measurement adaptor installed on the sampler's downtube. A leak check as described in the sampler's operation or instruction manual shall be conducted and must be properly passed before other tests are carried out.

(3) The inlet of the flow measurement adaptor shall be connected to the outlet of the flow rate meter.

(4) For the flow rate cut-off test, the valve or means for reducing sampler flow rate shall be installed between the flow measurement adaptor and the downtube or in another location within the sampler such that the sampler flow rate can be manually restricted during the test.

(f) *Procedure*. (1) Set up the sampler as specified in paragraph (e) of this section and otherwise prepare the sampler for normal sample collection operation as directed in the sampler's operation or instruction manual. Set the sampler to automatically start a 6–hour sample collection period at a convenient time.

(2) During the 6–hour operational flow rate portion of the test, measure and record the sample flow rate with the flow rate meter at intervals not to exceed 5 minutes. If ambient temperature and pressure corrections are necessary to calculate volumetric flow rate, ambient temperature and pressure shall be measured at the same frequency as that of the certified flow rate measurements. Note and record the actual start and stop times for the 6–hour flow rate test period.

(3) Following completion of the 6–hour flow rate test period, install the flow rate reduction device and change the sampler flow rate recording frequency to intervals of not more than 30 seconds. Reset the sampler to start a new sample collection period. Manually restrict the sampler flow rate such that the sampler flow rate is decreased slowly over several minutes to a flow rate slightly less than the flow rate cut-off value (15.0 L/min). Maintain this flow rate for at least 2.0 minutes or until the sampler stops the sample flow automatically. Manually terminate the sample period, if the sampler has not terminated it automatically.

(g) *Test results*. At the completion of the test, validate the test conditions and determine the test results as follows:

(1) *Mean sample flow rate*. (i) From the certified measurements (Q_{ref}) of the test sampler flow rate obtained by use of the flow rate meter, tabulate each flow rate measurement in units of L/min. If ambient temperature and pressure corrections are necessary to calculate volumetric flow rate, each measured flow rate shall be corrected using its corresponding temperature and pressure measurement values. Calculate the mean flow rate for the sample period ($Q_{ref,ave}$) as follows:

Equation 1

$$Q_{ref,ave} = \frac{\sum_{i=1}^{n} Q_{ref,i}}{n}$$

where:
n equals the number of discrete certified flow rate measurements over the 6–hour test period.

(ii)(A) Calculate the percent difference between this mean flow rate value and the design value of 16.67 L/min, as follows:

Equation 2

$$\%\ \text{Difference} = \frac{Q_{ref,ave} - 16.67}{16.67} \text{ x } 100\%$$

(B) To successfully pass the mean flow rate test, the percent difference calculated in Equation 2 of this paragraph (g)(1)(ii) must be within ±5 percent.

(2) *Sample flow rate regulation*. (i) From the certified measurements of the test sampler flow rate, calculate the sample coefficient of variation (CV) of the discrete measurements as follows:

Equation 3

$$\%CV_{ref} = \frac{1}{Q_{ref,ave}} \text{ x} \sqrt{\frac{\sum_{i=1}^{n} Q_{ref,i}^2 - \frac{1}{n}\left(\sum_{i-1}^{n} Q_{ref,i}\right)^2}{n-1}} \text{ x } 100\%$$

(ii) To successfully pass the flow rate regulation test, the calculated coefficient of variation for the certified flow rates must not exceed 2 percent.

(3) *Flow rate measurement accuracy*. (i) Using the mean volumetric flow rate reported by the candidate test sampler at the completion of the 6–hour test period ($Q_{ind,ave}$), determine the accuracy of the reported mean flow rate as:

Equation 4

$$\% \text{ Difference} = \frac{|Q_{ind,ave} - Q_{ref,ave}|}{Q_{ref,ave}} \times 100\%$$

(ii) To successfully pass the flow rate measurement accuracy test, the percent difference calculated in Equation 4 of this paragraph (g)(3) shall not exceed 2 percent.

(4) *Flow rate coefficient of variation measurement accuracy*. (i) Using the flow rate coefficient of variation indicated by the candidate test sampler at the completion of the 6–hour test ($\%CV_{ind}$), determine the accuracy of this reported coefficient of variation as:

Equation 5

$$\text{Difference } (\%) = |\%CV_{ind} - \%CV_{ref}|$$

(ii) To successfully pass the flow rate CV measurement accuracy test, the absolute difference in values calculated in Equation 5 of this paragraph (g)(4) must not exceed 0.3 (CV%).

(5) *Flow rate cut-off*. (i) Inspect the measurements of the sample flow rate during the flow rate cut-off test and determine the time at which the sample flow rate decreased to a value less than the cut-off value specified in Table E-1 of this subpart. To pass this test, the sampler must have automatically stopped the sample flow at least 30 seconds but not more than 90 seconds after the time at which the sampler flow rate was determined to have decreased to a value less than the cut-off value.

(ii) At the completion of the flow rate cut-off test, download the archived data from the test sampler and verify that the sampler's required Flow-out-of-spec and Incorrect sample period flag indicators are properly set.

§ 53.54 Test for proper sampler operation following power interruptions.

(a) *Overview*. (1) This test procedure is designed to test certain performance parameters of the candidate sampler during a test period in which power interruptions of various duration occur. The performance parameters tested are:

(i) Proper flow rate performance of the sampler.

(ii) Accuracy of the sampler's average flow rate, CV, and sample volume measurements.

(iii) Accuracy of the sampler's reported elapsed sampling time.

(iv) Accuracy of the reported time and duration of power interruptions.

(2) This test shall be conducted during operation of the test sampler over a continuous 6–hour test period during which the sampler's flow rate shall be measured and recorded at intervals not to exceed 5 minutes. The performance parameters tested under this procedure, the corresponding minimum performance specifications, and the applicable test conditions are summarized in Table E-1 of this subpart. Each performance parameter tested, as described or determined in the test procedure, must meet or exceed the associated performance specification to successfully pass this test.

(b) *Required test equipment*. (1) Flow rate meter, suitable for measuring and recording the actual volumetric sample flow rate at the sampler downtube, with a minimum range of 10 to 25 L/min, 2 percent certified, NIST-traceable accuracy. Optional capability for continuous (analog) recording capability or digital recording at intervals not to exceed 5 minutes is recommended. While a flow meter which provides a direct indication of volumetric flow rate is preferred for this test, an alternative certified flow measurement device may be used as long as appropriate volumetric flow rate corrections are made based on measurements of actual ambient temperature and pressure conditions.

(2) Ambient air temperature sensor (if needed for volumetric corrections to flow rate measurements), with a resolution of 0.1 °C, certified accurate to within 0.5 °C, and continuous (analog) recording capability or digital recording at intervals not to exceed 5 minutes.

(3) Barometer (if needed for volumetric corrections to flow rate measurements), range 600 mm Hg to 800 mm Hg, certified accurate to 2 mm Hg, with continuous (analog) recording capability or digital recording at intervals not to exceed 5 minutes.

(4) Flow measurement adaptor (40 CFR part 50, Appendix L, Figure L-30) or equivalent adaptor to facilitate measurement of sample flow rate at the sampler downtube.

(5) Means for creating an additional pressure drop of 55 mm Hg in the sampler to simulate a heavily loaded filter, such as an orifice or flow restrictive plate installed in the filter holder or a valve or other flow restrictor temporarily installed in the flow path near the filter.

(6) Teflon sample filter, as specified in section 6 of 40 CFR part 50, Appendix L (if required).

(7) Time measurement system, accurate to within 10 seconds per day.

(c) *Calibration of test measurement instruments*. Submit documentation showing evidence of appropriately recent calibration, certification of calibration accuracy, and NIST-traceability (if required) of all measurement instruments used in the tests. The accuracy of flow rate meters shall be verified at the highest and lowest pressures and temperatures used in the tests and shall be checked at zero and at least one flow rate within ±3 percent of 16.7 L/min within 7 days prior to use for this test. Where an instrument's measurements are to be recorded with an analog recording device, the accuracy of the entire instrument-recorder system shall be calibrated or verified.

(d) *Test setup*. (1) Setup of the sampler shall be performed as required in this paragraph (d) and otherwise as described in the sampler's operation or instruction manual referred to in § 53.4(b)(3). The sampler shall be installed upright and set up in its normal configuration for collecting $PM_{2.5}$ samples. A sample filter and (or) the device for creating an additional 55 mm Hg pressure drop shall be installed for the duration of these tests. The sampler's ambient temperature, ambient pressure, and flow measurement systems shall all be calibrated per the sampler's operating manual within 7 days prior to this test.

(2) The inlet of the candidate sampler shall be removed and the flow measurement adaptor installed on the sample downtube. A leak check as described in the sampler's operation or instruction manual shall be conducted and must be properly passed before other tests are carried out.

(3) The inlet of the flow measurement adaptor shall be connected to the outlet of the flow rate meter.

(e) *Procedure*. (1) Set up the sampler as specified in paragraph (d) of this section and otherwise prepare the sampler for normal sample collection operation as directed in the sampler's operation or instruction manual. Set the sampler to automatically start a 6–hour sample collection period at a convenient time.

(2) During the entire 6–hour operational flow rate portion of the test, measure and record the sample flow rate with the flow rate meter at intervals not to exceed 5 minutes. If ambient temperature and pressure corrections are necessary to calculate volumetric flow rate, ambient temperature and pressure shall be measured at the same frequency as that of the certified flow rate measurements. Note and record the actual start and stop times for the 6–hour flow rate test period.

(3) During the 6–hour test period, interrupt the AC line electrical power to

the sampler 5 times, with durations of 20 seconds, 40 seconds, 2 minutes, 7 minutes, and 20 minutes (respectively), with not less than 10 minutes of normal electrical power supplied between each power interruption. Record the hour and minute and duration of each power interruption.

(4) At the end of the test, terminate the sample period (if not automatically terminated by the sampler) and download all archived instrument data from the test sampler.

(f) *Test results.* At the completion of the sampling period, validate the test conditions and determine the test results as follows:

(1) *Mean sample flow rate.* (i) From the certified measurements (Q_{ref}) of the test sampler flow rate, tabulate each flow rate measurement in units of L/min. If ambient temperature and pressure corrections are necessary to calculate volumetric flow rate, each measured flow rate shall be corrected using its corresponding temperature and pressure measurement values. Calculate the mean flow rate for the sample period ($Q_{ref,ave}$) as follows:

Equation 6

$$Q_{ref,ave} = \frac{\sum_{i=1}^{n} Q_{ref,i}}{n}$$

where:

n equals the number of discrete certified flow rate measurements over the 6–hour test period, excluding flow rate values obtained during periods of power interruption.

(ii)(A) Calculate the percent difference between this mean flow rate value and the design value of 16.67 L/min, as follows:

Equation 7

$$\%\ \text{Difference} = \frac{Q_{ref,ave} - 16.67}{16.67} \text{ x } 100\%$$

(B) To successfully pass this test, the percent difference calculated in Equation 7 of this paragraph (f)(1)(ii) must be within ±5 percent.

(2) *Sample flow rate regulation.* (i) From the certified measurements of the test sampler flow rate, calculate the sample coefficient of variation of the discrete measurements as follows:

Equation 8

$$\%CV_{ref} = \frac{1}{Q_{ref,ave}} \text{ x} \sqrt{\frac{\sum_{i=1}^{n} Q_{ref,i}^2 - \frac{1}{n}\left(\sum_{i-1}^{n} Q_{ref,i}\right)^2}{n-1}} \text{ x } 100\%$$

(ii) To successfully pass this test, the calculated coefficient of variation for the certified flow rates must not exceed 2 percent.

(3) *Flow rate measurement accuracy.* (i) Using the mean volumetric flow rate reported by the candidate test sampler at the completion of the 6–hour test ($Q_{ind,ave}$), determine the accuracy of the reported mean flow rate as:

Equation 9

$$\%\ \text{Difference} = \frac{|Q_{ind,ave} - Q_{ref,ave}|}{Q_{ref,ave}} \text{ x } 100\%$$

(ii) To successfully pass this test, the percent difference calculated in Equation 9 of this paragraph (f)(3) shall not exceed 2 percent.

(4) *Flow rate CV measurement accuracy.* (i) Using the flow rate coefficient of variation indicated by the candidate test sampler at the completion of the 6–hour test ($\%CV_{ind}$), determine the accuracy of the reported coefficient of variation as:

Equation 10

$$\text{Difference } (\%) = |\%CV_{ind} - \%CV_{ref}|$$

(ii) To successfully pass this test, the absolute difference in values calculated in Equation 10 of this paragraph (f)(4) must not exceed 0.3 (CV%).

(5) Verify that the sampler properly provided a record and visual display of the correct year, month, day-of-month, hour, and minute with an accuracy of ± 2 minutes, of the start of each power interruption of duration greater than 60 seconds.

(6) Calculate the actual elapsed sample time, excluding the periods of electrical power interruption. Verify that the elapsed sample time reported by the sampler is accurate to within ± 20 seconds for the 6–hour test run.

(7) Calculate the sample volume as $Q_{ref,ave}$ the sample time, excluding periods of power interruption. Verify that the sample volume reported by the sampler is within 2 percent of the calculated sample volume to successfully pass this test.

(8) Inspect the downloaded instrument data from the test sampler and verify that all data are consistent with normal operation of the sampler.

§ 53.55 Test for effect of variations in power line voltage and ambient temperature.

(a) *Overview.* (1) This test procedure is a combined procedure to test various performance parameters under variations in power line voltage and ambient temperature. Tests shall be conducted in a temperature controlled environment over four 6–hour time periods during which reference temperature and flow rate measurements shall be made at intervals not to exceed 5 minutes. Specific parameters to be evaluated at line voltages of 105 and 125 volts and temperatures of -20 °C and +40 °C are as follows:

(i) Sample flow rate.

(ii) Flow rate regulation.

(iii) Flow rate measurement accuracy.

(iv) Coefficient of variability measurement accuracy.

(v) Ambient air temperature measurement accuracy.

(vi) Proper operation of the sampler when exposed to power line voltage and ambient temperature extremes.

(2) The performance parameters tested under this procedure, the corresponding minimum performance specifications, and the applicable test conditions are summarized in Table E-1 of this subpart. Each performance parameter tested, as described or determined in the test procedure, must meet or exceed the associated performance specification given. The candidate sampler must meet all specifications for the associated $PM_{2.5}$ method to pass this test procedure.

(b) *Technical definition.* Sample flow rate means the quantitative volumetric flow rate of the air stream caused by the sampler to enter the sampler inlet and pass through the sample filter, measured in actual volume units at the temperature and pressure of the air as it enters the inlet.

(c) *Required test equipment.* (1) Environmental chamber or other temperature-controlled environment or environments, capable of obtaining and maintaining temperatures at -20 °C and +40 °C as required for the test with an accuracy of ±2 °C. The test environment(s) must be capable of maintaining these temperatures within the specified limits continuously with the additional heat load of the operating test sampler in the environment. Henceforth, where the test procedures specify a test or environmental ''chamber,'' an alternative temperature-controlled environmental area or areas may be substituted, provided the required test temperatures and all other test requirements are met.

(2) Variable voltage AC power transformer, range 100 Vac to 130 Vac, with sufficient current capacity to operate the test sampler continuously under the test conditions.

(3) Flow rate meter, suitable for measuring and recording the actual volumetric sample flow rate at the sampler downtube, with a minimum range of 10 to 25 actual L/min, 2 percent certified, NIST-traceable accuracy. Optional capability for continuous (analog) recording capability or digital recording at intervals not to exceed 5 minutes is recommended. While a flow

meter which provides a direct indication of volumetric flow rate is preferred for this test, an alternative certified flow measurement device may be used as long as appropriate volumetric flow rate corrections are made based on measurements of actual ambient temperature and pressure conditions.

(4) Ambient air temperature recorder, range -30 °C to +50 °C, with a resolution of 0.1 °C and certified accurate to within 0.5 °C. Ambient air temperature measurements must be made using continuous (analog) recording capability or digital recording at intervals not to exceed 5 minutes.

(5) Barometer, range 600 mm Hg to 800 mm Hg, certified accurate to 2 mm Hg. If the certified flow rate meter does not provide direct volumetric flow rate readings, ambient pressure measurements must be made using continuous (analog) recording capability or digital recording at intervals not to exceed 5 minutes.

(6) Flow measurement adaptor (40 CFR part 50, Appendix L, Figure L-30) or equivalent adaptor to facilitate measurement of sampler flow rate at the sampler downtube.

(7) Means for creating an additional pressure drop of 55 mm Hg in the sampler to simulate a heavily loaded filter, such as an orifice or flow restrictive plate installed in the filter holder or a valve or other flow restrictor temporarily installed in the flow path near the filter.

(8) AC RMS voltmeter, accurate to 1.0 volt.

(9) Teflon sample filter, as specified in section 6 of 40 CFR part 50, Appendix L (if required).

(d) *Calibration of test measurement instruments.* Submit documentation showing evidence of appropriately recent calibration, certification of calibration accuracy, and NIST-traceability (if required) of all measurement instruments used in the tests. The accuracy of flow rate meters shall be verified at the highest and lowest pressures and temperatures used in the tests and shall be checked at zero and at least one flow rate within ±3 percent of 16.7 L/min within 7 days prior to use for this test. Where an instrument's measurements are to be recorded with an analog recording device, the accuracy of the entire instrument-recorder system shall be calibrated or verified.

(e) *Test setup.* (1) Setup of the sampler shall be performed as required in this paragraph (e) and otherwise as described in the sampler's operation or instruction manual referred to in § 53.4(b)(3). The sampler shall be installed upright and set up in the temperature-controlled chamber in its normal configuration for collecting $PM_{2.5}$ samples. A sample filter and (or) the device for creating an additional 55 mm Hg pressure drop shall be installed for the duration of these tests. The sampler's ambient temperature, ambient pressure, and flow measurement systems shall all be calibrated per the sampler's operating manual within 7 days prior to this test.

(2) The inlet of the candidate sampler shall be removed and the flow measurement adaptor installed on the sampler's downtube. A leak check as described in the sampler's operation or instruction manual shall be conducted and must be properly passed before other tests are carried out.

(3) The inlet of the flow measurement adaptor shall be connected to the outlet of the flow rate meter.

(4) The ambient air temperature recorder shall be installed in the test chamber such that it will accurately measure the temperature of the air in the vicinity of the candidate sampler without being unduly affected by the chamber's air temperature control system.

(f) *Procedure.* (1) Set up the sampler as specified in paragraph (e) of this section and otherwise prepare the sampler for normal sample collection operation as directed in the sampler's operation or instruction manual.

(2) The test shall consist of four test runs, one at each of the following conditions of chamber temperature and electrical power line voltage (respectively):

(i) -20 °C ±2 °C and 105 ±1 Vac.

(ii) -20 °C ±2 °C and 125 ±1 Vac.

(iii) +40 °C ±2 °C and 105 ±1 Vac.

(iv) +40 °C ±2 °C and 125 ±1 Vac.

(3) For each of the four test runs, set the selected chamber temperature and power line voltage for the test run. Upon achieving each temperature setpoint in the chamber, the candidate sampler and flow meter shall be thermally equilibrated for a period of at least 2 hours prior to the test run. Following the thermal conditioning time, set the sampler to automatically start a 6–hour sample collection period at a convenient time.

(4) During each 6–hour test period:

(i) Measure and record the sample flow rate with the flow rate meter at intervals not to exceed 5 minutes. If ambient temperature and pressure corrections are necessary to calculate volumetric flow rate, ambient temperature and pressure shall be measured at the same frequency as that of the certified flow rate measurements. Note and record the actual start and stop times for the 6–hour flow rate test period.

(ii) Determine and record the ambient (chamber) temperature indicated by the sampler and the corresponding ambient (chamber) temperature measured by the ambient temperature recorder specified in paragraph (c)(4) of this section at intervals not to exceed 5 minutes.

(iii) Measure the power line voltage to the sampler at intervals not greater than 1 hour.

(5) At the end of each test run, terminate the sample period (if not automatically terminated by the sampler) and download all archived instrument data from the test sampler.

(g) *Test results.* For each of the four test runs, examine the chamber temperature measurements and the power line voltage measurements. Verify that the temperature and line voltage met the requirements specified in paragraph (f) of this section at all times during the test run. If not, the test run is not valid and must be repeated. Determine the test results as follows:

(1) *Mean sample flow rate.* (i) From the certified measurements (Q_{ref}) of the test sampler flow rate, tabulate each flow rate measurement in units of L/min. If ambient temperature and pressure corrections are necessary to calculate volumetric flow rate, each measured flow rate shall be corrected using its corresponding temperature and pressure measurement values. Calculate the mean flow rate for each sample period ($Q_{ref,ave}$) as follows:

Equation 11

$$Q_{ref,ave} = \frac{\sum_{i=1}^{n} Q_{ref,i}}{n}$$

where:

n equals the number of discrete certified flow rate measurements over each 6–hour test period.

(ii)(A) Calculate the percent difference between this mean flow rate value and the design value of 16.67 L/min, as follows:

Equation 12

$$\%\ \text{Difference} = \frac{Q_{ref,ave} - 16.67}{16.67} \times 100\%$$

(B) To successfully pass this test, the percent difference calculated in Equation 12 of this paragraph (g)(1)(ii) must be within ±5 percent for each test run.

(2) *Sample flow rate regulation.* (i) From the certified measurements of the test sampler flow rate, calculate the sample coefficient of variation of the discrete measurements as follows:

Equation 13

$$\%CV_{ref} = \frac{1}{Q_{ref,ave}} x \sqrt{\frac{\sum_{i=1}^{n} Q_{ref,i}^2 - \frac{1}{n}\left(\sum_{i-1}^{n} Q_{ref,i}\right)^2}{n-1}} x\ 100\%$$

(ii) To successfully pass this test, the calculated coefficient of variation for the certified flow rates must not exceed 2 percent.

(3) *Flow rate measurement accuracy*. (i) Using the mean volumetric flow rate reported by the candidate test sampler at the completion of each 6–hour test ($Q_{ind,ave}$), determine the accuracy of the reported mean flow rate as:

Equation 14

$$\%\ Difference = \frac{|Q_{ind,ave} - Q_{ref,ave}|}{Q_{ref,ave}} x\ 100\%$$

(ii) To successfully pass this test, the percent difference calculated in Equation 14 of this paragraph (g)(3) shall not exceed 2 percent for each test run.

(4) *Flow rate coefficient of variation measurement accuracy*. (i) Using the flow rate coefficient of variation indicated by the candidate test sampler ($\%CV_{ind}$), determine the accuracy of the reported coefficient of variation as:

Equation 15

$$Difference\ \% = |\%CV_{ind} - \%CV_{ref}|$$

(ii) To successfully pass this test, the absolute difference calculated in Equation 15 of this paragraph (g)(4) must not exceed 0.3 (CV%) for each test run.

(5) *Ambient temperature measurement accuracy*. (i) Calculate the absolute value of the difference between the mean ambient air temperature indicated by the test sampler and the mean ambient (chamber) air temperature measured with the ambient air temperature recorder as:

Equation 16

$$T_{diff} = |T_{ind,ave} - T_{ref,ave}|$$

where:
$T_{ind,ave}$ = mean ambient air temperature indicated by the test sampler, °C; and
$T_{ref,ave}$ = mean ambient air temperature measured by the reference temperature instrument, °C.

(ii) The calculated temperature difference must be less than 2 °C for each test run.

(6) *Sampler functionality*. To pass the sampler functionality test, the following two conditions must both be met for each test run:

(i) The sampler must not shutdown during any portion of the 6–hour test.

(ii) An inspection of the downloaded data from the test sampler verifies that all the data are consistent with normal operation of the sampler.

§ 53.56 Test for effect of variations in ambient pressure.

(a) *Overview*. (1) This test procedure is designed to test various sampler performance parameters under variations in ambient (barometric) pressure. Tests shall be conducted in a pressure-controlled environment over two 6–hour time periods during which reference pressure and flow rate measurements shall be made at intervals not to exceed 5 minutes. Specific parameters to be evaluated at operating pressures of 600 and 800 mm Hg are as follows:

(i) Sample flow rate.

(ii) Flow rate regulation.

(iii) Flow rate measurement accuracy.

(iv) Coefficient of variability measurement accuracy.

(v) Ambient pressure measurement accuracy.

(vi) Proper operation of the sampler when exposed to ambient pressure extremes.

(2) The performance parameters tested under this procedure, the corresponding minimum performance specifications, and the applicable test conditions are summarized in Table E-1 of this subpart. Each performance parameter tested, as described or determined in the test procedure, must meet or exceed the associated performance specification given. The candidate sampler must meet all specifications for the associated $PM_{2.5}$ method to pass this test procedure.

(b) *Technical definition*. Sample flow rate means the quantitative volumetric flow rate of the air stream caused by the sampler to enter the sampler inlet and pass through the sample filter, measured in actual volume units at the temperature and pressure of the air as it enters the inlet.

(c) *Required test equipment*. (1) Hypobaric chamber or other pressure-controlled environment or environments, capable of obtaining and maintaining pressures at 600 mm Hg and 800 mm Hg required for the test with an accuracy of 5 mm Hg. Henceforth, where the test procedures specify a test or environmental chamber, an alternative pressure-controlled environmental area or areas may be substituted, provided the test pressure requirements are met. Means for simulating ambient pressure using a closed-loop sample air system may also be approved for this test; such a proposed method for simulating the test pressure conditions may be described and submitted to EPA at the address given in § 53.4(a) prior to conducting the test for a specific individual determination of acceptability.

(2) Flow rate meter, suitable for measuring and recording the actual volumetric sampler flow rate at the sampler downtube, with a minimum range of 10 to 25 L/min, 2 percent certified, NIST-traceable accuracy. Optional capability for continuous (analog) recording capability or digital recording at intervals not to exceed 5 minutes is recommended. While a flow meter which provides a direct indication of volumetric flow rate is preferred for this test, an alternative certified flow measurement device may be used as long as appropriate volumetric flow rate corrections are made based on measurements of actual ambient temperature and pressure conditions.

(3) Ambient air temperature recorder (if needed for volumetric corrections to flow rate measurements) with a range -30 °C to +50 °C, certified accurate to within 0.5 °C. If the certified flow meter does not provide direct volumetric flow rate readings, ambient temperature measurements must be made using continuous (analog) recording capability or digital recording at intervals not to exceed 5 minutes.

(4) Barometer, range 600 mm Hg to 800 mm Hg, certified accurate to 2 mm Hg. Ambient air pressure measurements must be made using continuous (analog) recording capability or digital recording at intervals not to exceed 5 minutes.

(5) Flow measurement adaptor (40 CFR part 50, Appendix L, Figure L-30) or equivalent adaptor to facilitate measurement of sampler flow rate at the sampler downtube.

(6) Means for creating an additional pressure drop of 55 mm Hg in the sampler to simulate a heavily loaded filter, such as an orifice or flow restrictive plate installed in the filter holder or a valve or other flow restrictor temporarily installed in the flow path near the filter.

(7) Teflon sample filter, as specified in section 6 of 40 CFR part 50, Appendix L (if required).

(d) *Calibration of test measurement instruments*. Submit documentation showing evidence of appropriately recent calibration, certification of calibration accuracy, and NIST-traceability (if required) of all measurement instruments used in the tests. The accuracy of flow rate meters shall be verified at the highest and lowest pressures and temperatures used in the tests and shall be checked at zero and at least one flow rate within ±3 percent of 16.7 L/min within 7 days prior to use for this test. Where an instrument's measurements are to be

recorded with an analog recording device, the accuracy of the entire instrument-recorder system shall be calibrated or verified.

(e) *Test setup*. (1) Setup of the sampler shall be performed as required in this paragraph (e) and otherwise as described in the sampler's operation or instruction manual referred to in § 53.4(b)(3). The sampler shall be installed upright and set up in the pressure-controlled chamber in its normal configuration for collecting $PM_{2.5}$ samples. A sample filter and (or) the device for creating an additional 55 mm Hg pressure drop shall be installed for the duration of these tests. The sampler's ambient temperature, ambient pressure, and flow measurement systems shall all be calibrated per the sampler's operating manual within 7 days prior to this test.

(2) The inlet of the candidate sampler shall be removed and the flow measurement adaptor installed on the sampler's downtube. A leak check as described in the sampler's operation or instruction manual shall be conducted and must be properly passed before other tests are carried out.

(3) The inlet of the flow measurement adaptor shall be connected to the outlet of the flow rate meter.

(4) The barometer shall be installed in the test chamber such that it will accurately measure the air pressure to which the candidate sampler is subjected.

(f) *Procedure*. (1) Set up the sampler as specified in paragraph (e) of this section and otherwise prepare the sampler for normal sample collection operation as directed in the sampler's operation or instruction manual.

(2) The test shall consist of two test runs, one at each of the following conditions of chamber pressure:

(i) 600 mm Hg.

(ii) 800 mm Hg.

(3) For each of the two test runs, set the selected chamber pressure for the test run. Upon achieving each pressure setpoint in the chamber, the candidate sampler shall be pressure-equilibrated for a period of at least 30 minutes prior to the test run. Following the conditioning time, set the sampler to automatically start a 6–hour sample collection period at a convenient time.

(4) During each 6–hour test period:

(i) Measure and record the sample flow rate with the flow rate meter at intervals not to exceed 5 minutes. If ambient temperature and pressure corrections are necessary to calculate volumetric flow rate, ambient temperature and pressure shall be measured at the same frequency as that of the certified flow rate measurements. Note and record the actual start and stop times for the 6–hour flow rate test period.

(ii) Determine and record the ambient (chamber) pressure indicated by the sampler and the corresponding ambient (chamber) pressure measured by the barometer specified in paragraph (c)(4) of this section at intervals not to exceed 5 minutes.

(5) At the end of each test period, terminate the sample period (if not automatically terminated by the sampler) and download all archived instrument data from the test sampler.

(g) *Test results*. For each of the two test runs, examine the chamber pressure measurements. Verify that the pressure met the requirements specified in paragraph (f) of this section at all times during the test. If not, the test run is not valid and must be repeated. Determine the test results as follows:

(1) *Mean sample flow rate*. (i) From the certified measurements (Q_{ref}) of the test sampler flow rate, tabulate each flow rate measurement in units of L/min. If ambient temperature and pressure corrections are necessary to calculate volumetric flow rate, each measured flow rate shall be corrected using its corresponding temperature and pressure measurement values. Calculate the mean flow rate for the sample period ($Q_{ref,ave}$) as follows:

Equation 17

$$Q_{ref,ave} = \frac{\sum_{i=1}^{n} Q_{ref,i}}{n}$$

where:

n equals the number of discrete certified flow measurements over the 6–hour test period.

(ii)(A) Calculate the percent difference between this mean flow rate value and the design value of 16.67 L/min, as follows:

Equation 18

$$\%\ \text{Difference} = \frac{Q_{ref,ave} - 16.67}{16.67} \times 100\%$$

(B) To successfully pass this test, the percent difference calculated in Equation 18 of this paragraph (g)(1) must be within ±5 percent for each test run.

(2) *Sample flow rate regulation*. (i) From the certified measurements of the test sampler flow rate, calculate the sample coefficient of variation of the discrete measurements as follows:

Equation 19

$$\%CV_{ref} = \frac{1}{Q_{ref,ave}} \times \sqrt{\frac{\sum_{i=1}^{n} Q_{ref,i}^2 - \frac{1}{n}\left(\sum_{i-1}^{n} Q_{ref,i}\right)^2}{n-1}} \times 100\%$$

(ii) To successfully pass this test, the calculated coefficient of variation for the certified flow rates must not exceed 2 percent.

(3) *Flow rate measurement accuracy*. (i) Using the mean volumetric flow rate reported by the candidate test sampler at the completion of each 6–hour test ($Q_{ind,ave}$), determine the accuracy of the reported mean flow rate as:

Equation 20

$$\%\ \text{Difference} = \frac{|Q_{ind,ave} - Q_{ref,ave}|}{Q_{ref,ave}} \times 100\%$$

(ii) To successfully pass this test, the percent difference calculated in Equation 20 of this paragraph (g)(3) shall not exceed 2 percent for each test run.

(4) *Flow rate CV measurement accuracy*. (i) Using the flow rate coefficient of variation indicated by the candidate test sampler at the completion of the 6–hour test ($\%CV_{ind}$), determine the accuracy of the reported coefficient of variation as:

Equation 21

$$\text{Difference}\ (\%) = |\%CV_{ind} - \%CV_{ref}|$$

(ii) To successfully pass this test, the absolute difference in values calculated in Equation 21 of this paragraph (g)(4) must not exceed 0.3 (CV%) for each test run.

(5) *Ambient pressure measurement accuracy*. (i) Calculate the absolute difference between the mean ambient air pressure indicated by the test sampler and the ambient (chamber) air pressure measured with the reference barometer as:

Equation 22

$$P_{diff} = |P_{ind,ave} - P_{ref,ave}|$$

where:
$P_{ind,ave}$ = mean ambient pressure indicated by the test sampler, mm Hg; and
$P_{ref,ave}$ = mean barometric pressure measured by the reference barometer, mm Hg.

(ii) The calculated pressure difference must be less than 10 mm Hg for each test run to pass the test.

(6) *Sampler functionality*. To pass the sampler functionality test, the following two conditions must both be met for each test run:

(i) The sampler must not shut down during any part of the 6–hour tests; and

(ii) An inspection of the downloaded data from the test sampler verifies that all the data are consistent with normal operation of the sampler.

§ 53.57 Test for filter temperature control during sampling and post-sampling periods.

(a) *Overview*. This test is intended to measure the candidate sampler's ability to prevent excessive overheating of the $PM_{2.5}$ sample collection filter (or filters) under conditions of elevated solar insolation. The test evaluates radiative effects on filter temperature during a 4–hour period of active sampling as well as during a subsequent 4–hour non-sampling time period prior to filter retrieval. Tests shall be conducted in an environmental chamber which provides the proper radiant wavelengths and energies to adequately simulate the sun's radiant effects under clear conditions at sea level. For additional guidance on conducting solar radiative tests under controlled conditions, consult military standard specification 810-E (Reference 6 in Appendix A of this subpart). The performance parameters tested under this procedure, the corresponding minimum performance specifications, and the applicable test conditions are summarized in Table E-1 of this subpart. Each performance parameter tested, as described or determined in the test procedure, must meet or exceed the associated performance specification to successfully pass this test.

(b) *Technical definition*. Filter temperature control during sampling is the ability of a sampler to maintain the temperature of the particulate matter sample filter within the specified deviation (5 °C) from ambient temperature during any active sampling period. Post-sampling temperature control is the ability of a sampler to maintain the temperature of the particulate matter sample filter within the specified deviation from ambient temperature during the period from the end of active sample collection of the $PM_{2.5}$ sample by the sampler until the filter is retrieved from the sampler for laboratory analysis.

(c) *Required test equipment*. (1) Environmental chamber providing the means, such as a bank of solar-spectrum lamps, for generating or simulating thermal radiation in approximate spectral content and intensity equivalent to solar insolation of 1000 ± 50 W/m² inside the environmental chamber. To properly simulate the sun's radiative effects on the sampler, the solar bank must provide the spectral energy distribution and permitted tolerances specified in Table E-2 of this subpart. The solar radiation source area shall be such that the width of the candidate sampler shall not exceed one-half the dimensions of the solar bank. The solar bank shall be located a minimum of 76 cm (30 inches) from any surface of the candidate sampler. To meet requirements of the solar radiation tests, the chamber's internal volume shall be a minimum of 10 times that of the volume of the candidate sampler. Air velocity in the region of the sampler must be maintained continuously during the radiative tests at 2.0 ± 0.5 m/sec.

(2) Ambient air temperature recorder, range -30 °C to +50 °C, with a resolution of 0.1 °C and certified accurate to within 0.5 °C. Ambient air temperature measurements must be made using continuous (analog) recording capability or digital recording at intervals not to exceed 5 minutes.

(3) Flow measurement adaptor (40 CFR part 50, Appendix L, Figure L-30) or equivalent adaptor to facilitate measurement of sampler flow rate at the sampler downtube.

(4) Miniature temperature sensor(s), capable of being installed in the sampler without introducing air leakage and capable of measuring the sample air temperature within 1 cm of the center of the filter, downstream of the filter; with a resolution of 0.1 °C, certified accurate to within 0.5 °C, NIST-traceable, with continuous (analog) recording capability or digital recording at intervals of not more than 5 minutes.

(5) Solar radiometer, to measure the intensity of the simulated solar radiation in the test environment, range of 0 to approximately 1500 W/m². Optional capability for continuous (analog) recording or digital recording at intervals not to exceed 5 minutes is recommended.

(6) Sample filter or filters, as specified in section 6 of 40 CFR part 50, Appendix L.

(d) *Calibration of test measurement instruments*. Submit documentation showing evidence of appropriately recent calibration, certification of calibration accuracy, and NIST-traceability (if required) of all measurement instruments used in the tests. The accuracy of flow rate meters shall be verified at the highest and lowest pressures and temperatures used in the tests and shall be checked at zero and at least one flow rate within ±3 percent of 16.7 L/min within 7 days prior to use for this test. Where an instrument's measurements are to be recorded with an analog recording device, the accuracy of the entire instrument-recorder system shall be calibrated or verified.

(e) *Test setup*. (1) Setup of the sampler shall be performed as required in this paragraph (e) and otherwise as described in the sampler's operation or instruction manual referred to in § 53.4(b)(3). The sampler shall be installed upright and set up in the solar radiation environmental chamber in its normal configuration for collecting $PM_{2.5}$ samples (with the inlet installed). The sampler's ambient and filter temperature measurement systems shall be calibrated per the sampler's operating manual within 7 days prior to this test. A sample filter shall be installed for the duration of this test. For sequential samplers, a sample filter shall also be installed in each available sequential channel or station intended for collection of a sequential sample (or at least 5 additional filters for magazine-type sequential samplers) as directed by the sampler's operation or instruction manual.

(2) The miniature temperature sensor shall be temporarily installed in the test sampler such that it accurately measures the air temperature 1 cm from the center of the filter on the downstream side of the filter. The sensor shall be installed such that no external or internal air leakage is created by the sensor installation. The sensor's dimensions and installation shall be selected to minimize temperature measurement uncertainties due to thermal conduction along the sensor mounting structure or sensor conductors. For sequential samplers, similar temperature sensors shall also be temporarily installed in the test sampler to monitor the temperature 1 cm from the center of each filter stored in the sampler for sequential sample operation.

(3) The solar radiant energy source shall be installed in the test chamber such that the entire test sampler is irradiated in a manner similar to the way it would be irradiated by solar radiation if it were located outdoors in an open area on a sunny day, with the radiation arriving at an angle of between 30° and 45° from vertical. The intensity of the radiation received by all sampler

surfaces that receive direct radiation shall average 1000 ± 50 W/m², measured in a plane perpendicular to the incident radiation. The incident radiation shall be oriented with respect to the sampler such that the area of the sampler's ambient temperature sensor (or temperature shield) receives full, direct radiation as it would or could during normal outdoor installation. Also, the temperature sensor must not be shielded or shaded from the radiation by a sampler part in a way that would not occur at other normal insolation angles or directions.

(4) The solar radiometer shall be installed in a location where it measures thermal radiation that is generally representative of the average thermal radiation intensity that the upper portion of the sampler and sampler inlet receive. The solar radiometer shall be oriented so that it measures the radiation in a plane perpendicular to its angle of incidence.

(5) The ambient air temperature recorder shall be installed in the test chamber such that it will accurately measure the temperature of the air in the chamber without being unduly affected by the chamber's air temperature control system or by the radiant energy from the solar radiation source that may be present inside the test chamber.

(f) *Procedure*. (1) Set up the sampler as specified in paragraph (e) of this section and otherwise prepare the sampler for normal sample collection operation as directed in the sampler's operation or instruction manual.

(2) Remove the inlet of the candidate test sampler and install the flow measurement adaptor on the sampler's downtube. Conduct a leak check as described in the sampler's operation or instruction manual. The leak test must be properly passed before other tests are carried out.

(3) Remove the flow measurement adaptor from the downtube and re-install the sampling inlet.

(4) Activate the solar radiation source and verify that the resulting energy distribution prescribed in Table E-2 of this subpart is achieved.

(5) Program the test sampler to conduct a single sampling run of 4 continuous hours. During the 4-hour sampling run, measure and record the radiant flux, ambient temperature, and filter temperature (all filter temperatures for sequential samplers) at intervals not to exceed 5 minutes.

(6) At the completion of the 4–hour sampling phase, terminate the sample period, if not terminated automatically by the sampler. Continue to measure and record the radiant flux, ambient temperature, and filter temperature or temperatures for 4 additional hours at intervals not to exceed 5 minutes. At the completion of the 4–hour post-sampling period, discontinue the measurements and turn off the solar source.

(7) Download all archived sampler data from the test run.

(g) *Test results*. Chamber temperature control. Examine the continuous record of the chamber radiant flux and verify that the flux met the requirements specified in Table E-2 of this subpart at all times during the test. If not, the entire test is not valid and must be repeated.

(1) *Filter temperature measurement accuracy*. (i) For each 4–hour test period, calculate the absolute value of the difference between the mean filter temperature indicated by the sampler (active filter) and the mean filter temperature measured by the reference temperature sensor installed within 1 cm downstream of the (active) filter as:

Equation 23

$$T_{diff,filter} = |T_{ind,filter} - T_{ref,filter}|$$

where:
$T_{ind,filter}$ = mean filter temperature indicated by the test sampler, °C; and
$T_{ref,filter}$ = mean filter temperature measured by the reference temperature sensor, °C.

(ii) To successfully pass the indicated filter temperature accuracy test, the calculated difference between the measured means ($T_{diff,filter}$) must not exceed 2 °C for each 4-hour test period.

(2) *Ambient temperature measurement accuracy*. (i) For each 4-hour test period, calculate the absolute value of the difference between the mean ambient air temperature indicated by the test sampler and the mean ambient air temperature measured by the reference ambient air temperature recorder as:

Equation 24

$$T_{diff,ambient} = |T_{ind,ambient} - T_{ref,ambient}|$$

where:
$T_{ind,ambient}$ = mean ambient air temperature indicated by the test sampler, °C; and
$T_{ref,ambient}$ = mean ambient air temperature measured by the reference ambient air temperature recorder, °C.

(ii) To successfully pass the indicated ambient temperature accuracy test, the calculated difference between the measured means ($T_{diff,ambient}$) must not exceed 2 °C for each 4-hour test period.

(3) *Filter temperature control accuracy*. (i) For each temperature measurement interval over each 4–hour test period, calculate the difference between the filter temperature indicated by the reference temperature sensor and the ambient temperature indicated by the test sampler as:

Equation 25

$$T_{diff} = T_{ref,filter} - T_{ind,ambient}$$

(ii) Tabulate and inspect the calculated differences as a function of time. To successfully pass the indicated filter temperature control test, the calculated difference between the measured values must not exceed 5 °C for any consecutive intervals covering more than a 30–minute time period.

(iii) For sequential samplers, repeat the test calculations for each of the stored sequential sample filters. All stored filters must also meet the 5 °C temperature control test.

§ 53.58 Operational field precision and blank test.

(a) *Overview*. This test is intended to determine the operational precision of the candidate sampler during a minimum of 10 days of field operation, using three collocated test samplers. Measurements of $PM_{2.5}$ are made at a test site with all of the samplers and then compared to determine replicate precision. Candidate sequential samplers are also subject to a test for possible deposition of particulate matter on inactive filters during a period of storage in the sampler. This procedure is applicable to both reference and equivalent methods. In the case of equivalent methods, this test may be combined and conducted concurrently with the comparability test for equivalent methods (described in subpart C of this part), using three reference method samplers collocated with three candidate equivalent method samplers and meeting the applicable site and other requirements of subpart C of this part.

(b) *Technical definition*. (1) Field precision is defined as the standard deviation or relative standard deviation of a set of $PM_{2.5}$ measurements obtained concurrently with three or more collocated samplers in actual ambient air field operation.

(2) Storage deposition is defined as the mass of material inadvertently deposited on a sample filter that is stored in a sequential sampler either prior to or subsequent to the active sample collection period.

(c) *Test site*. Any outdoor test site having $PM_{2.5}$ concentrations that are reasonably uniform over the test area and that meet the minimum level requirement of paragraph (g)(2) of this section is acceptable for this test.

(d) *Required facilities and equipment*. (1) An appropriate test site and suitable

electrical power to accommodate three test samplers are required.

(2) Teflon sample filters, as specified in section 6 of 40 CFR part 50, Appendix L, conditioned and preweighed as required by section 8 of 40 CFR part 50, Appendix L, as needed for the test samples.

(e) *Test setup*. (1) Three identical test samplers shall be installed at the test site in their normal configuration for collecting $PM_{2.5}$ samples in accordance with the instructions in the associated manual referred to in § 53.4(b)(3) and should be in accordance with applicable supplemental guidance provided in Reference 3 in Appendix A of this subpart. The test samplers' inlet openings shall be located at the same height above ground and between 2 and 4 meters apart horizontally. The samplers shall be arranged or oriented in a manner that will minimize the spatial and wind directional effects on sample collection of one sampler on any other sampler.

(2) Each test sampler shall be successfully leak checked, calibrated, and set up for normal operation in accordance with the instruction manual and with any applicable supplemental guidance provided in Reference 3 in Appendix A of this subpart.

(f) *Test procedure*. (1) Install a conditioned, preweighed filter in each test sampler and otherwise prepare each sampler for normal sample collection. Set identical sample collection start and stop times for each sampler. For sequential samplers, install a conditioned, preweighed specified filter in each available channel or station intended for automatic sequential sample filter collection (or at least 5 additional filters for magazine-type sequential samplers), as directed by the sampler's operation or instruction manual. Since the inactive sequential channels are used for the storage deposition part of the test, they may not be used to collect the active $PM_{2.5}$ test samples.

(2) Collect either a 24–hour or a 48–hour atmospheric $PM_{2.5}$ sample simultaneously with each of the three test samplers.

(3) Following sample collection, retrieve the collected sample from each sampler. For sequential samplers, retrieve the additional stored (blank, unsampled) filters after at least 5 days (120 hours) storage in the sampler if the active samples are 24–hour samples, or after at least 10 days (240 hours) if the active samples are 48–hour samples.

(4) Determine the measured $PM_{2.5}$ mass concentration for each sample in accordance with the applicable procedures prescribed for the candidate method in Appendix L, 40 CFR part 50 of this chapter, in the associated manual referred to in § 53.4(b)(3) and in accordance with supplemental guidance in Reference 2 in Appendix A of this subpart. For sequential samplers, also similarly determine the storage deposition as the net weight gain of each blank, unsampled filter after the 5–day (or 10–day) period of storage in the sampler.

(5) Repeat this procedure to obtain a total of 10 sets of any combination of 24–hour or 48–hour $PM_{2.5}$ measurements over 10 test periods. For sequential samplers, repeat the 5–day (or 10–day) storage test of additional blank filters once for a total of two sets of blank filters.

(g) *Calculations*. (1) Record the $PM_{2.5}$ concentration for each test sampler for each test period as $C_{i,j}$, where i is the sampler number (i=1,2,3) and j is the test period (j=1,2, . . . 10).

(2)(i) For each test period, calculate and record the average of the three measured $PM_{2.5}$ concentrations as C_j where j is the test period:

Equation 26

$$C_{ave,j} = \frac{1}{3} x \sum_{i=1}^{3} C_{i,j}$$

(ii) If $C_{ave,j} < 10$ μg/m³ for any test period, data from that test period are unacceptable, and an additional sample collection set must be obtained to replace the unacceptable data.

(3)(i) Calculate and record the precision for each of the 10 test days as:

Equation 27

$$P_j = \sqrt{\frac{\sum_{i=1}^{3} C_{i,j}^2 - \frac{1}{3}\left(\sum_{i=1}^{3} C_{i,j}\right)^2}{2}}$$

(ii) If $C_{ave,j}$ is below 40 μg/m³ for 24–hour measurements or below 30 μg/m³ for 48–hour measurements; or

Equation 28

$$RP_j = 100\% \text{ x } \frac{1}{C_{ave,j}} \sqrt{\frac{\sum_{i=1}^{3} C_{i,j}^2 - \frac{1}{3}\left(\sum_{i=1}^{3} C_{i,j}\right)^2}{2}}$$

(iii) If $C_{ave,j}$ is above 40 μg/m³ for 24-hour measurements or above 30 μg/m³ for 48-hour measurements.

(h) *Test results*. (1) The candidate method passes the precision test if all 10 P_j or RP_j values meet the specifications in Table E-1 of this subpart.

(2) The candidate sequential sampler passes the blank filter storage deposition test if the average net storage deposition weight gain of each set of blank filters (total of the net weight gain of each blank filter divided by the number of filters in the set) from each test sampler (six sets in all) is less than 50 μg.

§ 53.59 Aerosol transport test for Class I equivalent method samplers.

(a) *Overview*. This test is intended to verify adequate aerosol transport through any modified or air flow splitting components that may be used in a Class I candidate equivalent method sampler such as may be necessary to achieve sequential sampling capability. This test is applicable to all Class I candidate samplers in which the aerosol flow path (the flow path through which sample air passes upstream of sample collection filter) differs from that specified for reference method samplers as specified in 40 CFR part 50, Appendix L. The test requirements and performance specifications for this test are summarized in Table E-1 of this subpart.

(b) *Technical definitions*. (1) Aerosol transport is the percentage of a laboratory challenge aerosol which penetrates to the active sample filter of the candidate equivalent method sampler.

(2) The active sample filter is the exclusive filter through which sample air is flowing during performance of this test.

(3) A no-flow filter is a sample filter through which no sample air is intended to flow during performance of this test.

(4) A channel is any of two or more flow paths that the aerosol may take, only one of which may be active at a time.

(5) An added component is any physical part of the sampler which is different in some way from that specified for a reference method sampler in 40 CFR part 50, Appendix L, such as a device or means to allow or cause the aerosol to be routed to one of several channels.

(c) *Required facilities and test equipment*. (1) Aerosol generation system, as specified in § 53.62(c)(2).

(2) Aerosol delivery system, as specified in § 53.64(c)(2).

(3) Particle size verification equipment, as specified in § 53.62(c)(3).

(4) Fluorometer, as specified in § 53.62(c)(7).

(5) Candidate test sampler, with the inlet and impactor or impactors removed, and with all internal surfaces of added components electroless nickel coated as specified in § 53.64(d)(2).

(6) Filters that are appropriate for use with fluorometric methods (e.g., glass fiber).

(d) *Calibration of test measurement instruments.* Submit documentation showing evidence of appropriately recent calibration, certification of calibration accuracy, and NIST-traceability (if required) of all measurement instruments used in the tests. The accuracy of flow rate meters shall be verified at the highest and lowest pressures and temperatures used in the tests and shall be checked at zero and at least one flow rate within ±3 percent of 16.7 L/min within 7 days prior to use for this test. Where an instrument's measurements are to be recorded with an analog recording device, the accuracy of the entire instrument-recorder system shall be calibrated or verified.

(e) *Test setup.* (1) The candidate test sampler shall have its inlet and impactor or impactors removed. The lower end of the down tube shall be reconnected to the filter holder, using an extension of the downtube, if necessary. If the candidate sampler has a separate impactor for each channel, then for this test, the filter holder assemblies must be connected to the physical location on the sampler where the impactors would normally connect.

(2) The test particle delivery system shall be connected to the sampler downtube so that the test aerosol is introduced at the top of the downtube.

(f) *Test procedure.* (1) All surfaces of the added or modified component or components which come in contact with the aerosol flow shall be thoroughly washed with 0.01 N NaOH and then dried.

(2) Generate aerosol. (i) Generate aerosol composed of oleic acid with a uranine fluorometric tag of 3 ± 0.25 μm aerodynamic diameter using a vibrating orifice aerosol generator according to conventions specified in § 53.61(g).

(ii) Check for the presence of satellites and adjust the generator to minimize their production.

(iii) Calculate the aerodynamic particle size using the operating parameters of the vibrating orifice aerosol generator. The calculated aerodynamic diameter must be 3 ± 0.25 μm aerodynamic diameter.

(3) Verify the particle size according to procedures specified in § 53.62(d)(4)(i).

(4) Collect particles on filters for a time period such that the relative error of the resulting measured fluorometric concentration for the active filter is less than 5 percent.

(5) Determine the quantity of material collected on the active filter using a calibrated fluorometer. Record the mass of fluorometric material for the active filter as $M_{active\ (i)}$ where i = the active channel number.

(6) Determine the quantity of material collected on each no-flow filter using a calibrated fluorometer. Record the mass of fluorometric material on each no-flow filter as $M_{no\text{-}flow}$.

(7) Using 0.01 N NaOH, wash the surfaces of the added component or components which contact the aerosol flow. Determine the quantity of material collected using a calibrated fluorometer. Record the mass of fluorometric material collected in the wash as M_{wash}.

(8) Calculate the aerosol transport as:

Equation 29

$$T_{(i)} = \frac{M_{active}}{M_{active+}M_{wash+}\sum M_{no\text{-}flow}} \times 100\%$$

where:
i = the active channel number.

(9) Repeat paragraphs (f)(1) through (8) of this section for each channel, making each channel in turn the exclusive active channel.

(g) *Test results.* The candidate Class I sampler passes the aerosol transport test if $T_{(i)}$ is at least 97 percent for each channel.

Tables to Subpart E of Part 53

Table E-1.—Summary of Test Requirements for Reference and Class I Equivalent Methods for $PM_{2.5}$

Subpart E Procedure	Performance Test	Performance Specification	Test Conditions	Part 50, Appendix L Reference
§ 53.52 Sampler leak check test	Sampler leak check facility	External leakage: 80 mL/min, max Internal leakage: 80 mL/min, max	Controlled leak flow rate of 80 mL/min	Sec. 7.4.6
§ 53.53 Base flow rate test	Sample flow rate: 1. Mean 2. Regulation 3. Meas. accuracy 4. CV accuracy 5. Cut-off	1. 16.67 ± 5%, L/min 2. 2%, max 3. 2%, max 4. 0.3%, max 5. Flow rate cut-off if flow rate deviates more than 10% from design flow rate for >60 ± 30 seconds	(a) 6-hour normal operational test plus flow rate cut-off test (b) Nominal conditions (c) Additional 55 mm Hg pressure drop to simulate loaded filter (d) Variable flow restriction used for cut-off test	Sec. 7.4.1 Sec. 7.4.2 Sec. 7.4.3 Sec. 7.4.4 Sec. 7.4.5
§ 53.54 Power interruption test	Sample flow rate: 1. Mean 2. Regulation 3. Meas. accuracy 4. CV accuracy 5. Occurrence time of power interruptions 6. Elapsed sample time 7. Sample volume	1. 16.67 ± 5%, L/min 2. 2%, max 3. 2%, max 4. 0.3%, max 5. ±2 min if >60 seconds 6. ±20 seconds 7. ±2%, max	(a) 6-hour normal operational test (b) Nominal conditions (c) Additional 55 mm Hg pressure drop to simulate loaded filter (d) 6 power interruptions of various durations	Sec. 7.4.1 Sec. 7.4.2 Sec. 7.4.3 Sec. 7.4.5 Sec. 7.4.12 Sec. 7.4.13 Sec. 7.4.15.4 Sec. 7.4.15.5

Table E-1.—Summary of Test Requirements for Reference and Class I Equivalent Methods for $PM_{2.5}$—Continued

Subpart E Procedure	Performance Test	Performance Specification	Test Conditions	Part 50, Appendix L Reference
§ 53.55 Temperature and line voltage effect test	Sample flow rate: 1. Mean 2. Regulation 3. Meas. accuracy 4. CV accuracy 5. Temperature meas. accuracy 6. Proper operation	1. 16.67 ± 5%, L/min 2. 2 %, max 3. 2 %, max 4. 0.3 %, max 5. 2 °C	(a) 6-hour normal operational test (b) Nominal conditions (c) Additional 55 mm Hg pressure drop to simulate loaded filter (d) Ambient temperature at -20 and +40 °C (e) Line voltage: 105 Vac to 125 Vac	Sec. 7.4.1 Sec. 7.4.2 Sec. 7.4.3 Sec. 7.4.5 Sec. 7.4.8 Sec. 7.4.15.1
§ 53.56 Barometric pressure effect test	Sample flow rate: 1. Mean 2. Regulation 3. Meas. accuracy 4. CV accuracy 5. Pressure meas. accuracy 6. Proper operation	1. 16.67 ± 5%, L/min 2. 2%, max 3. 2%, max 4. 0.3%, max 5. 10 mm Hg	(a) 6-hour normal operational test (b) Nominal conditions (c) Additional 55 mm Hg pressure drop to simulate loaded filter (d) Barometric pressure at 600 and 800 mm Hg.	Sec. 7.4.1 Sec. 7.4.2 Sec. 7.4.3 Sec. 7.4.5 Sec. 7.4.9
§ 53.57 Filter temperature control test	1. Filter temp meas. accuracy 2. Ambient temp. meas. accuracy 3. Filter temp control accuracy, sampling and non-sampling	1. 2 °C 2. 2 °C 3. Not more than 5 °C above ambient temp. for more than 30 min	(a) 4-hour simulated solar radiation, sampling (b) 4-hour simulated solar radiation, non-sampling (c) Solar flux of 1000 W/m²	Sec. 7.4.8 Sec. 7.4.10 Sec. 7.4.11
§ 53.58 Field precision test	1. Measurement precision 2. Storage deposition test for sequential samplers	1. P_j <2 μg/m³ for conc. <40 μg/m³ (24-hr) or <30 μg/m³ (48-hr); or RP_j < 5% for conc. >40 μg/m3 (24-hr) or >30 μg/m3 (48-hr) 2. 50 μg, max weight gain	(a) 3 collocated samplers at 1 site for at least 10 days (b) $PM_{2.5}$ conc.≤10 μg/m³ (c) 24- or 48-hour samples (d) 5- or 10-day storage period for inactive stored filters	Sec. 5.1 Sec. 7.3.5 Sec. 8 Sec. 9 Sec. 10
The Following Requirement is Applicable to Candidate Equivalent Methods Only				
§ 53.59 Aerosol transport test	Aerosol transport	97%, min, for all channels	Determine aerosol transport through any new or modified components with respect to the reference method sampler before the filter for each channel.	

TABLE E-2.—SPECTRAL ENERGY DISTRIBUTION AND PERMITTED TOLERANCE FOR CONDUCTING RADIATIVE TESTS

Chacteristic	Spectral Region			
	Ultraviolet		Visible	Infrared
Bandwidth (μm)	0.28 to 0.32	10.32 to 0.40	0.40 to 0.78	0.78 to 3.00
Irradiance (W/m²)	5	56	450 to 550	439
Allowed Tolerance	2± 35%	2± 25%	2± 10%	2± 10%

Figures to Subpart E of Part 53

Figure E-1.—Designation Testing Checklist

DESIGNATION TESTING CHECKLIST

Auditee	Auditor signature	Date

Compliance Status: Y = Yes N = No NA = Not applicable/Not available				
Verification			Verified by Direct Observation of Process or of Documented Evidence: Performance, Design or Application Spec. Corresponding to Sections of 40 CFR Part 53 or 40 CFR Part 50, Appendix L	Verification Comments (Includes documentation of who, what, where, when, why) (Doc. #, Rev. #, Rev. Date)
Y	N	NA		
			Performance Specification Tests Sample flow rate coefficient of variation (§ 53.53) (L 7.4.3)	
			Filter temperature control (sampling) (§ 53.57) (L 7.4.10)	
			Elapsed sample time accuracy (§ 53.54) (L 7.4.13)	
			Filter temperature control (post sampling) (§ 53.57) (L 7.4.10)	
			Application Specification Tests	
			Field Precision (§ 53.58) (L 5.1)	
			Meets all Appendix L requirements (part 53, subpart A, § 53.2(a)(3)) (part 53, subpart E, § 53.51(a),(d))	
			Filter Weighing (L-8)	
			Field Sampling Procedure (§ 53.30, .31, .34)	
			Design Specification Tests	
			Filter (L-6)	
			Range of Operational Conditions (L-7.4.7)	
The Following Requirements Apply Only to Class I Candidate Equivalent Methods				
			Aerosol Transport (§ 53.59)	

Figure E-2.—Product Manufacturing Checklist

PRODUCT MANUFACTURING CHECKLIST

Auditee	Auditor signature	Date

Compliance Status: Y = Yes N = No NA = Not applicable/Not available				Verification Comments (Includes documentation of who, what, where, when, why) (Doc. #, Rev. #, Rev. Date)
Verification			Verified by Direct Observation of Process or of Documented Evidence: Performance, Design or Application Spec. Corresponding to Sections of 40 CFR Part 53 or 40 CFR Part 50, Appendix L	
Y	N	NA		
			Performance Specification Tests	
			Assembled operational performance (Burn-in test) (§ 53.53)	
			Sample flow rate (§ 53.53) (L 7.4.1, L 7.4.2)	
			Sample flow rate regulation (§ 53.53) (L 7.4.3)	
			Flow rate and average flow rate measurement accuracy (§ 53.53) (L 7.4.5)	
			Ambient air temperature measurement accuracy (§ 53.55) (L 7.4.8)	
			Ambient barometric pressure measurement accuracy (§ 53.56) (L 7.4.9)	
			Sample flow rate cut-off (§ 53.53) (L 7.4.4)	
			Sampler leak check facility (§ 53.52) (L 7.4.6)	
			Application Specification Tests	
			Flow rate calibration transfer standard (L-9.2)	
			Operational /Instructional manual (L-7.4.18)	
			Design Specification Tests	
			Impactor (jet width) (§ 53.51(d)(1)) (L-7.3.4.1)	
			Surface finish (§ 53.51(d)(2)) (L-7.3.7)	

Appendix A to Subpart E of Part 53--References

(1) Quality systems--Model for quality assurance in design, development, production, installation and servicing, ISO 9001. July 1994. Available from American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, WI 53202.

(2) American National Standard--Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs. ANSI/ASQC E4-1994. January 1995. Available from American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, WI 53202.

(3) Copies of section 2.12 of the Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Specific Methods, EPA/600/R-94/038b, are available from Department E (MD-77B), U.S. EPA, Research Triangle Park, NC 27711.

(4) Military standard specification (mil. spec.) 8625F, Type II, Class 1 as listed in Department of Defense Index of Specifications and Standards (DODISS), available from DODSSP-Customer Service, Standardization Documents Order Desk, 700 Robbins Avenue, Building 4D, Philadelphia, PA 1911-5094.

(5) Quality Assurance Handbook for Air Pollution Measurement Systems, Volume IV: Meteorological Measurements. Revised March, 1995. EPA-600/R-94-038d. Available from U.S. EPA, ORD Publications Office, Center for Environmental Research Information (CERI), 26 West Martin Luther King Drive, Cincinnati, Ohio 45268-1072 (513-569-7562).

(6) Military standard specification (mil. spec.) 810-E as listed in Department of Defense Index of Specifications and Standards (DODISS), available from DODSSP-Customer Service, Standardization Documents Order Desk, 700 Robbins Avenue, Building 4D, Philadelphia, PA 1911-5094.

e. Subpart F is added to read as follows:

Subpart F—Procedures for Testing Performance Characteristics of Class II Equivalent Methods for $PM_{2.5}$

Sec.

53.60 General provisions.
53.61 Test conditions for $PM_{2.5}$ reference method equivalency.
53.62 Test procedure: Full wind tunnel test.
53.63 Test procedure: Wind tunnel inlet aspiration test.
53.64 Test procedure: Static fractionator test.
53.65 Test procedure: Loading test.
53.66 Test procedure: Volatility test.

Tables to Subpart F of Part 53

Table F-1—Performance Specifications for $PM_{2.5}$ Class II Equivalent Samplers
Table F-2—Particle Sizes and Wind Speeds for Full Wind Tunnel Test, Wind Tunnel

Inlet Aspiration Test, and Static Chamber Test
Table F-3—Critical Parameters of Idealized Ambient Particle Size Distributions
Table F-4—Estimated Mass Concentration Measurement of $PM_{2.5}$ for Idealized Coarse Aerosol Size Distribution
Table F-5—Estimated Mass Concentration Measurement of $PM_{2.5}$ for Idealized ''Typical'' Coarse Aerosol Size Distribution
Table F-6 Estimated Mass Concentration Measurement of $PM_{2.5}$ for Idealized Fine Aerosol Size Distribution

Figures to Subpart F of Part 53

Figure F-1—Designation Testing Checklist

Appendix A to Subpart F of Part 53—References

Subpart F—Procedures for Testing Performance Characteristics of Class II Equivalent Methods for $PM_{2.5}$

§ 53.60 General provisions.

(a) This subpart sets forth the specific requirements that a $PM_{2.5}$ sampler associated with a candidate Class II equivalent method must meet to be designated as an equivalent method for $PM_{2.5}$. This subpart also sets forth the explicit test procedures that must be carried out and the test results, evidence, documentation, and other materials that must be provided to EPA to demonstrate that a sampler meets all specified requirements for designation as an equivalent method.

(b) A candidate method described in an application for a reference or equivalent method application submitted under § 53.4 shall be determined by the EPA to be a Class II candidate equivalent method on the basis of the definition of a Class II equivalent method given in § 53.1.

(c) Any sampler associated with a Class II candidate equivalent method (Class II sampler) must meet all requirements for reference method samplers and Class I equivalent method samplers specified in subpart E of this part, as appropriate. In addition, a Class II sampler must meet the additional requirements as specified in paragraph (d) of this section.

(d) Except as provided in paragraphs (d)(1), (2), and (3) of this section, all Class II samplers are subject to the additional tests and performance requirements specified in § 53.62 (full wind tunnel test), § 53.65 (loading test), and § 53.66 (volatility test). Alternative tests and performance requirements, as described in paragraphs (d)(1), (2), and (3) of this section, are optionally available for certain Class II samplers which meet the requirements for reference method or Class I samplers given in 40 CFR part 50, Appendix L, and in subpart E of this part, except for specific deviations of the inlet, fractionator, or filter.

(1) *Inlet deviation*. A sampler which has been determined to be a Class II sampler solely because the design or construction of its inlet deviates from the design or construction of the inlet specified in 40 CFR part 50, Appendix L, for reference method samplers shall not be subject to the requirements of § 53.62 (full wind tunnel test), provided that it meets all requirements of § 53.63 (wind tunnel inlet aspiration test), § 53.65 (loading test), and § 53.66 (volatility test).

(2) *Fractionator deviation*. A sampler which has been determined to be a Class II sampler solely because the design or construction of its particle size fractionator deviates from the design or construction of the particle size fractionator specified in 40 CFR part 50, Appendix L for reference method samplers shall not be subject to the requirements of § 53.62 (full wind tunnel test), provided that it meets all requirements of § 53.64 (static fractionator test), § 53.65 (loading test), and § 53.66 (volatility test).

(3) *Filter size deviation*. A sampler which has been determined to be a Class II sampler solely because its effective filtration area deviates from that of the reference method filter specified in 40 CFR part 50, Appendix L, for reference method samplers shall not be subject to the requirements of § 53.62 (full wind tunnel test) nor § 53.65 (loading test), provided it meets all requirements of § 53.66 (volatility test).

(e) *The test specifications and acceptance criteria for each test are summarized in Table F-1 of this subpart*. The candidate sampler must demonstrate performance that meets the acceptance criteria for each applicable test to be designated as an equivalent method.

(f) *Overview of various test procedures for Class II samplers*—(1) *Full wind tunnel test*. This test procedure is designed to ensure that the candidate sampler's effectiveness (aspiration of an ambient aerosol and penetration of the sub 2.5-micron fraction to its sample filter) will be comparable to that of a reference method sampler. The candidate sampler is challenged at wind speeds of 2 and 24 km/hr with monodisperse aerosols of the size specified in Table F-2 of this subpart. The experimental test results are then integrated with three idealized ambient distributions (typical, fine, and coarse) to yield the expected mass concentration measurement for each. The acceptance criteria are based on the results of this numerical analysis and the particle diameter for which the sampler effectiveness is 50 percent.

(2) *Wind tunnel inlet aspiration test*. The wind tunnel inlet aspiration test directly compares the inlet of the candidate sampler to the inlet of a reference method sampler with the single-sized, liquid, monodisperse challenge aerosol specified in Table F-2 of this subpart at wind speeds of 2 km/hr and 24 km/hr. The acceptance criteria, presented in Table F-1 of this subpart, is based on the relative aspiration between the candidate inlet and the reference method inlet.

(3) *Static fractionator test*. The static fractionator test determines the effectiveness of the candidate sampler's 2.5-micron fractionator under static conditions for aerosols of the size specified in Table F-2 of this subpart. The numerical analysis procedures and acceptance criteria are identical to those in the full wind tunnel test.

(4) *Loading test*. The loading test is conducted to ensure that the performance of a candidate sampler is not significantly affected by the amount of particulate deposited on its interior surfaces between periodic cleanings. The candidate sampler is artificially loaded by sampling a test environment containing aerosolized, standard test dust. The duration of the loading phase is dependent on both the time between cleaning as specified by the candidate method and the aerosol mass concentration in the test environment. After loading, the candidate's performance must then be evaluated by § 53.62 (full wind tunnel evaluation), § 53.64 (wind tunnel inlet aspiration test), or § 53.64 (static fractionator test). If the results of the appropriate test meet the criteria presented in Table F-1 of this subpart, then the candidate sampler passes the loading test under the condition that it be cleaned at least as often as the cleaning frequency proposed by the candidate method and that has been demonstrated to be acceptable by this test.

(5) *Volatility test*. The volatility test challenges the candidate sampler with a polydisperse, semi-volatile liquid aerosol. This aerosol is simultaneously sampled by the candidate method sampler and a reference method sampler for a specified time period. Clean air is then passed through the samplers during a blow-off time period. Residual mass is then calculated as the weight of the filter after the blow-off phase is subtracted from the initial weight of the filter. Acceptance criteria are based on a comparison of the residual mass measured by the candidate sampler (corrected for flow rate variations from that of the reference method) to the

residual mass measured by the reference method sampler for several specified clean air sampling time periods.

(g) *Test data.* All test data and other documentation obtained from or pertinent to these tests shall be identified, dated, signed by the analyst performing the test, and submitted to EPA as part of the equivalent method application. Schematic drawings of each particle delivery system and other information showing complete procedural details of the test atmosphere generation, verification, and delivery techniques for each test performed shall be submitted to EPA. All pertinent calculations shall be clearly presented. In addition, manufacturers are required to submit as part of the application, a Designation Testing Checklist (Figure F-1 of this subpart) which has been completed and signed by an ISO-certified auditor.

§ 53.61 Test conditions for $PM_{2.5}$ reference method equivalency.

(a) *Sampler surface preparation.* Internal surfaces of the candidate sampler shall be cleaned and dried prior to performing any Class II sampler test in this subpart. The internal collection surfaces of the sampler shall then be prepared in strict accordance with the operating instructions specified in the sampler's operating manual referred to in section 7.4.18 of 40 CFR part 50, Appendix L.

(b) *Sampler setup.* Set up and start up of all test samplers shall be in strict accordance with the operating instructions specified in the manual referred to in section 7.4.18 of 40 CFR part 50, Appendix L, unless otherwise specified within this subpart.

(c) *Sampler adjustments.* Once the test sampler or samplers have been set up and the performance tests started, manual adjustment shall be permitted only between test points for all applicable tests. Manual adjustments and any periodic maintenance shall be limited to only those procedures prescribed in the manual referred to in section 7.4.18 of 40 CFR part 50, Appendix L. The submitted records shall clearly indicate when any manual adjustment or periodic maintenance was made and shall describe the operations performed.

(d) *Sampler malfunctions.* If a test sampler malfunctions during any of the applicable tests, that test run shall be repeated. A detailed explanation of all malfunctions and the remedial actions taken shall be submitted as part of the equivalent method application.

(e) *Particle concentration measurements.* All measurements of particle concentration must be made such that the relative error in measurement is less than 5.0 percent. Relative error is defined as (s × 100 percent)/(X), where s is the sample standard deviation of the particle concentration detector, X is the measured concentration, and the units of s and X are identical.

(f) *Operation of test measurement equipment.* All test measurement equipment shall be set up, calibrated, and maintained by qualified personnel according to the manufacturer's instructions. All appropriate calibration information and manuals for this equipment shall be kept on file.

(g) *Vibrating orifice aerosol generator conventions.* This section prescribes conventions regarding the use of the vibrating orifice aerosol generator (VOAG) for the size-selective performance tests outlined in §§ 53.62, 53.63, 53.64, and 53.65.

(1) *Particle aerodynamic diameter.* The VOAG produces near-monodisperse droplets through the controlled breakup of a liquid jet. When the liquid solution consists of a non-volatile solute dissolved in a volatile solvent, the droplets dry to form particles of near-monodisperse size.

(i) The physical diameter of a generated spherical particle can be calculated from the operating parameters of the VOAG as:

Equation 1

$$D_p = \left(\frac{6\ Q\ C_{vol}}{\pi\ f} \right)^{1/3}$$

where:
D_p = particle physical diameter, μm;
Q = liquid volumetric flow rate, μm^3/sec;
C_{vol} = volume concentration (particle volume produced per drop volume), dimensionless; and
f = frequency of applied vibrational signal, 1/sec.

(ii) A given particle's aerodynamic behavior is a function of its physical particle size, particle shape, and density. Aerodynamic diameter is defined as the diameter of a unit density (ρ_o = 1 g/m^3) sphere having the same settling velocity as the particle under consideration. For converting a spherical particle of known density to aerodynamic diameter, the governing relationship is:

Equation 2

$$D_{ae} = \frac{\sqrt{\rho_p}\ \sqrt{C_{D_p}}\ D_p}{\sqrt{\rho_o}\ \sqrt{C_{Dae}}}$$

where:
D_{ae} = particle aerodynamic diameter, μm;
ρ_p = particle density, g/cm^3;
ρ_o = aerodynamic particle density = 1 g/m^3;
C_{Dp} = Cunningham's slip correction factor for physical particle diameter, dimensionless; and
C_{Dae} = Cunningham's slip correction factor for aerodynamic particle diameter, dimensionless.

(iii) At room temperature and standard pressure, the Cunningham's slip correction factor is solely a function of particle diameter:

Equation 3

$$C_{Dae} = 1 + \frac{0.1659}{D_{ae}} + \frac{0.053}{D_{ae}}\ \exp\left(-8.33\ D_{ae}\right)$$

or

Equation 4

$$C_{D_p} = 1 + \frac{0.1659}{D_p} + \frac{0.053}{D_p}\ \exp\left(-8.33\ D_p\right)$$

(iv) Since the slip correction factor is itself a function of particle diameter, the aerodynamic diameter in Equation 2 of paragraph (g)(1)(ii) of this section cannot be solved directly but must be determined by iteration.

(2) *Solid particle generation.* (i) Solid particle tests performed in this subpart shall be conducted using particles composed of ammonium fluorescein. For use in the VOAG, liquid solutions of known volumetric concentration can be prepared by diluting fluorescein powder ($C_20H_{12}O_5$, FW = 332.31, CAS 2321-07-5) with aqueous ammonia. Guidelines for preparation of fluorescein solutions of the desired volume concentration (C_{vol}) are presented by Vanderpool and Rubow (1988) (Reference 2 in Appendix A of this subpart). For purposes of converting particle physical diameter to aerodynamic diameter, an ammonium fluorescein density of 1.35 g/cm^3 shall be used.

(ii) Mass deposits of ammonium fluorescein shall be extracted and analyzed using solutions of 0.01 N ammonium hydroxide.

(3) *Liquid particle generation.* (i) Tests prescribed in § 53.63 for inlet aspiration require the use of liquid particle tests composed of oleic acid tagged with uranine to enable subsequent fluorometric quantitation of collected aerosol mass deposits. Oleic acid ($C_{18}H_{34}O_2$, FW = 282.47, CAS 112-80-1) has a density of 0.8935 g/cm^3. Because the viscosity of oleic acid is relatively high, significant errors can occur when dispensing oleic acid using volumetric pipettes. For this reason, it is recommended that oleic acid solutions be prepared by quantifying dispensed oleic acid gravimetrically. The volume of oleic acid dispensed can then be calculated simply by dividing the

dispensed mass by the oleic acid density.

(ii) Oleic acid solutions tagged with uranine shall be prepared as follows. A known mass of oleic acid shall first be diluted using absolute ethanol. The desired mass of the uranine tag should then be diluted in a separate container using absolute ethanol. Uranine ($C_{20}H_{10}O_5Na_2$, FW = 376.3, CAS 518-47-8) is the disodium salt of fluorescein and has a density of 1.53 g/cm^3. In preparing uranine tagged oleic acid particles, the uranine content shall not exceed 20 percent on a mass basis. Once both oleic acid and uranine solutions are properly prepared, they can then be combined and diluted to final volume using absolute ethanol.

(iii) Calculation of the physical diameter of the particles produced by the VOAG requires knowledge of the liquid solution's volume concentration (C_{vol}). Because uranine is essentially insoluble in oleic acid, the total particle volume is the sum of the oleic acid volume and the uranine volume. The volume concentration of the liquid solution shall be calculated as:

Equation 5

$$C_{vol} = \frac{V_u + V_{oleic}}{V_{sol}} = \frac{(M_u/\rho_u) + (M_{oleic}/\rho_{oleic})}{V_{sol}}$$

where:
V_u = uranine volume, ml;
V_{oleic} = oleic acid volume, ml;
V_{sol} = total solution volume, ml;
M_u = uranine mass, g;
ρ_u = uranine density, g/cm^3;
M_{oleic} = oleic acid mass, g; and
ρ_{oleic} = oleic acid density, g/cm^3.

(iv) For purposes of converting the particles' physical diameter to aerodynamic diameter, the density of the generated particles shall be calculated as:

Equation 6

$$\rho_p = \frac{M_u + M_{oleic}}{(M_u/\rho_u) + (M_{oleic}/\rho_{oleic})}$$

(v) Mass deposits of oleic acid shall be extracted and analyzed using solutions of 0.01 N sodium hydroxide.

§ 53.62 Test procedure: Full wind tunnel test.

(a) *Overview*. The full wind tunnel test evaluates the effectiveness of the candidate sampler at 2 km/hr and 24 km/hr for aerosols of the size specified in Table F-2 of this subpart (under the heading, ''Full Wind Tunnel Test''). For each wind speed, a smooth curve is fit to the effectiveness data and corrected for the presence of multiplets in the wind tunnel calibration aerosol. The cutpoint diameter (D_{p50}) at each wind speed is then determined from the corrected effectiveness curves. The two resultant penetration curves are then each numerically integrated with three idealized ambient particle size distributions to provide six estimates of measured mass concentration. Critical parameters for these idealized distributions are presented in Table F-3 of this subpart.

(b) *Technical definitions*. Effectiveness is the ratio (expressed as a percentage) of the mass concentration of particles of a specific size reaching the sampler filter or filters to the mass concentration of particles of the same size approaching the sampler.

(c) *Facilities and equipment required*—(1) *Wind tunnel*. The particle delivery system shall consist of a blower system and a wind tunnel having a test section of sufficiently large cross-sectional area such that the test sampler, or portion thereof, as installed in the test section for testing, blocks no more than 15 percent of the test section area. The wind tunnel blower system must be capable of maintaining uniform wind speeds at the 2 km/hr and 24 km/hr in the test section.

(2) *Aerosol generation system*. A vibrating orifice aerosol generator shall be used to produce monodisperse solid particles of ammonium fluorescein with equivalent aerodynamic diameters as specified in Table F-2 of this subpart. The geometric standard deviation for each particle size generated shall not exceed 1.1 (for primary particles) and the proportion of multiplets (doublets and triplets) in all test particle atmosphere shall not exceed 10 percent of the particle population. The aerodynamic particle diameter, as established by the operating parameters of the vibrating orifice aerosol generator, shall be within the tolerance specified in Table F-2 of this subpart.

(3) *Particle size verification equipment*. The size of the test particles shall be verified during this test by use of a suitable instrument (e.g., scanning electron microscope, optical particle sizer, time-of-flight apparatus). The instrument must be capable of measuring solid and liquid test particles with a size resolution of 0.1 μm or less. The accuracy of the particle size verification technique shall be 0.15 μm or better.

(4) *Wind speed measurement*. The wind speed in the wind tunnel shall be determined during the tests using an appropriate technique capable of a precision of 2 percent and an accuracy of 5 percent or better (e.g., hot-wire anemometry). For the wind speeds specified in Table F-2 of this subpart, the wind speed shall be measured at a minimum of 12 test points in a cross-sectional area of the test section of the wind tunnel. The mean wind speed in the test section must be within ± 10 percent of the value specified in Table F-2 of this subpart, and the variation at any test point in the test section may not exceed 10 percent of the measured mean.

(5) *Aerosol rake*. The cross-sectional uniformity of the particle concentration in the sampling zone of the test section shall be established during the tests using an array of isokinetic samplers, referred to as a rake. Not less than five evenly spaced isokinetic samplers shall be used to determine the particle concentration spatial uniformity in the sampling zone. The sampling zone shall be a rectangular area having a horizontal dimension not less than 1.2 times the width of the test sampler at its inlet opening and a vertical dimension not less than 25 centimeters.

(6) *Total aerosol isokinetic sampler*. After cross-sectional uniformity has been confirmed, a single isokinetic sampler may be used in place of the array of isokinetic samplers for the determination of particle mass concentration used in the calculation of sampling effectiveness of the test sampler in paragraph (d)(5) of this section. In this case, the array of isokinetic samplers must be used to demonstrate particle concentration uniformity prior to the replicate measurements of sampling effectiveness.

(7) *Fluorometer*. A fluorometer used for quantifying extracted aerosol mass deposits shall be set up, maintained, and calibrated according to the manufacturer's instructions. A series of calibration standards shall be prepared to encompass the minimum and maximum concentrations measured during size-selective tests. Prior to each calibration and measurement, the fluorometer shall be zeroed using an aliquot of the same solvent used for extracting aerosol mass deposits.

(8) *Sampler flow rate measurements*. All flow rate measurements used to calculate the test atmosphere concentrations and the test results must be accurate to within ± 2 percent, referenced to a NIST-traceable primary standard. Any necessary flow rate measurement corrections shall be clearly documented. All flow rate measurements shall be performed and reported in actual volumetric units.

(d) *Test procedures*—(1) *Establish and verify wind speed*. (i) Establish a wind speed specified in Table F-2 of this subpart.

(ii) Measure the wind speed at a minimum of 12 test points in a cross-sectional area of the test section of the wind tunnel using a device as described in paragraph (c)(4) of this section.

(iii) Verify that the mean wind speed in the test section of the wind tunnel during the tests is within 10 percent of the value specified in Table F-2 of this subpart. The wind speed measured at any test point in the test section shall not differ by more than 10 percent from the mean wind speed in the test section.

(2) *Generate aerosol.* (i) Generate particles of a size specified in Table F-2 of this subpart using a vibrating orifice aerosol generator.

(ii) Check for the presence of satellites and adjust the generator as necessary.

(iii) Calculate the physical particle size using the operating parameters of the vibrating orifice aerosol generator and record.

(iv) Determine the particle's aerodynamic diameter from the calculated physical diameter and the known density of the generated particle. The calculated aerodynamic diameter must be within the tolerance specified in Table F-2 of this subpart.

(3) *Introduce particles into the wind tunnel.* Introduce the generated particles into the wind tunnel and allow the particle concentration to stabilize.

(4) *Verify the quality of the test aerosol.* (i) Extract a representative sample of the aerosol from the sampling test zone and measure the size distribution of the collected particles using an appropriate sizing technique. If the measurement technique does not provide a direct measure of aerodynamic diameter, the geometric mean aerodynamic diameter of the challenge aerosol must be calculated using the known density of the particle and the measured mean physical diameter. The determined geometric mean aerodynamic diameter of the test aerosol must be within 0.15 μm of the aerodynamic diameter calculated from the operating parameters of the vibrating orifice aerosol generator. The geometric standard deviation of the primary particles must not exceed 1.1.

(ii) Determine the population of multiplets in the collected sample. The multiplet population of the particle test atmosphere must not exceed 10 percent of the total particle population.

(5) *Aerosol uniformity and concentration measurement.* (i) Install an array of five or more evenly spaced isokinetic samplers in the sampling zone (paragraph (c)(5) of this section). Collect particles on appropriate filters over a time period such that the relative error of the measured particle concentration is less than 5.0 percent.

(ii) Determine the quantity of material collected with each isokinetic sampler in the array using a calibrated fluorometer. Calculate and record the mass concentration for each isokinetic sampler as:

Equation 7

$$C_{iso(ij)} = \frac{M_{iso(ij)}}{Q_{(ij)} \times t_{(ij)}}$$

where:
i = replicate number;
j = isokinetic sampler number;
M_{iso} = mass of material collected with the isokinetic sampler;
Q = isokinetic sampler volumetric flow rate; and
t = sampling time.

(iii) Calculate and record the mean mass concentration as:

Equation 8

$$\overline{C}_{iso(i)} = \frac{\sum_{j=1}^{n} C_{iso(ij)}}{n}$$

where:
i = replicate number;
j = isokinetic sampler number; and
n = total number of isokinetic samplers.

(iv) Precision calculation. (A) Calculate the coefficient of variation of the mass concentration measurements as:

Equation 9

$$CV_{iso(i)} = \frac{\sqrt{\sum_{j=1}^{n} C_{iso(ij)}^2 - \frac{1}{n}\left(\sum_{j=1}^{n} C_{iso(ij)}\right)^2}}{n-1} / \overline{C}_{iso(i)} \times 100\%$$

where:
i = replicate number;
j = isokinetic sampler number; and
n = total number of isokinetic samplers.

(B) If the value of $CV_{iso(i)}$ for any replicate exceeds 10 percent, the particle concentration uniformity is unacceptable and step 5 must be repeated. If adjustment of the vibrating orifice aerosol generator or changes in the particle delivery system are necessary to achieve uniformity, steps 1 through 5 must be repeated. When an acceptable aerosol spatial uniformity is achieved, remove the array of isokinetic samplers from the wind tunnel.

(6) *Alternative measure of wind tunnel total concentration.* If a single isokinetic sampler is used to determine the mean aerosol concentration in the wind tunnel, install the sampler in the wind tunnel with the sampler nozzle centered in the sampling zone (paragraph (c)(6) of this section).

(i) Collect particles on an appropriate filter over a time period such that the relative error of the measured concentration is less than 5.0 percent.

(ii) Determine the quantity of material collected with the isokinetic sampler using a calibrated fluorometer.

(iii) Calculate and record the mass concentration as $C_{iso(i)}$ as in paragraph (d)(5)(ii) of this section.

(iv) Remove the isokinetic sampler from the wind tunnel.

(7) *Measure the aerosol with the candidate sampler.* (i) Install the test sampler (or portion thereof) in the wind tunnel with the sampler inlet opening centered in the sampling zone. To meet the maximum blockage limit of paragraph (c)(1) of this section or for convenience, part of the test sampler may be positioned external to the wind tunnel provided that neither the geometry of the sampler nor the length of any connecting tube or pipe is altered. Collect particles for a time period such that the relative error of the measured concentration is less than 5.0 percent.

(ii) Remove the test sampler from the wind tunnel.

(iii) Determine the quantity of material collected with the test sampler using a calibrated fluorometer. Calculate and record the mass concentration for each replicate as:

Equation 10

$$C_{cand(i)} = \frac{M_{cand(i)}}{Q_{(i)} \times t_{(i)}}$$

where:
i = replicate number;
M_{cand} = mass of material collected with the candidate sampler;
Q = candidate sampler volumetric flow rate; and
t = sampling time.

(iv)(A) Calculate and record the sampling effectiveness of the candidate sampler as:

Equation 11

$$E_{(i)} = \frac{C_{cand(i)}}{\overline{C}_{iso(i)}} \times 100\%$$

where:
i = replicate number.

(B) If a single isokinetic sampler is used for the determination of particle mass concentration, replace $C_{iso(i)}$ with C_{iso}.

(8) *Replicate measurements and calculation of mean sampling effectiveness*. (i) Repeat steps in paragraphs (d)(5) through (d)(7) of this section, as appropriate, to obtain a minimum of three valid replicate measurements of sampling effectiveness.

(ii) Calculate and record the average sampling effectiveness of the test sampler for the particle size as:

Equation 12

$$\overline{E} = \frac{\sum_{i=1}^{n} E_{(i)}}{n}$$

where:
i = replicate number; and
n = number of replicates.

(iii) Sampling effectiveness precision. (A) Calculate and record the coefficient of variation for the replicate sampling effectiveness measurements of the test sampler as:

Equation 13

$$CV_E = \frac{\sqrt{\sum_{i=1}^{n} E_{(i)}^2 - \frac{1}{n}\left(\sum_{i=1}^{n} E_{(i)}\right)^2}}{n-1} \frac{1}{\overline{E}} \times 100\%$$

where:
i = replicate number, and
n = number of replicates.

(B) If the value of CV_E exceeds 10 percent, the test run (steps in paragraphs (d)(2) through (d)(8) of this section) must be repeated until an acceptable value is obtained.

(9) Repeat steps in paragraphs (d)(2) through (d)(8) of this section until the sampling effectiveness has been measured for all particle sizes specified in Table F-2 of this subpart.

(10) Repeat steps in paragraphs (d)(1) through (d)(9) of this section until tests have been successfully conducted for both wind speeds of 2 km/hr and 24 km/hr.

(e) *Calculations*—(1) *Graphical treatment of effectiveness data*. For each wind speed given in Table F-2 of this subpart, plot the particle average sampling effectiveness of the candidate sampler as a function of aerodynamic particle diameter (D_{ae}) on semi-logarithmic graph paper where the aerodynamic particle diameter is the particle size established by the parameters of the VOAG in conjunction with the known particle density. Construct a best-fit, smooth curve through the data by extrapolating the sampling effectiveness curve through 100 percent at an aerodynamic particle size of 0.5 μm and 0 percent at an aerodynamic particle size of 10 μm. Correction for the presence of multiplets shall be performed using the techniques presented by Marple, et al (1987). This multiplet-corrected effectiveness curve shall be used for all remaining calculations in this paragraph (e).

(2) *Cutpoint determination*. For each wind speed determine the sampler Dp_{50} cutpoint defined as the aerodynamic particle size corresponding to 50 percent effectiveness from the multiplet corrected smooth curve.

(3) *Expected mass concentration calculation*. For each wind speed, calculate the estimated mass concentration measurement for the test sampler under each particle size distribution (Tables F-4, F-5, and F-6 of this subpart) and compare it to the mass concentration predicted for the reference sampler as follows:

(i) Determine the value of corrected effectiveness using the best-fit, multiplet-corrected curve at each of the particle sizes specified in the first column of Table F-4 of this subpart. Record each corrected effectiveness value as a decimal between 0 and 1 in column 2 of Table F-4 of this subpart.

(ii) Calculate the interval estimated mass concentration measurement by multiplying the values of corrected effectiveness in column 2 by the interval mass concentration values in column 3 and enter the products in column 4 of Table F-4 of this subpart.

(iii) Calculate the estimated mass concentration measurement by summing the values in column 4 and entering the total as the estimated mass concentration measurement for the test sampler at the bottom of column 4 of Table F-4 of this subpart.

(iv) Calculate the estimated mass concentration ratio between the candidate method and the reference method as:

Equation 14

$$R_c = \frac{C_{cand(est)}}{C_{ref(est)}} \times 100\%$$

where:
$C_{cand(est)}$ = estimated mass concentration measurement for the test sampler, μg/m³; and
$C_{ref(est)}$ = estimated mass concentration measurement for the reference sampler, μg/m³ (calculated for the reference sampler and specified at the bottom of column 7 of Table F-4 of this subpart).

(v) Repeat steps in paragraphs (e) (1) through (e)(3) of this section for Tables F-5 and F-6 of this subpart.

(f) *Evaluation of test results*. The candidate method passes the wind tunnel effectiveness test if the R_c value for each wind speed meets the specification in Table F-1 of this subpart for each of the three particle size distributions.

§ 53.63 Test procedure: Wind tunnel inlet aspiration test.

(a) *Overview*. This test applies to a candidate sampler which differs from the reference method sampler only with respect to the design of the inlet. The purpose of this test is to ensure that the aspiration of a Class II candidate sampler is such that it representatively extracts an ambient aerosol at elevated wind speeds. This wind tunnel test uses a single-sized, liquid aerosol in conjunction with wind speeds of 2 km/hr and 24 km/hr. The test atmosphere concentration is alternately measured with the candidate sampler and a reference method device, both of which are operated without the 2.5-micron fractionation device installed. The test conditions are summarized in Table F-2 of this subpart (under the heading of ''wind tunnel inlet aspiration test''). The candidate sampler must meet or exceed the acceptance criteria given in Table F-1 of this subpart.

(b) *Technical definition*. Relative aspiration is the ratio (expressed as a percentage) of the aerosol mass concentration measured by the candidate sampler to that measured by a reference method sampler.

(c) *Facilities and equipment required*. The facilities and equipment are identical to those required for the full wind tunnel test (§ 53.62(c)).

(d) *Setup*. The candidate and reference method samplers shall be operated with the $PM_{2.5}$ fractionation device removed from the flow path throughout this entire test procedure. Modifications to accommodate this requirement shall be limited to removal of the fractionator and insertion of the filter holder directly into the downtube of the inlet.

(e) *Test procedure*—(1) *Establish the wind tunnel test atmosphere*. Follow the procedures in § 53.62(d)(1) through (d)(4) to establish a test atmosphere for one of the two wind speeds specified in Table F-2 of this subpart.

(2) *Measure the aerosol concentration with the reference sampler.* (i) Install the reference sampler (or portion thereof) in the wind tunnel with the sampler inlet opening centered in the sampling zone. To meet the maximum blockage limit of § 53.62(c)(1) or for convenience, part of the test sampler may be positioned external to the wind tunnel provided that neither the geometry of the sampler nor the length of any connecting tube or pipe is altered. Collect particles for a time period such that the relative error of the measured concentration is less than 5.0 percent.

(ii) Determine the quantity of material collected with the reference method sampler using a calibrated fluorometer. Calculate and record the mass concentration as:

Equation 15

$$C_{ref(i)} = \frac{M_{ref(i)}}{Q_{(i)} \times t_{(i)}}$$

where:
i = replicate number;
M_{ref} = mass of material collected with the reference method sampler;
Q = reference method sampler volumetric flow rate; and
t = sampling time.

(iii) Remove the reference method sampler from the tunnel.

(3) *Measure the aerosol concentration with the candidate sampler.* (i) Install the candidate sampler (or portion thereof) in the wind tunnel with the sampler inlet centered in the sampling zone. To meet the maximum blockage limit of § 53.62(c)(1) or for convenience, part of the test sampler may be positioned external to the wind tunnel provided that neither the geometry of the sampler nor the length of any connecting tube or pipe is altered. Collect particles for a time period such that the relative error of the measured concentration is less than 5.0 percent.

(ii) Determine the quantity of material collected with the candidate sampler using a calibrated fluorometer. Calculate and record the mass concentration as:

Equation 16

$$C_{cand(i)} = \frac{M_{cand(i)}}{Q_{(i)} \times t_{(i)}}$$

where:
i = replicate number;
M_{cand} = mass of material collected with the candidate sampler;
Q = candidate sampler volumetric flow rate; and
t = sampling time.

(iii) Remove the candidate sampler from the wind tunnel.

(4) Repeat steps in paragraphs (d) (2) and (d)(3) of this section. Alternately measure the tunnel concentration with the reference sampler and the candidate sampler until four reference sampler and three candidate sampler measurements of the wind tunnel concentration are obtained.

(5) *Calculations.* (i) Calculate and record aspiration ratio for each candidate sampler run as:

Equation 17

$$A_{(i)} = \frac{C_{cand(i)}}{\left(C_{ref(i)} + C_{ref(i+1)}\right) \times \frac{1}{2}}$$

where:
i = replicate number.

(ii) Calculate and record the mean aspiration ratio as:

Equation 18

$$\overline{A} = \frac{\sum_{i=1}^{n} A_{(i)}}{n}$$

where:
i = replicate number; and
n = total number of measurements of aspiration ratio.

(iii) Precision of the aspiration ratio. (A) Calculate and record the precision of the aspiration ratio measurements as the coefficient of variation as:

Equation 19

$$CV_A = \frac{\sqrt{\sum_{i=1}^{n} A_{(i)}^2 - \frac{1}{n}\left(\sum_{i=1}^{n} A_{(i)}\right)^2}}{n-1} / \overline{A}_{(i)} \times 100\%$$

where:
i = replicate number; and
n = total number of measurements of aspiration ratio.

(B) If the value of CV_A exceeds 10 percent, the entire test procedure must be repeated.

(f) *Evaluation of test results.* The candidate method passes the inlet aspiration test if all values of A meet the acceptance criteria specified in Table F-1 of this subpart.

§ 53.64 Test procedure: Static fractionator test.

(a) *Overview.* This test applies only to those candidate methods in which the sole deviation from the reference method is in the design of the 2.5-micron fractionation device. The purpose of this test is to ensure that the fractionation characteristics of the candidate fractionator are acceptably similar to that of the reference method sampler. It is recognized that various methodologies exist for quantifying fractionator effectiveness. The following commonly-employed techniques are provided for purposes of guidance. Other methodologies for determining sampler effectiveness may be used contingent upon prior approval by the Agency.

(1) *Wash-off method.* Effectiveness is determined by measuring the aerosol mass deposited on the candidate sampler's after filter versus the aerosol mass deposited in the fractionator. The material deposited in the fractionator is recovered by washing its internal surfaces. For these wash-off tests, a fluorometer must be used to quantitate the aerosol concentration. Note that if this technique is chosen, the candidate must be reloaded with coarse aerosol prior to each test point when reevaluating the curve as specified in the loading test.

(2) *Static chamber method.* Effectiveness is determined by measuring the aerosol mass concentration sampled by the candidate sampler's after filter versus that which exists in a static chamber. A calibrated fluorometer shall be used to quantify the collected aerosol deposits. The aerosol concentration is calculated as the measured aerosol mass divided by the sampled air volume.

(3) *Divided flow method.* Effectiveness is determined by comparing the aerosol concentration upstream of the candidate sampler's fractionator versus that concentration which exists downstream of the candidate fractionator. These tests may utilize either fluorometry or a real-time aerosol measuring device to determine the aerosol concentration.

(b) *Technical definition.* Effectiveness under static conditions is the ratio (expressed as a percentage) of the mass concentration of particles of a given size reaching the sampler filter to the mass concentration of particles of the same size existing in the test atmosphere.

(c) *Facilities and equipment required*—(1) *Aerosol generation.* Methods for generating aerosols shall be identical to those prescribed in § 53.62(c)(2).

(2) *Particle delivery system.* Acceptable apparatus for delivering the generated aerosols to the candidate fractionator is dependent on the effectiveness measurement methodology and shall be defined as follows:

(i) *Wash-off test apparatus.* The aerosol may be delivered to the candidate fractionator through direct piping (with or without an in-line mixing chamber). Validation particle size and quality shall be conducted at a point directly upstream of the fractionator.

(ii) *Static chamber test apparatus.* The aerosol shall be introduced into a chamber and sufficiently mixed such that the aerosol concentration within the chamber is spatially uniform. The chamber must be of sufficient size to house at least four total filter samplers in addition to the inlet of the candidate method size fractionator. Validation of particle size and quality shall be conducted on representative aerosol samples extracted from the chamber.

(iii) *Divided flow test apparatus.* The apparatus shall allow the aerosol concentration to be measured upstream and downstream of the fractionator. The aerosol shall be delivered to a manifold with two symmetrical branching legs. One of the legs, referred to as the bypass leg, shall allow the challenge aerosol to pass unfractionated to the detector. The other leg shall accommodate the fractionation device.

(3) *Particle concentration measurement*—(i) *Fluorometry.* Refer to § 53.62(c)(7).

(ii) *Number concentration measurement.* A number counting particle sizer may be used in conjunction with the divided flow test apparatus in lieu of fluorometric measurement. This device must have a minimum range of 1 to 10 μm, a resolution of 0.1 μm, and an accuracy of 0.15 μm such that primary particles may be distinguished from multiplets for all test aerosols. The measurement of number concentration shall be accomplished by integrating the primary particle peak.

(d) *Setup*—(1) *Remove the inlet and downtube from the candidate fractionator.* All tests procedures shall be conducted with the inlet and downtube removed from the candidate sampler.

(2) *Surface treatment of the fractionator.* Rinsing aluminum surfaces with alkaline solutions has been found to adversely affect subsequent fluorometric quantitation of aerosol mass deposits. If wash-off tests are to be used for quantifying aerosol penetration, internal surfaces of the fractionator must first be plated with electroless nickel. Specifications for this plating are specified in Society of Automotive Engineers Aerospace Material Specification (SAE AMS) 2404C, Electroless Nickel Plating (Reference 3 in Appendix A of Subpart F).

(e) *Test procedure: Wash-off method*—(1) *Clean the candidate sampler.* Note: The procedures in this step may be omitted if this test is being used to evaluate the fractionator after being loaded as specified in § 53.65.

(i) Clean and dry the internal surfaces of the candidate sampler.

(ii) Prepare the internal fractionator surfaces in strict accordance with the operating instructions specified in the sampler's operating manual referred to in section 7.4.18 of 40 CFR part 50, Appendix L.

(2) *Generate aerosol.* Follow the procedures for aerosol generation prescribed in § 53.62(d)(2).

(3) *Verify the quality of the test aerosol.* Follow the procedures for verification of test aerosol size and quality prescribed in § 53.62(d)(4).

(4) *Determine effectiveness for the particle size being produced.* (i) Collect particles downstream of the fractionator on an appropriate filter over a time period such that the relative error of the fluorometric measurement is less than 5.0 percent.

(ii) Determine the quantity of material collected on the after filter of the candidate method using a calibrated fluorometer. Calculate and record the aerosol mass concentration for the sampler filter as:

Equation 20

$$C_{cand(i)} = \frac{M_{cand(i)}}{Q_{(i)} \times t_{(i)}}$$

where:
i = replicate number;
M_{cand} = mass of material collected with the candidate sampler;
Q = candidate sampler volumetric flowrate; and
t = sampling time.

(iii) Wash all interior surfaces upstream of the filter and determine the quantity of material collected using a calibrated fluorometer. Calculate and record the fluorometric mass concentration of the sampler wash as:

Equation 21

$$C_{wash(i)} = \frac{M_{wash(i)}}{Q_{(i)} \times t_{(i)}}$$

where:
i = replicate number;
M_{wash} = mass of material washed from the interior surfaces of the fractionator;
Q = candidate sampler volumetric flowrate; and
t = sampling time.

(iv) Calculate and record the sampling effectiveness of the test sampler for this particle size as:

Equation 22

$$E_{(i)} = \frac{C_{wash(i)}}{C_{cand(i)} + C_{wash(i)}} \times 100\%$$

where:
i = replicate number.

(v) Repeat steps in paragraphs (e)(4) of this section, as appropriate, to obtain a minimum of three replicate measurements of sampling effectiveness. Note: The procedures for loading the candidate in § 53.65 must be repeated between repetitions if this test is being used to evaluate the fractionator after being loaded as specified in § 53.65.

(vi) Calculate and record the average sampling effectiveness of the test sampler as:

Equation 23

$$\overline{E} = \frac{\sum_{i=1}^{n} E_{(i)}}{n}$$

where:
i = replicate number; and
n = number of replicates.

(vii)(A) Calculate and record the coefficient of variation for the replicate sampling effectiveness measurements of the test sampler as:

Equation 24

$$CV_E = \frac{\sqrt{\sum_{i=1}^{n} E_{(i)}^2 - \frac{1}{n}\left(\sum_{i=1}^{n} E_{(i)}\right)^2}}{n-1} \times \frac{1}{\overline{E}} \times 100\%$$

where:
i = replicate number; and
n = total number of measurements.

(B) If the value of CV_E exceeds 10 percent, then steps in paragraphs (e) (2) through (e)(4) of this section must be repeated.

(5) Repeat steps in paragraphs (e) (1) through (e)(4) of this section for each particle size specified in Table F-2 of this subpart.

(f) *Test procedure: Static chamber method*—(1) *Generate aerosol.* Follow the procedures for aerosol generation prescribed in § 53.62(d)(2).

(2) *Verify the quality of the test aerosol.* Follow the procedures for verification of test aerosol size and quality prescribed in § 53.62(d)(4).

(3) *Introduce particles into chamber.* Introduce the particles into the static chamber and allow the particle concentration to stabilize.

(4) *Install and operate the candidate sampler's fractionator and its after-filter and at least four total filters.* (i) Install the fractionator and an array of four or more equally spaced total filter samplers such that the total filters surround and are in the same plane as the inlet of the fractionator.

(ii) Simultaneously collect particles onto appropriate filters with the total filter samplers and the fractionator for a time period such that the relative error

of the measured concentration is less than 5.0 percent.

(5) *Calculate the aerosol spatial uniformity in the chamber.* (i) Determine the quantity of material collected with each total filter sampler in the array using a calibrated fluorometer. Calculate and record the mass concentration for each total filter sampler as:

Equation 25

$$C_{total(ij)} = \frac{M_{total(ij)}}{Q_{(ij)} \times t_{(ij)}}$$

where:
i = replicate number;
j = total filter sampler number;
M_{total} = mass of material collected with the total filter sampler;
Q = total filter sampler volumetric flowrate; and
t = sample time.

(ii) Calculate and record the mean mass concentration as:

Equation 26

$$\overline{C}_{total(i)} = \frac{\sum_{j=1}^{n} C_{total(ij)}}{n}$$

where:
n = total number of samplers;
i = replicate number; and
j = filter sampler number.

(iii) (A) Calculate and record the coefficient of variation of the total mass concentration as:

Equation 27

$$CV_{total} = \frac{\sqrt{\sum_{j=1}^{n} C_{total(ij)}^2 - \frac{1}{n}\left(\sum_{j=1}^{n} C_{total(ij)}\right)^2}}{n-1} \times \frac{1}{\overline{C}_{total(i)}} \times 100\%$$

where:
i = replicate number;
j = total filter sampler number; and
n = number of total filter samplers.

(B) If the value of CV_{total} exceeds 10 percent, then the particle concentration uniformity is unacceptable, alterations to the static chamber test apparatus must be made, and steps in paragraphs (f)(1) through (f)(5) of this section must be repeated.

(6) *Determine the effectiveness of the candidate sampler.* (i) Determine the quantity of material collected on the candidate sampler's after filter using a calibrated fluorometer. Calculate and record the mass concentration for the candidate sampler as:

Equation 28

$$C_{cand(i)} = \frac{M_{cand(i)}}{Q_{(i)} \times t_{(i)}}$$

where:
i = replicate number;
M_{cand} = mass of material collected with the candidate sampler;
Q = candidate sampler volumetric flowrate; and
t = sample time.

(ii) Calculate and record the sampling effectiveness of the candidate sampler as:

Equation 29

$$E_{(i)} = \frac{C_{cand(i)}}{\overline{C}_{total(i)}} \times 100\%$$

where:
i = replicate number.

(iii) Repeat step in paragraph (f)(4) through (f)(6) of this section, as appropriate, to obtain a minimum of three replicate measurements of sampling effectiveness.

(iv) Calculate and record the average sampling effectiveness of the test sampler as:

Equation 30

$$\overline{E} = \frac{\sum_{i=1}^{n} E_{(i)}}{n}$$

where:
i= replicate number.

(v)(A) Calculate and record the coefficient of variation for the replicate sampling effectiveness measurements of the test sampler as:

Equation 31

$$CV_E = \frac{\sqrt{\sum_{i=1}^{n} E_{(i)}^2 - \frac{1}{n}\left(\sum_{i=1}^{n} E_{(i)}\right)^2}}{n-1} \times \frac{1}{\overline{E}} \times 100\%$$

where:
i = replicate number; and
n = number of measurements of effectiveness.

(B) If the value of CV_E exceeds 10 percent, then the test run (steps in paragraphs (f)(2) through (f)(6) of this section) is unacceptable and must be repeated.

(7) Repeat steps in paragraphs (f)(1) through (f)(6) of this section for each particle size specified in Table F-2 of this subpart.

(g) *Test procedure: Divided flow method*—(1) *Generate calibration aerosol.* Follow the procedures for aerosol generation prescribed in § 53.62(d)(2).

(2) *Verify the quality of the calibration aerosol.* Follow the procedures for verification of calibration aerosol size and quality prescribed in § 53.62(d)(4).

(3) *Introduce aerosol.* Introduce the calibration aerosol into the static chamber and allow the particle concentration to stabilize.

(4) *Validate that transport is equal for the divided flow option.* (i) With fluorometry as a detector:

(A) Install a total filter on each leg of the divided flow apparatus.

(B) Collect particles simultaneously through both legs at 16.7 L/min onto an appropriate filter for a time period such that the relative error of the measured concentration is less than 5.0 percent.

(C) Determine the quantity of material collected on each filter using a calibrated fluorometer. Calculate and record the mass concentration measured in each leg as:

Equation 32

$$C_{(i)} = \frac{M_{(i)}}{Q_{(i)} \times t_{(i)}}$$

where:
i = replicate number,
M = mass of material collected with the total filter; and
Q = candidate sampler volumetric flowrate.

(D) Repeat steps in paragraphs (g)(4)(i)(A) through (g)(4)(i)(C) of this section until a minimum of three replicate measurements are performed.

(ii) With a number counting device such as an aerosol detector:

(A) Remove all flow obstructions from the flow paths of the two legs.

(B) Quantify the aerosol concentration of the primary particles in each leg of the apparatus.

(C) Repeat steps in paragraphs (g)(4)(ii)(A) through (g)(4)(ii)(B) of this section until a minimum of three replicate measurements are performed.

(iii) (A) Calculate the mean concentration and coefficient of variation as:

Equation 33

$$\overline{C} = \frac{\sum_{i=1}^{n} C_{(i)}}{n}$$

Equation 34

$$CV = \frac{\sqrt{\sum_{i=1}^{n} C_{(i)}^2 - \frac{1}{n}\left(\sum_{i=1}^{n} C_{(i)}\right)^2}}{n-1} \times \frac{1}{\overline{C}} \times 100\%$$

where:
i = replicate number; and
n = number of replicates.

(B) If the measured mean concentrations through the two legs do not agree within 5 percent, then adjustments may be made in the setup, and this step must be repeated.

(5) *Determine effectiveness.* Determine the sampling effectiveness of the test sampler with the inlet removed by one of the following procedures:

(i) With fluorometry as a detector:

(A) Prepare the divided flow apparatus for particle collection. Install a total filter into the bypass leg of the divided flow apparatus. Install the particle size fractionator with a total filter placed immediately downstream of it into the other leg.

(B) Collect particles simultaneously through both legs at 16.7 L/min onto appropriate filters for a time period such that the relative error of the measured concentration is less than 5.0 percent.

(C) Determine the quantity of material collected on each filter using a calibrated fluorometer. Calculate and record the mass concentration measured by the total filter and that measured after penetrating through the candidate fractionator as follows:

Equation 35

$$C_{total_{(i)}} = \frac{M_{total(i)}}{Q_{(i)} \times t_{(i)}}$$

Equation 36

$$C_{cand_{(i)}} = \frac{M_{cand(i)}}{Q_{(i)} \times t_{(i)}}$$

where:
i = replicate number.

(ii) With a number counting device as a detector:

(A) Install the particle size fractionator into one of the legs of the divided flow apparatus.

(B) Quantify and record the aerosol number concentration of the primary particles passing through the fractionator as $C_{cand(i)}$.

(C) Divert the flow from the leg containing the candidate fractionator to the bypass leg. Allow sufficient time for the aerosol concentration to stabilize.

(D) Quantify and record the aerosol number concentration of the primary particles passing through the bypass leg as $C_{total(i)}$.

(iii) Calculate and record sampling effectiveness of the candidate sampler as:

Equation 37

$$E_{(i)} = \frac{C_{cand(i)}}{\overline{C}_{total(i)}} \times 100\%$$

where:
i = replicate number.

(6) Repeat step in paragraph (g)(5) of this section, as appropriate, to obtain a minimum of three replicate measurements of sampling effectiveness.

(7) *Calculate the mean and coefficient of variation for replicate measurements of effectiveness.* (i) Calculate and record the mean sampling effectiveness of the candidate sampler as:

Equation 38

$$\overline{E} = \frac{\sum_{i=1}^{n} E_{(i)}}{n}$$

where:
i = replicate number.

(ii)(A) Calculate and record the coefficient of variation for the replicate sampling effectiveness measurements of the candidate sampler as:

Equation 39

$$CV_E = \frac{\sqrt{\sum_{i=1}^{n} E_{(i)}^2 - \frac{1}{n}\left(\sum_{i=1}^{n} E_{(i)}\right)^2}}{n-1} \times \frac{1}{\overline{E}} \times 100\%$$

where:
i = replicate number; and
n = number of replicates.

(B) If the coefficient of variation is not less than 10 percent, then the test run must be repeated (steps in paragraphs (g)(1) through (g)(7) of this section).

(8) Repeat steps in paragraphs (g)(1) through (g)(7) of this section for each particle size specified in Table F-2 of this subpart.

(h) *Calculations*—(1) *Treatment of multiplets.* For all measurements made by fluorometric analysis, data shall be corrected for the presence of multiplets as described in § 53.62(f)(1). Data collected using a real-time device (as described in paragraph (c)(3)(ii)) of this section will not require multiplet correction.

(2) *Cutpoint determination.* For each wind speed determine the sampler Dp_{50} cutpoint defined as the aerodynamic particle size corresponding to 50 percent effectiveness from the multiplet corrected smooth curve.

(3) *Graphical analysis and numerical integration with ambient distributions.* Follow the steps outlined in § 53.62(e)(3) through (e)(4) to calculate the estimated concentration measurement ratio between the candidate sampler and a reference method sampler.

(i) *Test evaluation.* The candidate method passes the static fractionator test if the values of Rc and Dp_{50} for each distribution meets the specifications in Table F-1 of this subpart.

§ 53.65 Test procedure: Loading test.

(a) *Overview.* (1) The loading tests are designed to quantify any appreciable changes in a candidate method sampler's performance as a function of coarse aerosol collection. The candidate sampler is exposed to a mass of coarse aerosol equivalent to sampling a mass concentration of 150 $\mu g/m^3$ over the time period that the manufacturer has specified between periodic cleaning. After loading, the candidate sampler is then evaluated by performing the test in § 53.62 (full wind tunnel test), § 53.63 (wind tunnel inlet aspiration test), or § 53.64 (static fractionator test). If the acceptance criteria are met for this evaluation test, then the candidate sampler is approved for multi-day sampling with the periodic maintenance schedule as specified by the candidate method. For example, if the candidate sampler passes the reevaluation tests following loading with an aerosol mass equivalent to sampling a 150 $\mu g/m^3$ aerosol continuously for 7 days, then the sampler is approved for 7 day field operation before cleaning is required.

(b) *Technical definition.* Effectiveness after loading is the ratio (expressed as a percentage) of the mass concentration of particles of a given size reaching the sampler filter to the mass concentration of particles of the same size approaching the sampler.

(c) *Facilities and equipment required*—(1) *Particle delivery system.* The particle delivery system shall consist of a static chamber or a low velocity wind tunnel having a

sufficiently large cross-sectional area such that the test sampler, or portion thereof, may be installed in the test section. At a minimum, the system must have a sufficiently large cross section to house the candidate sampler inlet as well as a collocated isokinetic nozzle for measuring total aerosol concentration. The mean velocity in the test section of the static chamber or wind tunnel shall not exceed 2 km/hr.

(2) *Aerosol generation equipment.* For purposes of these tests, the test aerosol shall be produced from commercially available, bulk Arizona road dust. To provide direct interlaboratory comparability of sampler loading characteristics, the bulk dust is specified as 0-10 μm ATD available from Powder Technology Incorporated (Burnsville, MN). A fluidized bed aerosol generator, Wright dust feeder, or sonic nozzle shall be used to efficiently deagglomerate the bulk test dust and transform it into an aerosol cloud. Other dust generators may be used contingent upon prior approval by the Agency.

(3) *Isokinetic sampler.* Mean aerosol concentration within the static chamber or wind tunnel shall be established using a single isokinetic sampler containing a preweighed high-efficiency total filter.

(4) *Analytic balance.* An analytical balance shall be used to determine the weight of the total filter in the isokinetic sampler. The precision and accuracy of this device shall be such that the relative measurement error is less than 5.0 percent for the difference between the initial and final weight of the total filter. The identical analytic balance shall be used to perform both initial and final weighing of the total filter.

(d) *Test procedure.* (1) Calculate and record the target time weighted concentration of Arizona road dust which is equivalent to exposing the sampler to an environment of 150 μg/m^3 over the time between cleaning specified by the candidate sampler's operations manual as:

Equation 40

$$\text{Target TWC} = 150\,\mu g/m^3 \times t$$

where:
t = the number of hours specified by the candidate method prior to periodic cleaning.

(2) Clean the candidate sampler. (i) Clean and dry the internal surfaces of the candidate sampler.

(ii) Prepare the internal surfaces in strict accordance with the operating manual referred to in section 7.4.18 of 40 CFR part 50, Appendix L.

(3) Determine the preweight of the filter that shall be used in the isokinetic sampler. Record this value as InitWt.

(4) Install the candidate sampler's inlet and the isokinetic sampler within the test chamber or wind tunnel.

(5) Generate a dust cloud. (i) Generate a dust cloud composed of Arizona test dust.

(ii) Introduce the dust cloud into the chamber.

(iii) Allow sufficient time for the particle concentration to become steady within the chamber.

(6) Sample aerosol with a total filter and the candidate sampler. (i) Sample the aerosol for a time sufficient to produce an equivalent TWC equal to that of the target TWC ± 15 percent.

(ii) Record the sampling time as t.

(7) Determine the time weighted concentration. (i) Determine the postweight of the isokinetic sampler's total filter.

(ii) Record this value as FinalWt.

(iii) Calculate and record the TWC as:

Equation 41

$$TWC = \frac{(FinalWt - InitWt) \times t}{Q}$$

where:
Q = the flow rate of the candidate method.

(iv) If the value of TWC deviates from the target TWC ± 15 percent, then the loaded mass is unacceptable and the entire test procedure must be repeated.

(8) Determine the candidate sampler's effectiveness after loading. The candidate sampler's effectiveness as a function of particle aerodynamic diameter must then be evaluated by performing the test in § 53.62 (full wind tunnel test). A sampler which fits the category of inlet deviation in § 53.60(e)(1) may opt to perform the test in § 53.63 (inlet aspiration test) in lieu of the full wind tunnel test. A sampler which fits the category of fractionator deviation in § 53.60(e)(2) may opt to perform the test in § 53.64 (static fractionator test) in lieu of the full wind tunnel test.

(e) *Test results.* If the candidate sampler meets the acceptance criteria for the evaluation test performed in paragraph (d)(8) of this section, then the candidate sampler passes this test with the stipulation that the sampling train be cleaned as directed by and as frequently as that specified by the candidate sampler's operations manual.

§ 53.66 Test procedure: Volatility test.

(a) *Overview.* This test is designed to ensure that the candidate method's losses due to volatility when sampling semi-volatile ambient aerosol will be comparable to that of a federal reference method sampler. This is accomplished by challenging the candidate sampler with a polydisperse, semi-volatile liquid aerosol in three distinct phases. During phase A of this test, the aerosol is elevated to a steady-state, test-specified mass concentration and the sample filters are conditioned and preweighed. In phase B, the challenge aerosol is simultaneously sampled by the candidate method sampler and a reference method sampler onto the preweighed filters for a specified time period. In phase C (the blow-off phase), aerosol and aerosol-vapor free air is sampled by the samplers for an additional time period to partially volatilize the aerosol on the filters. The candidate sampler passes the volatility test if the acceptance criteria presented in Table F-1 of this subpart are met or exceeded.

(b) *Technical definitions.* (1) Residual mass (RM) is defined as the weight of the filter after the blow-off phase subtracted from the initial weight of the filter.

(2) Corrected residual mass (CRM) is defined as the residual mass of the filter from the candidate sampler multiplied by the ratio of the reference method flow rate to the candidate method flow rate.

(c) *Facilities and equipment required*—(1) *Environmental chamber.* Because the nature of a volatile aerosol is greatly dependent upon environmental conditions, all phases of this test shall be conducted at a temperature of 22.0 ± 0.5 °C and a relative humidity of 40 ± 3 percent. For this reason, it is strongly advised that all weighing and experimental apparatus be housed in an environmental chamber capable of this level of control.

(2) *Aerosol generator.* The aerosol generator shall be a pressure nebulizer operated at 20 to 30 psig (140 to 207 kPa) to produce a polydisperse, semi-voltile aerosol with a mass median diameter larger than 1 μm and smaller than 2.5 μm. The nebulized liquid shall be A.C.S. reagent grade glycerol (C_3H_8O, FW = 92.09, CAS 56–81–5) of 99.5 percent minimum purity. For the purpose of this test the accepted mass median diameter is predicated on the stable aerosol inside the internal chamber and not on the aerosol emerging from the nebulizer nozzle. Aerosol monitoring and its stability are described in (c)(3) and (c)(4) of this section.

(3) *Aerosol monitoring equipment.* The evaporation and condensation dynamics of a volatile aerosol is greatly dependent upon the vapor pressure of the volatile component in the carrier gas. The size of an aerosol becomes fixed only when an equilibrium is established between the aerosol and the surrounding vapor; therefore, aerosol

size measurement shall be used as a surrogate measure of this equilibrium. A suitable instrument with a range of 0.3 to 10 μm, an accuracy of 0.5 μm, and a resolution of 0.2 μm (e.g., an optical particle sizer, or a time-of-flight instrument) shall be used for this purpose. The parameter monitored for stability shall be the mass median instrument measured diameter (i.e. optical diameter if an optical particle counter is used). A stable aerosol shall be defined as an aerosol with a mass median diameter that has changed less than 0.25 μm over a 4 hour time period.

(4) *Internal chamber.* The time required to achieve a stable aerosol depends upon the time during which the aerosol is resident with the surrounding air. This is a function of the internal volume of the aerosol transport system and may be facilitated by recirculating the challenge aerosol. A chamber with a volume of 0.5 m^3 and a recirculating loop (airflow of approximately 500 cfm) is recommended for this purpose. In addition, a baffle is recommended to dissipate the jet of air that the recirculating loop can create. Furthermore, a HEPA filtered hole in the wall of the chamber is suggested to allow makeup air to enter the chamber or excess air to exit the chamber to maintain a system flow balance. The concentration inside the chamber shall be maintained at 1 $mg/m^3 \pm 20$ percent to obtain consistent and significant filter loading.

(5) *Aerosol sampling manifold.* A manifold shall be used to extract the aerosol from the area in which it is equilibrated and transport it to the candidate method sampler, the reference method sampler, and the aerosol monitor. The losses in each leg of the manifold shall be equivalent such that the three devices will be exposed to an identical aerosol.

(6) *Chamber air temperature recorders.* Minimum range 15-25 °C, certified accuracy to within 0.2 °C, resolution of 0.1 °C. Measurement shall be made at the intake to the sampling manifold and adjacent to the weighing location.

(7) *Chamber air relative humidity recorders.* Minimum range 30 - 50 percent, certified accuracy to within 1 percent, resolution of 0.5 percent. Measurement shall be made at the intake to the sampling manifold and adjacent to the weighing location.

(8) *Clean air generation system.* A source of aerosol and aerosol-vapor free air is required for phase C of this test. This clean air shall be produced by filtering air through an absolute (HEPA) filter.

(9) *Balance.* Minimum range 0 - 200 mg, certified accuracy to within 10 μg, resolution of 1 μg.

(d) *Additional filter handling conditions.* (1) *Filter handling.* Careful handling of the filter during sampling, conditioning, and weighing is necessary to avoid errors due to damaged filters or loss of collected particles from the filters. All filters must be weighed immediately after phase A dynamic conditioning and phase C.

(2) *Dynamic conditioning of filters.* Total dynamic conditioning is required prior to the initial weight determined in phase A. Dynamic conditioning refers to pulling clean air from the clean air generation system through the filters. Total dynamic conditioning can be established by sequential filter weighing every 30 minutes following repetitive dynamic conditioning. The filters are considered sufficiently conditioned if the sequential weights are repeatable to ± 3 μg.

(3) *Static charge.* The following procedure is suggested for minimizing charge effects. Place six or more Polonium static control devices (PSCD) inside the microbalance weighing chamber, (MWC). Two of them must be placed horizontally on the floor of the MWC and the remainder placed vertically on the back wall of the MWC. Taping two PSCD's together or using double-sided tape will help to keep them from falling. Place the filter that is to be weighed on the horizontal PSCDs facing aerosol coated surface up. Close the MWC and wait 1 minute. Open the MWC and place the filter on the balance dish. Wait 1 minute. If the charges have been neutralized the weight will stabilize within 30-60 seconds. Repeat the procedure of neutralizing charges and weighing as prescribed above several times (typically 2-4 times) until consecutive weights will differ by no more than 3 micrograms. Record the last measured weight and use this value for all subsequent calculations.

(e) *Test procedure*—(1) *Phase A - Preliminary steps.* (i) Generate a polydisperse glycerol test aerosol.

(ii) Introduce the aerosol into the transport system.

(iii) Monitor the aerosol size and concentration until stability and level have been achieved.

(iv) Condition the candidate method sampler and reference method sampler filters until total dynamic conditioning is achieved as specified in paragraph (d)(2) of this section.

(v) Record the dynamically conditioned weight as $InitWt_c$ and $InitWt_r$ where c is the candidate method sampler and r is the reference method sampler.

(2) *Phase B - Aerosol loading.* (i) Install the dynamically conditioned filters into the appropriate samplers.

(ii) Attach the samplers to the manifold.

(iii) Operate the candidate and the reference samplers such that they simultaneously sample the test aerosol for 30 minutes.

(3) *Phase C - Blow-off.* (i) Alter the intake of the samplers to sample air from the clean air generation system.

(ii) Sample clean air for one of the required blow-off time durations (1, 2, 3, and 4 hours).

(iii) Remove the filters from the samplers.

(iv) Weigh the filters immediately and record this weight, $FinalWt_c$ and $FinalWt_r$, where c is the candidate method sampler and r is the reference method sampler.

(v) Calculate the residual mass for the reference method sampler:

Equation 41a

$$RM_{(ij)} = \left(FinalWt_r - InitWt_r\right)$$

where:
i = repetition number; and
j = blow-off time period.

(vi) Calculate the corrected residual mass for the candidate method sampler as:

Equation 41b

$$CRM_{(ij)} = \left(FinalWt_r - InitWt_r\right) \times \frac{Q_r}{Q_c}$$

where:
i = repetition number;
j = blow-off time period;
Q_c = candidate method sampler flow rate, and
Q_r = reference method sampler flow rate.

(4) Repeat steps in paragraph (e)(1) through (e)(3) of this section until three repetitions have been completed for each of the required blow-off time durations (1, 2, 3, and 4 hours).

(f) *Calculations and analysis.* (1) Perform a linear regression with the candidate method CRM as the dependent variable and the reference method RM as the independent variable.

(2) Determine the following regression parameters: slope, intercept, and correlation coefficient (r).

(g) *Test results.* The candidate method passes the volatility test if the regression parameters meet the acceptance criteria specified in Table F-1 of this subpart.

Tables to Subpart F of Part 53

TABLE F–1.—PERFORMANCE SPECIFICATIONS FOR $PM_{2.5}$ CLASS II EQUIVALENT SAMPLERS

Performance Test	Specifications	Acceptance Criteria
§ 53.62 Full Wind Tunnel Evaluation	Solid VOAG produced aerosol at 2 km/hr and 24 km/hr.	Dp_{50} = 2.5 μm ± 0.2 μm; Numerical Analysis Results: 95% ≤R_c≤105%
§ 53.63 Wind Tunnel Inlet Aspiration Test	Liquid VOAG produced aerosol at 2 km/hr and 24 km/hr	Relative Aspiration: 95% ≤A≤105%
§ 53.64 Static Fractionator Test	Evaluation of the fractionator under static conditions	Dp_{50} = 2.5 μm ± 0.2 μm; Numerical Analysis Results: 95% ≤R_c≤105%
§ 53.65 Loading Test	Loading of the clean candidate under laboratory conditions	Acceptance criteria as specified in the post-loading evaluation test (§ 53.62, § 53.63, or § 53.64)
§ 53.66 Volatility Test	Polydisperse liquid aerosol produced by air nebulization of A.C.S. reagent grade glycerol, 99.5% minimum purity	Regression Parameters Slope = 1 ± 0.1, Intercept = 0 ± 0.15 r ≥ 0.97

TABLE F–2.—PARTICLE SIZES AND WIND SPEEDS FOR FULL WIND TUNNEL TEST, WIND TUNNEL INLET ASPIRATION TEST, AND STATIC CHAMBER TEST

Primary Partical Mean Size[a] (μm)	Full Wind Tunnel Test		Inlet Aspiration Test		Static Fractionator Test	Volatility Test
	2 km/hr	24 km/hr	2 km/hr	24 km/hr		
1.5±0.25	S	S			S	
2.0±0.25	S	S			S	
2.2±0.25	S	S			S	
2.5±0.25	S	S			S	
2.8±0.25	S	S			S	
3.0±0.25			L	L		
3.5±0.25	S	S			S	
4.0±0.5	S	S			S	
Polydisperse Glycerol Aerosol						L

[a] Aerodynamic diameter.
S=Solid particles.
L=Liquid particles.

TABLE F–3.—CRITICAL PARAMETERS OF IDEALIZED AMBIENT PARTICLE SIZE DISTRIBUTIONS

Idealized Distribution	Fine Particle Mode			Coarse Particle Mode			$PM_{2.5}$/PM_{10} Ratio	FRM Sampler Expected Mass Conc. (μg/m³)
	MMD (μm)	Geo. Std. Dev.	Conc. (μg/m³)	MMD (μm)	Geo. Std. Dev.	Conc. (μg/m³)		
Coarse	0.50	2	12.0	10	2	88.0	0.27	13.814
"Typical"	0.50	2	33.3	10	2	66.7	0.55	34.284
Fine	0.85	2	85.0	15	2	15.0	0.94	78.539

TABLE F-4.—ESTIMATED MASS CONCENTRATION MEASUREMENT OF $PM_{2.5}$ FOR IDEALIZED COARSE AEROSOL SIZE DISTRIBUTION

Particle Aerodynamic Diameter (μm)	Test Sampler			Ideal Sampler		
	Fractional Sampling Effectiveness	Interval Mass Concentration (μg/m³)	Estimated Mass Concentration Measurement (μg/m³)	Fractional Sampling Effectiveness	Interval Mass Concentration (μg/m³)	Estimated Mass Concentration Measurement (μg/m³)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
<0.500	1.000	6.001		1.000	6.001	6.001
0.625		2.129		0.999	2.129	2.127
0.750		0.982		0.998	0.982	0.980
0.875		0.730		0.997	0.730	0.728
1.000		0.551		0.995	0.551	0.548
1.125		0.428		0.991	0.428	0.424
1.250		0.346		0.987	0.346	0.342
1.375		0.294		0.980	0.294	0.288
1.500		0.264		0.969	0.264	0.256
1.675		0.251		0.954	0.251	0.239
1.750		0.250		0.932	0.250	0.233
1.875		0.258		0.899	0.258	0.232

TABLE F-4.—ESTIMATED MASS CONCENTRATION MEASUREMENT OF $PM_{2.5}$ FOR IDEALIZED COARSE AEROSOL SIZE DISTRIBUTION—Continued

Particle Aerodynamic Diameter (μm)	Test Sampler			Ideal Sampler		
	Fractional Sampling Effectiveness	Interval Mass Concentration (μg/m³)	Estimated Mass Concentration Measurement (μg/m³)	Fractional Sampling Effectiveness	Interval Mass Concentration (μg/m³)	Estimated Mass Concentration Measurement (μg/m³)
2.000		0.272		0.854	0.272	0.232
2.125		0.292		0.791	0.292	0.231
2.250		0.314		0.707	0.314	0.222
2.375		0.339		0.602	0.339	0.204
2.500		0.366		0.480	0.366	0.176
2.625		0.394		0.351	0.394	0.138
2.750		0.422		0.230	0.422	0.097
2.875		0.449		0.133	0.449	0.060
3.000		0.477		0.067	0.477	0.032
3.125		0.504		0.030	0.504	0.015
3.250		0.530		0.012	0.530	0.006
3.375		0.555		0.004	0.555	0.002
3.500		0.579		0.001	0.579	0.001
3.625		0.602		0.000000	0.602	0.000000
3.750		0.624		0.000000	0.624	0.000000
3.875		0.644		0.000000	0.644	0.000000
4.000		0.663		0.000000	0.663	0.000000
4.125		0.681		0.000000	0.681	0.000000
4.250		0.697		0.000000	0.697	0.000000
4.375		0.712		0.000000	0.712	0.000000
4.500		0.726		0.000000	0.726	0.000000
4.625		0.738		0.000000	0.738	0.000000
4.750		0.750		0.000000	0.750	0.000000
4.875		0.760		0.000000	0.760	0.000000
5.000		0.769		0.000000	0.769	0.000000
5.125		0.777		0.000000	0.777	0.000000
5.250		0.783		0.000000	0.783	0.000000
5.375		0.789		0.000000	0.789	0.000000
5.500		0.794		0.000000	0.794	0.000000
5.625		0.798		0.000000	0.798	0.000000
5.75		0.801		0.000000	0.801	0.000000
		$C_{sam(exp)}$=			$C_{ideal(exp)}$=	13.814

TABLE F-5.—ESTIMATED MASS CONCENTRATION MEASUREMENT OF $PM_{2.5}$ FOR IDEALIZED "TYPICAL" COARSE AEROSOL SIZE DISTRIBUTION

Particle Aerodynamic Diameter (μm)	Test Sampler			Ideal Sampler		
	Fractional Sampling Effectiveness	Interval Mass Concentration (μg/m³)	Estimated Mass Concentration Measurement (μg/m³)	Fractional Sampling Effectiveness	Interval Mass Concentration (μg/m³)	Estimated Mass Concentration Measurement (μg/m³)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
<0.500	1.000	16.651		1.000	16.651	16.651
0.625		5.899		0.999	5.899	5.893
0.750		2.708		0.998	2.708	2.703
0.875		1.996		0.997	1.996	1.990
1.000		1.478		0.995	1.478	1.471
1.125		1.108		0.991	1.108	1.098
1.250		0.846		0.987	0.846	0.835
1.375		0.661		0.980	0.661	0.648
1.500		0.532		0.969	0.532	0.516
1.675		0.444		0.954	0.444	0.424
1.750		0.384		0.932	0.384	0.358
1.875		0.347		0.899	0.347	0.312
2.000		0.325		0.854	0.325	0.277
2.125		0.314		0.791	0.314	0.248
2.250		0.312		0.707	0.312	0.221
2.375		0.316		0.602	0.316	0.190
2.500		0.325		0.480	0.325	0.156
2.625		0.336		0.351	0.336	0.118
2.750		0.350		0.230	0.350	0.081
2.875		0.366		0.133	0.366	0.049
3.000		0.382		0.067	0.382	0.026
3.125		0.399		0.030	0.399	0.012
3.250		0.416		0.012	0.416	0.005
3.375		0.432		0.004	0.432	0.002
3.500		0.449		0.001	0.449	0.000000
3.625		0.464		0.000000	0.464	0.000000
3.750		0.480		0.000000	0.480	0.000000
3.875		0.494		0.000000	0.494	0.000000
4.000		0.507		0.000000	0.507	0.000000
4.125		0.520		0.000000	0.520	0.000000
4.250				0.000000	0.532	0.000000
4.375				0.000000	0.543	0.000000
4.500				0.000000	0.553	0.000000
4.625				0.000000	0.562	0.000000
4.750				0.000000	0.570	0.000000
4.875				0.000000	0.577	0.000000
5.000				0.000000	0.584	0.000000
5.125				0.000000	0.590	0.000000
5.250				0.000000	0.595	0.000000
5.375				0.000000	0.599	0.000000
5.500				0.000000	0.603	0.000000
5.625				0.000000	0.605	0.000000
5.75				0.000000	0.608	0.000000
		$C_{sam(exp)}$=			$C_{ideal(exp)}$=	34.284

TABLE F-6.—ESTIMATED MASS CONCENTRATION MEASUREMENT OF $PM_{2.5}$ FOR IDEALIZED FINE AEROSOL SIZE DISTRIBUTION

Particle Aerodynamic Diameter (μm)	Test Sampler			Ideal Sampler		
	Fractional Sampling Effectiveness	Interval Mass Concentration (μg/m³)	Estimated Mass Concentration Measurement (μg/m³)	Fractional Sampling Effectiveness	Interval Mass Concentration (μg/m³)	Estimated Mass Concentration Measurement (μg/m³)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
<0.500	1.000	18.868		1.000	18.868	18.868
0.625		13.412		0.999	13.412	13.399
0.750		8.014		0.998	8.014	7.998
0.875		6.984		0.997	6.984	6.963
1.000		5.954		0.995	5.954	5.924
1.125		5.015		0.991	5.015	4.970
1.250		4.197		0.987	4.197	4.142
1.375		3.503		0.980	3.503	3.433
1.500		2.921		0.969	2.921	2.830
1.675		2.438		0.954	2.438	2.326
1.750		2.039		0.932	2.039	1.900
1.875		1.709		0.899	1.709	1.536
2.000		1.437		0.854	1.437	1.227
2.125		1.212		0.791	1.212	0.959
2.250		1.026		0.707	1.026	0.725
2.375		0.873		0.602	0.873	0.526
2.500		0.745		0.480	0.745	0.358
2.625		0.638		0.351	0.638	0.224
2.750		0.550		0.230	0.550	0.127
2.875		0.476		0.133	0.476	0.063
3.000		0.414		0.067	0.414	0.028
3.125		0.362		0.030	0.362	0.011
3.250		0.319		0.012	0.319	0.004
3.375		0.282		0.004	0.282	0.001
3.500		0.252		0.001	0.252	0.000000
3.625		0.226		0.000000	0.226	0.000000
3.750		0.204		0.000000	0.204	0.000000
3.875		0.185		0.000000	0.185	0.000000
4.000		0.170		0.000000	0.170	0.000000
4.125		0.157		0.000000	0.157	0.000000
4.250		0.146		0.000000	0.146	0.000000
4.375		0.136		0.000000	0.136	0.000000
4.500		0.129		0.000000	0.129	0.000000
4.625		0.122		0.000000	0.122	0.000000
4.750		0.117		0.000000	0.117	0.000000
4.875		0.112		0.000000	0.112	0.000000
5.000		0.108		0.000000	0.108	0.000000
5.125		0.105		0.000000	0.105	0.000000
5.250		0.102		0.000000	0.102	0.000000
5.375		0.100		0.000000	0.100	0.000000
5.500		0.098		0.000000	0.098	0.000000
5.625		0.097		0.000000	0.097	0.000000
5.75		0.096		0.000000	0.096	0.000000
		$C_{sam(exp)}$=			$C_{ideal(exp)}$=	78.539

Figures to Subpart F of Part 53

Figure E-1.—Designation Testing Checklist

DESIGNATION TESTING CHECKLIST FOR CLASS II

Auditee	Auditor signature	Date

Compliance Status: Y = Yes N = No NA = Not applicable/Not available				Verification Comments (Includes documentation of who, what, where, when, why) (Doc. #, Rev. #, Rev. Date)
Verification			Verified by Direct Observation of Process or of Documented Evidence: Performance, Design or Application Spec. Corresponding to Sections of 40 CFR Part 53, Subparts E and F	
Y	N	NA		
			Subpart E: Performance Specification Tests	
			Evaluation completed according to Subpart E §53.50 to §53.56	
			Subpart E: Class I Sequential Tests	
			Class II samplers that are also Class I (sequentialized) have passed the tests in §53.57	
			Subpart F: Performance Spec/Test	
			Evaluation of Physical Characteristics of Clean Sampler - One of these tests must be performed: §53.62 - Full Wind Tunnel §53.63 - Inlet Aspiration §53.64 - Static Fractionator	
			Evaluation of Physical Characteristics of Loaded Sampler §53.65 Loading Test One of the following tests must be performed for evaluation after loading: §53.62, §53.63, §53.64	
			Evaluation of the Volatile Characteristics of the Class II Sampler §53.66	

Appendix A to Subpart F of Part 53—References

(1) Marple, V.A., K.L. Rubow, W. Turner, and J.D. Spangler, Low Flow Rate Sharp Cut Impactors for Indoor Air Sampling: Design and Calibration., JAPCA, 37: 1303-1307 (1987).

(2) Vanderpool, R.W. and K.L. Rubow, Generation of Large, Solid Calibration Aerosols, J. of Aer. Sci. and Tech., 9:65-69 (1988).

(3) Society of Automotive Engineers Aerospace Material Specification (SAE AMS) 2404C, Electroless Nickel Planting, SAE, 400 Commonwealth Drive, Warrendale PA-15096, Revised 7-1-84, pp. 1-6.

PART 58—[AMENDED]

2. In part 58:

a. The authority citation for part 58 continues to read as follows:

Authority: 42 U.S.C. 7410, 7601(a), 7613, 7619.

b. Section 58.1 is amended by removing the existing alphabetic paragraph designations, by alphabetizing the existing definitions, by revising the definition *Traceable* and by adding in alphabetical order the following definitions to read as follows:

§58.1 Definitions.

* * * * *

Annual State air monitoring report is an annual report, prepared by control agencies and submitted to EPA for approval, that consists of an annual data summary report for all pollutants and a detailed report describing any proposed changes to their air quality surveillance network.

* * * * *

Community Monitoring Zone (CMZ) means an optional averaging area with established, well defined boundaries, such as county or census block, within a MPA that has relatively uniform concentrations of annual $PM_{2.5}$ as defined by Appendix D of this part. Two or more core SLAMS and other monitors within a CMZ that meet certain requirements as set forth in Appendix D of this part may be averaged for making comparisons to the annual $PM_{2.5}$ NAAQS.

Consolidated Metropolitan Statistical Area (CMSA) means the most recent area as designated by the U.S. Office of Management and Budget and population figures from the Bureau of the Census. The Department of Commerce provides that within metropolitan complexes of 1 million or more population, separate component areas are defined if specific criteria are met. Such areas are designated primary metropolitan statistical areas (PMSAs; and any area containing PMSAs is designated CMSA.

Core $PM_{2.5}$ SLAMS means community-oriented monitoring sites representative of community-wide exposures that are the basic component sites of the $PM_{2.5}$ SLAMS regulatory network. Core $PM_{2.5}$ SLAMS include community-oriented

SLAMS monitors, and sites collocated at PAMS.

* * * * *

Correlated acceptable continuous (CAC) PM analyzer means an optional fine particulate matter analyzer that can be used to supplement a $PM_{2.5}$ reference or equivalent sampler, in accordance with the provisions of § 58.13(f).

* * * * *

Equivalent method means a method of sampling and analyzing the ambient air for an air pollutant that has been designated as an equivalent method in accordance with part 53 of this chapter; it does not include a method for which an equivalent method designation has been canceled in accordance with § 53.11 or § 53.16 of this chapter.

* * * * *

Metropolitan Statistical Area (MSA) means the most recent area as designated by the U.S. Office of Management and Budget and population figures from the U.S. Bureau of the Census. The Department of Commerce defines a metropolitan area as one of a large population nucleus, together with adjacent communities that have a high degree of economic and social integration with that nucleus.

* * * * *

Monitoring Planning Area (MPA) means a contiguous geographic area with established, well defined boundaries, such as a metropolitan statistical area, county or State, having a common area that is used for planning monitoring locations for $PM_{2.5}$. MPAs may cross State boundaries, such as the Philadelphia PA-NJ MSA, and be further subdivided into community monitoring zones. MPAs are generally oriented toward areas with populations greater than 200,000, but for convenience, those portions of a State that are not associated with MSAs can be considered as a single MPA. MPAs must be defined, where applicable, in a State PM monitoring network description.

* * * * *

Particulate matter monitoring network description, required by § 58.20(f), means a detailed plan, prepared by control agencies and submitted to EPA for approval, that describes their $PM_{2.5}$ and PM_{10} air quality surveillance network.

* * * * *

$PM_{2.5}$ means particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers as measured by a reference method based on 40 CFR part 50, Appendix L, and designated in accordance with part 53 of this chapter or by an equivalent method designated in accordance with part 53 of this chapter.

* * * * *

Population-oriented monitoring (or sites) applies to residential areas, commercial areas, recreational areas, industrial areas, and other areas where a substantial number of people may spend a significant fraction of their day.

Primary Metropolitan Statistical Area (PMSA) is a separate component of a consolidated metropolitan statistical area. For the purposes of this part, PMSA is used interchangeably with MSA.

* * * * *

Reference method means a method of sampling and analyzing the ambient air for an air pollutant that will be specified as a reference method in an appendix to part 50 of this chapter, or a method that has been designated as a reference method in accordance with this part; it does not include a method for which a reference method designation has been canceled in accordance with § 53.11 or § 53.16 of this chapter.

* * * * *

Special Purpose Monitor (SPM) is a generic term used for all monitors other than SLAMS, NAMS, PAMS, and PSD monitors included in an agency's monitoring network for monitors used in a special study whose data are officially reported to EPA.

* * * * *

Traceable means that a local standard has been compared and certified, either directly or via not more than one intermediate standard, to a National Institute of Standards and Technology (NIST)-certified primary standard such as a NIST-Traceable Reference Material (NTRM) or a NIST-certified Gas Manufacturer's Internal Standard (GMIS).

* * * * *

c. Section 58.13 is amended by revising paragraphs (b) and (d) and adding new paragraphs (e) and (f) to read as follows:

§ 58.13 Operating schedule.

* * * * *

(b) For manual methods (excluding PM_{10} samplers, $PM_{2.5}$ samplers, and PAMS VOC samplers), at least one 24–hour sample must be obtained every sixth day except during periods or seasons exempted by the Regional Administrator.

* * * * *

(d) For PM_{10} samplers--a 24–hour sample must be taken a minimum of every third day.

(e) For $PM_{2.5}$ samplers, a 24–hour sample is required everyday for certain core SLAMS, including certain PAMS, as described in section 2.8.1.3 of Appendix D of this part, except during seasons or periods of low $PM_{2.5}$ as otherwise exempted by the Regional Administrator. A waiver of the everyday sampling schedule for SLAMS may be granted by the Regional Administrator or designee, and for NAMS by the Administrator or designee, for 1 calendar year from the time a $PM_{2.5}$ sequential sampler (FRM or Class I equivalent) has been approved by EPA. A 24–hour sample must be taken a minimum of every third day for all other SLAMS, including NAMS, as described in section 2.8.1.3 of Appendix D of this part, except when exempted by the Regional Administrator in accordance with forthcoming EPA guidance. During periods for which exemptions to every third day or every day sampling are allowed for core $PM_{2.5}$ SLAMS, a minimum frequency of one in 6-day sampling is still required. However, alternative sampling frequencies are allowed for SLAMS sites that are principally intended for comparisons to the 24–hour NAAQS. Such modifications must be approved by the Regional Administrator.

(f) *Alternatives to everyday sampling at sites with correlated acceptable continuous analyzers.* (1) Certain $PM_{2.5}$ core SLAMS sites located in monitoring planning areas (as described in section 2.8 of Appendix D of this part) are required to sample every day with a reference or equivalent method operating in accordance with part 53 of this chapter and section 2 of Appendix C of this part. However, in accordance with the monitoring priority as defined in paragraph (f)(2) of this section, established by the control agency and approved by EPA, a core SLAMS monitor may operate with a reference or equivalent method on a 1 in 3-day schedule and produce data that may be compared to the NAAQS, provided that it is collocated with an acceptable continuous fine particulate PM analyzer that is correlated with the reference or equivalent method. If the alternative sampling schedule is selected by the control agency and approved by EPA, the alternative schedule shall be implemented on January 1 of the year in which everyday sampling is required. The selection of correlated acceptable continuous PM analyzers and procedures for correlation with the intermittent reference or equivalent method shall be in accordance with procedures approved by the Regional Administrator. Unless the continuous fine particulate analyzer satisfies the requirements of section 2 of Appendix C of this part, however, the data derived from the correlated acceptable continuous monitor are not eligible for direct comparisons to the NAAQS in accordance with part 50 of this chapter.

(2) A Metropolitan Statistical Area (MSA) (or primary metropolitan statistical area) with greater than 1 million population and high concentrations of $PM_{2.5}$ (greater than or equal to 80 percent of the NAAQS) shall be a Priority 1 PM monitoring area. Other monitoring planning areas may be designated as Priority 2 PM monitoring areas.

(3) Core SLAMS having a correlated acceptable continuous analyzer collocated with a reference or equivalent method in a Priority 1 PM monitoring area may operate on the 1 in 3 sampling frequency only after reference or equivalent data are collected for at least 2 complete years.

(4) In all monitoring situations, with a correlated acceptable continuous alternative, FRM samplers or filter-based equivalent analyzers should preferably accompany the correlated acceptable continuous monitor.

d. Section 58.14 is revised to read as follows:

§ 58.14 Special purpose monitors.

(a) Except as specified in paragraph (b) of this section, any ambient air quality monitoring station other than a SLAMS or PSD station from which the State intends to use the data as part of a demonstration of attainment or nonattainment or in computing a design value for control purposes of the National Ambient Air Quality Standards (NAAQS) must meet the requirements for SLAMS as described in § 58.22 and, after January 1, 1983, must also meet the requirements for SLAMS described in § 58.13 and Appendices A and E of this part.

(b) Based on the need, in transitioning to a $PM_{2.5}$ standard that newly addresses the ambient impacts of fine particles, to encourage a sufficiently extensive geographical deployment of $PM_{2.5}$ monitors and thus hasten the development of an adequate $PM_{2.5}$ ambient air quality monitoring infrastructure, $PM_{2.5}$ NAAQS violation determinations shall not be exclusively made based on data produced at a population-oriented SPM site during the first 2 complete calendar years of its operation. However, a notice of NAAQS violations resulting from population-oriented SPMs shall be reported to EPA in the State's annual monitoring report and be considered by the State in the design of its overall SLAMS network; these population-oriented SPMs should be considered to become a permanent SLAMS during the annual network review in accordance with § 58.25.

(c) Any ambient air quality monitoring station other than a SLAMS or PSD station from which the State intends to use the data for SIP-related functions other than as described in paragraph (a) of this section is not necessarily required to comply with the requirements for a SLAMS station under paragraph (a) of this section but must be operated in accordance with a monitoring schedule, methodology, quality assurance procedures, and probe or instrument-siting specifications approved by the Regional Administrator.

e. Section 58.20 is amended by revising the section heading, paragraph (d), and the introductory text of paragraph (e), by designating the flush text at the end of the section as paragraph (i) and amending the third sentence by removing the words ''(a) through (f)'' and adding in their place, ''(a) through (h)'', by redesignating paragraph (f) as paragraph (h), and adding new paragraphs (f) and (g) to read as follows:

§ 58.20 Air quality surveillance: plan content.

* * * * *

(d) Provide for the review of the air quality surveillance system on an annual basis to determine if the system meets the monitoring objectives defined in Appendix D of this part. Such review must identify needed modifications to the network such as termination or relocation of unnecessary stations or establishment of new stations that are necessary. For $PM_{2.5}$, the review must identify needed changes to core SLAMS, monitoring planning areas, the chosen community monitoring approach including optional community monitoring zones, SLAMS, or SPMs.

(e) Provide for having a SLAMS network description available for public inspection and submission to the Administrator upon request. The network description must be available at the time of plan revision submittal and must contain the following information for each SLAMS:

* * * * *

(f) Provide for having a PM monitoring network description available for public inspection which must provide for monitoring planning areas, and the community monitoring approach involving core monitors and optional community monitoring zones for $PM_{2.5}$. The PM monitoring network description for PM_{10} and $PM_{2.5}$ must be submitted to the Regional Administrator for approval by July 1, 1998, and must contain the following information for each PM SLAMS and $PM_{2.5}$ SPM:

(1) The AIRS site identification form for existing stations.

(2) The proposed location for scheduled stations.

(3) The sampling and analysis method.

(4) The operating schedule.

(5) The monitoring objective, spatial scale of representativeness, and additionally for $PM_{2.5}$, the monitoring planning area, optional community monitoring zone, and the site code designation to identify which site will be identified as core SLAMS; and SLAMS or population-oriented SPMs, if any, that are microscale or middle scale in their representativeness as defined in Appendix D of this part.

(6) A schedule for:

(i) Locating, placing into operation, and making available the AIRS site identification form for each SLAMS which is not located and operating at the time of plan revision submittal.

(ii) Implementing quality assurance procedures of Appendix A of this part for each SLAMS for which such procedures are not implemented at the time of plan revision submittal.

(iii) Resiting each SLAMS which does not meet the requirements of Appendix E of this part at the time of plan revision submittal.

(g) Provide for having a list of all $PM_{2.5}$ monitoring locations including SLAMS, NAMS, PAMS and population-oriented SPMs, that are included in the State's PM monitoring network description and are intended for comparison to the NAAQS, available for public inspection.

* * * * *

f. Section 58.23 is amended by revising the introductory text and adding a new paragraph (c) to read as follows:

§ 58.23 Monitoring network completion.

With the exception of the PM_{10} monitoring networks that shall be in place by March 16, 1998 and with the exception of the $PM_{2.5}$ monitoring networks as described in paragraph (c) of this section:

* * * * *

(c) Each $PM_{2.5}$ station in the SLAMS network must be in operation in accordance with the minimum requirements of Appendix D of this part, be sited in accordance with the criteria in Appendix E of this part, and be located as described on the station's AIRS site identification form, according to the following schedule:

(1) Within 1 year after September 16, 1997, at least one required core $PM_{2.5}$ SLAMS site in each MSA with population greater than 500,000, plus one site in each PAMS area, (plus at least two additional SLAMS sites per State) must be in operation.

(2) Within 2 years after September 16, 1997, all other required SLAMS,

including all required core SLAMS, required regional background and regional transport SLAMS, continuous PM monitors in areas with greater than 1 million population, and all additional required $PM_{2.5}$ SLAMS must be in operation.

(3) Within 3 years after September 16, 1997, all additional sites (e.g., sites classified as SLAMS/SPM to complete the mature network) must be in operation.

g. Section 58.26 is amended by revising the section heading and the introductory text of paragraph (b), and adding paragraphs (d) and (e) to read as follows:

§ 58.26 Annual state air monitoring report.

* * * * *

(b) The SLAMS annual data summary report must contain:

* * * * *

(d) For PM monitoring and data—(1) The State shall submit a summary to the appropriate Regional Office (for SLAMS) or Administrator (through the Regional Office) (for NAMS) that details proposed changes to the PM Monitoring Network Description and to be in accordance with the annual network review requirements in § 58.25. This shall discuss the existing PM networks, including modifications to the number, size or boundaries of monitoring planning areas and optional community monitoring zones; number and location of PM_{10} and $PM_{2.5}$ SLAMS; number and location of core $PM_{2.5}$ SLAMS; alternative sampling frequencies proposed for $PM_{2.5}$ SLAMS (including core $PM_{2.5}$ SLAMS and $PM_{2.5}$ NAMS), core $PM_{2.5}$ SLAMS to be designated $PM_{2.5}$ NAMS; and PM_{10} and $PM_{2.5}$ SLAMS to be designated PM_{10} and $PM_{2.5}$ NAMS respectively.

(2) The State shall submit an annual summary to the appropriate Regional Office of all the ambient air quality monitoring PM data from all special purpose monitors that are described in the State's PM monitoring network description and are intended for SIP purposes. These include those population-oriented SPMs that are eligible for comparison to the PM NAAQS. The State shall certify the data in accordance with paragraph (c) of this section.

(e) The Annual State Air Monitoring Report shall be submitted to the Regional Administrator by July 1 or by an alternative annual date to be negotiated between the State and Regional Administrator. The Region shall provide review and approval/disapproval within 60 days. After 3 years following September 16, 1997, the schedule for submitting the required annual revised $PM_{2.5}$ monitoring network description may be altered based on a new schedule determined by the Regional Administrator. States may submit an alternative PM monitoring network description in which it requests exemptions from specific required elements of the network design (e.g., required number of core sites, other SLAMS, sampling frequency, etc.). After 3 years following September 16, 1997 or once a CMZ monitoring area has been determined to violate the NAAQS, then changes to an MPA monitoring network affecting the violating locations shall require public review and notification.

h. Section 58.30 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 58.30 NAMS network establishment.

(a) By January 1, 1980, with the exception of PM_{10} and $PM_{2.5}$ samplers, which shall be by July 1, 1998, the State shall:

* * * * *

i. In § 58.31, paragraph (f) is revised to read as follows:

§ 58.31 NAMS network description.

* * * * *

(f) The monitoring objective, spatial scale of representativeness, and for $PM_{2.5}$, the monitoring planning area and community monitoring zone, as defined in Appendix D of this part.

* * * * *

j. In § 58.34, the introductory text is revised to read as follows:

§ 58.34 NAMS network completion.

With the exception of PM_{10} samplers, which shall be by 1 year after September 16, 1997, and $PM_{2.5}$, which shall be by 3 years after September 16, 1997:

* * * * *

k. In § 58.35, the first sentence of paragraph (b) is revised to read as follows:

§ 58.35 NAMS data submittal.

* * * * *

(b) The State shall report to the Administrator all ambient air quality data for SO^2, CO, O_3, NO_2, Pb, PM_{10}, and $PM_{2.5}$, and information specified by the AIRS Users Guide (Volume II, Air Quality Data Coding, and Volume III, Air Quality Data Storage) to be coded into the AIRS-AQS format. * * *

* * * * *

l. Revise Appendix A of part 58 to read as follows:

Appendix A—Quality Assurance Requirements for State and Local Air Monitoring Stations (SLAMS)

1. *General Information.*

1.1 This Appendix specifies the minimum quality assurance/quality control (QA/QC) requirements applicable to SLAMS air monitoring data submitted to EPA. State and local agencies are encouraged to develop and maintain quality assurance programs more extensive than the required minimum.

1.2 To assure the quality of data from air monitoring measurements, two distinct and important interrelated functions must be performed. One function is the control of the measurement process through broad quality assurance activities, such as establishing policies and procedures, developing data quality objectives, assigning roles and responsibilities, conducting oversight and reviews, and implementing corrective actions. The other function is the control of the measurement process through the implementation of specific quality control procedures, such as audits, calibrations, checks, replicates, routine self-assessments, etc. In general, the greater the control of a given monitoring system, the better will be the resulting quality of the monitoring data. The results of quality assurance reviews and assessments indicate whether the control efforts are adequate or need to be improved.

1.3 Documentation of all quality assurance and quality control efforts implemented during the data collection, analysis, and reporting phases is important to data users, who can then consider the impact of these control efforts on the data quality (see Reference 1 of this Appendix). Both qualitative and quantitative assessments of the effectiveness of these control efforts should identify those areas most likely to impact the data quality and to what extent.

1.4 Periodic assessments of SLAMS data quality are required to be reported to EPA. To provide national uniformity in this assessment and reporting of data quality for all SLAMS networks, specific assessment and reporting procedures are prescribed in detail in sections 3, 4, and 5 of this Appendix. On the other hand, the selection and extent of the QA and QC activities used by a monitoring agency depend on a number of local factors such as the field and laboratory conditions, the objectives for monitoring, the level of the data quality needed, the expertise of assigned personnel, the cost of control procedures, pollutant concentration levels, etc. Therefore, the quality system requirements, in section 2 of this Appendix, are specified in general terms to allow each State to develop a quality assurance program that is most efficient and effective for its own circumstances while achieving the Ambient Air Quality Programs data quality objectives.

2. *Quality System Requirements.*

2.1 Each State and local agency must develop a quality system (Reference 2 of this Appendix) to ensure that the monitoring results:

(a) Meet a well-defined need, use, or purpose.

(b) Satisfy customers' expectations.

(c) Comply with applicable standards specifications.

(d) Comply with statutory (and other) requirements of society.

(e) Reflect consideration of cost and economics.

(f) Implement a quality assurance program consisting of policies, procedures, specifications, standards, and documentation necessary to:

(1) Provide data of adequate quality to meet monitoring objectives, and

(2) Minimize loss of air quality data due to malfunctions or out-of-control conditions. This quality assurance program must be described in detail, suitably documented in accordance with Agency requirements (Reference 4 of this Appendix), and approved by the appropriate Regional Administrator, or the Regional Administrator's designee. The Quality Assurance Program will be reviewed during the systems audits described in section 2.5 of this Appendix.

2.2 Primary requirements and guidance documents for developing the quality assurance program are contained in References 2 through 7 of this Appendix, which also contain many suggested and required procedures, checks, and control specifications. Reference 7 of this Appendix describes specific guidance for the development of a QA Program for SLAMS. Many specific quality control checks and specifications for methods are included in the respective reference methods described in part 50 of this chapter or in the respective equivalent method descriptions available from EPA (Reference 8 of this Appendix). Similarly, quality control procedures related to specifically designated reference and equivalent method analyzers are contained in the respective operation or instruction manuals associated with those analyzers. Quality assurance guidance for meteorological systems at PAMS is contained in Reference 9 of this Appendix. Quality assurance procedures for VOC, NO_x (including NO and NO_2), O_3, and carbonyl measurements at PAMS must be consistent with Reference 15 of this Appendix. Reference 4 of this Appendix includes requirements for the development of quality assurance project plans, and quality assurance and control programs, and systems audits demonstrating attainment of the requirements.

2.3 Pollutant Concentration and Flow Rate Standards.

2.3.1 Gaseous pollutant concentration standards (permeation devices or cylinders of compressed gas) used to obtain test concentrations for CO, SO_2, NO, and NO_2 must be traceable to either a National Institute of Standards and Technology (NIST) NIST-Traceable Reference Material (NTRM) or a NIST-certified Gas Manufacturer's Internal Standard (GMIS), certified in accordance with one of the procedures given in Reference 10 of this Appendix.

2.3.2 Test concentrations for O_3 must be obtained in accordance with the UV photometric calibration procedure specified in 40 CFR part 50, Appendix D, or by means of a certified ozone transfer standard. Consult References 11 and 12 of this Appendix for guidance on primary and transfer standards for O_3.

2.3.3 Flow rate measurements must be made by a flow measuring instrument that is traceable to an authoritative volume or other applicable standard. Guidance for certifying some types of flowmeters is provided in Reference 7 of this Appendix.

2.4 National Performance Audit Program (NPAP). Agencies operating SLAMS are required to participate in EPA's NPAP. These audits are described in Reference 7 of this Appendix. For further instructions, agencies should contact either the appropriate EPA Regional QA Coordinator at the appropriate EPA Regional Office location, or the NPAP Coordinator, Emissions Monitoring and Analysis Division (MD–14), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711.

2.5 Systems Audit Programs. Systems audits of the ambient air monitoring programs of agencies operating SLAMS shall be conducted at least every 3 years by the appropriate EPA Regional Office. Systems audit programs are described in Reference 7 of this Appendix. For further instructions, agencies should contact either the appropriate EPA Regional QA Coordinator or the Systems Audit QA Coordinator, Office of Air Quality Planning and Standards, Emissions Monitoring and Analysis Division (MD-14), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711.

3. *Data Quality Assessment Requirements.*

3.0.1 All ambient monitoring methods or analyzers used in SLAMS shall be tested periodically, as described in this section, to quantitatively assess the quality of the SLAMS data. Measurement uncertainty is estimated for both automated and manual methods. Terminology associated with measurement uncertainty are found within this Appendix and includes:

(a) Precision. A measurement of mutual agreement among individual measurements of the same property usually under prescribed similar conditions, expressed generally in terms of the standard deviation;

(b) Accuracy. The degree of agreement between an observed value and an accepted reference value, accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations;

(c) Bias. The systematic or persistent distortion of a measurement process which causes errors in one direction. The individual results of these tests for each method or analyzer shall be reported to EPA as specified in section 4 of this Appendix. EPA will then calculate quarterly assessments of measurement uncertainty applicable to the SLAMS data as described in section 5 of this Appendix. Data assessment results should be reported to EPA only for methods and analyzers approved for use in SLAMS monitoring under Appendix C of this part.

3.0.2 Estimates of the data quality will be calculated on the basis of single monitors and reporting organizations and may also be calculated for each region and for the entire Nation. A reporting organization is defined as a State, subordinate organization within a State, or other organization that is responsible for a set of stations that monitors the same pollutant and for which data quality assessments can be pooled. States must define one or more reporting organizations for each pollutant such that each monitoring station in the State SLAMS network is included in one, and only one, reporting organization.

3.0.3 Each reporting organization shall be defined such that measurement uncertainty among all stations in the organization can be expected to be reasonably homogeneous, as a result of common factors.

(a) Common factors that should be considered by States in defining reporting organizations include:

(1) Operation by a common team of field operators.

(2) Common calibration facilities.

(3) Oversight by a common quality assurance organization.

(4) Support by a common laboratory or headquarters.

(b) Where there is uncertainty in defining the reporting organizations or in assigning specific sites to reporting organizations, States shall consult with the appropriate EPA Regional Office. All definitions of reporting organizations shall be subject to final approval by the appropriate EPA Regional Office.

3.0.4 Assessment results shall be reported as specified in section 4 of this Appendix. Table A-1 of this Appendix provides a summary of the minimum data quality assessment requirements, which are described in more detail in the following sections.

3.1 Precision of Automated Methods Excluding $PM_{2.5}$.

3.1.1 Methods for SO_2, NO_2, O_3 and CO. A one- point precision check must be performed at least once every 2 weeks on each automated analyzer used to measure SO_2, NO_2, O_3 and CO. The precision check is made by challenging the analyzer with a precision check gas of known concentration (effective concentration for open path analyzers) between 0.08 and 0.10 ppm for SO_2, NO_2, and O_3 analyzers, and between 8 and 10 ppm for CO analyzers. To check the precision of SLAMS analyzers operating on ranges higher than 0 to 1.0 ppm SO_2, NO_2, and O_3, or 0 to 100 ppm for CO, use precision check gases of appropriately higher concentration as approved by the appropriate Regional Administrator or their designee. However, the results of precision checks at concentration levels other than those specified above need not be reported to EPA. The standards from which precision check test concentrations are obtained must meet the specifications of section 2.3 of this Appendix.

3.1.1.1 Except for certain CO analyzers described below, point analyzers must operate in their normal sampling mode during the precision check, and the test atmosphere must pass through all filters, scrubbers, conditioners and other components used during normal ambient sampling and as much of the ambient air inlet system as is practicable. If permitted by the associated operation or instruction manual, a CO point analyzer may be temporarily modified during the precision check to reduce vent or purge flows, or the test atmosphere may enter the analyzer at a point other than the normal sample inlet, provided that the analyzer's response is not likely to be altered by these deviations from the normal operational mode. If a precision check is made in conjunction with a zero or span adjustment, it must be made prior to such zero or span adjustments. Randomization of the precision check with respect to time of day, day of week, and routine service and adjustments is encouraged where possible.

3.1.1.2 Open path analyzers are tested by inserting a test cell containing a precision check gas concentration into the optical measurement beam of the instrument. If possible, the normally used transmitter, receiver, and as appropriate, reflecting devices should be used during the test, and the normal monitoring configuration of the instrument should be altered as little as possible to accommodate the test cell for the test. However, if permitted by the associated operation or instruction manual, an alternate local light source or an alternate optical path that does not include the normal atmospheric monitoring path may be used. The actual concentration of the precision check gas in the test cell must be selected to produce an effective concentration in the range specified in section 3.1.1. Generally, the precision test concentration measurement will be the sum of the atmospheric pollutant concentration and the precision test concentration. If so, the result must be corrected to remove the atmospheric concentration contribution. The corrected concentration is obtained by subtracting the average of the atmospheric concentrations measured by the open path instrument under test immediately before and immediately after the precision check test from the precision test concentration measurement. If the difference between these before and after measurements is greater than 20 percent of the effective concentration of the test gas, discard the test result and repeat the test. If possible, open path analyzers should be tested during periods when the atmospheric pollutant concentrations are relatively low and steady.

3.1.1.3 Report the actual concentration (effective concentration for open path analyzers) of the precision check gas and the corresponding concentration measurement (corrected concentration, if applicable, for open path analyzers) indicated by the analyzer. The percent differences between these concentrations are used to assess the precision of the monitoring data as described in section 5.1. of this Appendix.

3.1.2 Methods for Particulate Matter Excluding $PM_{2.5}$. A one-point precision check must be performed at least once every 2 weeks on each automated analyzer used to measure PM_{10}. The precision check is made by checking the operational flow rate of the analyzer. If a precision flow rate check is made in conjunction with a flow rate adjustment, it must be made prior to such flow rate adjustment. Randomization of the precision check with respect to time of day, day of week, and routine service and adjustments is encouraged where possible.

3.1.2.1 Standard procedure: Use a flow rate transfer standard certified in accordance with section 2.3.3 of this Appendix to check the analyzer's normal flow rate. Care should be used in selecting and using the flow rate measurement device such that it does not alter the normal operating flow rate of the analyzer. Report the actual analyzer flow rate measured by the transfer standard and the corresponding flow rate measured, indicated, or assumed by the analyzer.

3.1.2.2 Alternative procedure:

3.1.2.2.1 It is permissible to obtain the precision check flow rate data from the analyzer's internal flow meter without the use of an external flow rate transfer standard, provided that:

3.1.2.2.1.1 The flow meter is audited with an external flow rate transfer standard at least every 6 months.

3.1.2.2.1.2 Records of at least the three most recent flow audits of the instrument's internal flow meter over at least several weeks confirm that the flow meter is stable, verifiable and accurate to ±4%.

3.1.2.2.1.3 The instrument and flow meter give no indication of improper operation.

3.1.2.2.2 With suitable communication capability, the precision check may thus be carried out remotely. For this procedure, report the set-point flow rate as the actual flow rate along with the flow rate measured or indicated by the analyzer flow meter.

3.1.2.2.3 For either procedure, the percent differences between the actual and indicated flow rates are used to assess the precision of the monitoring data as described in section 5.1 of this Appendix (using flow rates in lieu of concentrations). The percent differences between these concentrations are used to assess the precision of the monitoring data as described in section 5.1. of this Appendix.

3.2 Accuracy of Automated Methods Excluding $PM_{2.5}$.

3.2.1 Methods for SO_2, NO_2, O_3, or CO.

3.2.1.1 Each calendar quarter (during which analyzers are operated), audit at least 25 percent of the SLAMS analyzers that monitor for SO_2, NO_2, O_3, or CO such that each analyzer is audited at least once per year. If there are fewer than four analyzers for a pollutant within a reporting organization, randomly reaudit one or more analyzers so that at least one analyzer for that pollutant is audited each calendar quarter. Where possible, EPA strongly encourages more frequent auditing, up to an audit frequency of once per quarter for each SLAMS analyzer.

3.2.1.2 (a) The audit is made by challenging the analyzer with at least one audit gas of known concentration (effective concentration for open path analyzers) from each of the following ranges applicable to the analyzer being audited:

Audit Level	Concentration Range, PPM		
	SO_2, O_3	NO_2	CO
1	0.03–0.08	0.03–0.08	3–8
2	0.15–0.20	0.15–0.20	15–20
3	0.35–0.45	0.35–0.45	35–45
4	0.80–0.90	.....	80–90

(b) NO_2 audit gas for chemiluminescence-type NO_2 analyzers must also contain at least 0.08 ppm NO.

3.2.1.3 NO concentrations substantially higher than 0.08 ppm, as may occur when using some gas phase titration (GPT) techniques, may lead to audit errors in chemiluminescence analyzers due to inevitable minor NO-NO_x channel imbalance. Such errors may be atypical of routine monitoring errors to the extent that such NO concentrations exceed typical ambient NO concentrations at the site. These errors may be minimized by modifying the GPT technique to lower the NO concentrations remaining in the NO_2 audit gas to levels closer to typical ambient NO concentrations at the site.

3.2.1.4 To audit SLAMS analyzers operating on ranges higher than 0 to 1.0 ppm for SO_2, NO_2, and O_3 or 0 to 100 ppm for CO, use audit gases of appropriately higher concentration as approved by the appropriate Regional Administrator or the Administrators's designee. The results of audits at concentration levels other than those shown in the above table need not be reported to EPA.

3.2.1.5 The standards from which audit gas test concentrations are obtained must meet the specifications of section 2.3 of this Appendix. The gas standards and equipment used for auditing must not be the same as the standards and equipment used for calibration or calibration span adjustments. The auditor should not be the operator or analyst who conducts the routine monitoring, calibration, and analysis.

3.2.1.6 For point analyzers, the audit shall be carried out by allowing the analyzer to analyze the audit test atmosphere in its normal sampling mode such that the test atmosphere passes through all filters, scrubbers, conditioners, and other sample inlet components used during normal ambient sampling and as much of the ambient air inlet system as is practicable. The exception provided in section 3.1 of this Appendix for certain CO analyzers does not apply for audits.

3.2.1.7 Open path analyzers are audited by inserting a test cell containing the various audit gas concentrations into the optical measurement beam of the instrument. If possible, the normally used transmitter, receiver, and, as appropriate, reflecting devices should be used during the audit, and the normal monitoring configuration of the instrument should be modified as little as possible to accommodate the test cell for the audit. However, if permitted by the associated operation or instruction manual, an alternate local light source or an alternate optical path that does not include the normal atmospheric monitoring path may be used. The actual concentrations of the audit gas in the test cell must be selected to produce effective concentrations in the ranges specified in this section 3.2 of this Appendix.

Generally, each audit concentration measurement result will be the sum of the atmospheric pollutant concentration and the audit test concentration. If so, the result must be corrected to remove the atmospheric concentration contribution. The corrected concentration is obtained by subtracting the average of the atmospheric concentrations measured by the open path instrument under test immediately before and immediately after the audit test (or preferably before and after each audit concentration level) from the audit concentration measurement. If the difference between the before and after measurements is greater than 20 percent of the effective concentration of the test gas standard, discard the test result for that concentration level and repeat the test for that level. If possible, open path analyzers should be audited during periods when the atmospheric pollutant concentrations are relatively low and steady. Also, the monitoring path length must be reverified to within ±3 percent to validate the audit, since the monitoring path length is critical to the determination of the effective concentration.

3.2.1.8 Report both the actual concentrations (effective concentrations for open path analyzers) of the audit gases and the corresponding concentration measurements (corrected concentrations, if applicable, for open path analyzers) indicated or produced by the analyzer being tested. The percent differences between these concentrations are used to assess the accuracy of the monitoring data as described in section 5.2 of this Appendix.

3.2.2 Methods for Particulate Matter Excluding $PM_{2.5}$.

3.2.2.1 Each calendar quarter, audit the flow rate of at least 25 percent of the SLAMS PM_{10} analyzers such that each PM_{10} analyzer is audited at least once per year. If there are fewer than four PM_{10} analyzers within a reporting organization, randomly re-audit one or more analyzers so that at least one analyzer is audited each calendar quarter. Where possible, EPA strongly encourages more frequent auditing, up to an audit frequency of once per quarter for each SLAMS analyzer.

3.2.2.2 The audit is made by measuring the analyzer's normal operating flow rate, using a flow rate transfer standard certified in accordance with section 2.3.3 of this Appendix. The flow rate standard used for auditing must not be the same flow rate standard used to calibrate the analyzer. However, both the calibration standard and the audit standard may be referenced to the same primary flow rate or volume standard. Great care must be used in auditing the flow rate to be certain that the flow measurement device does not alter the normal operating flow rate of the analyzer. Report the audit (actual) flow rate and the corresponding flow rate indicated or assumed by the sampler. The percent differences between these flow rates are used to calculate accuracy (PM_{10}) as described in section 5.2 of this Appendix.

3.3 Precision of Manual Methods Excluding $PM_{2.5}$.

3.3.1 For each network of manual methods other than for $PM_{2.5}$, select one or more monitoring sites within the reporting organization for duplicate, collocated sampling as follows: for 1 to 5 sites, select 1 site; for 6 to 20 sites, select 2 sites; and for over 20 sites, select 3 sites. Where possible, additional collocated sampling is encouraged. For purposes of precision assessment, networks for measuring TSP and PM_{10} shall be considered separately from one another. PM_{10} and TSP sites having annual mean particulate matter concentrations among the highest 25 percent of the annual mean concentrations for all the sites in the network must be selected or, if such sites are impractical, alternative sites approved by the Regional Administrator may be selected.

3.3.2 In determining the number of collocated sites required for PM_{10}, monitoring networks for lead should be treated independently from networks for particulate matter, even though the separate networks may share one or more common samplers. However, a single pair of samplers collocated at a common-sampler monitoring site that meets the requirements for both a collocated lead site and a collocated particulate matter site may serve as a collocated site for both networks.

3.3.3 The two collocated samplers must be within 4 meters of each other, and particulate matter samplers must be at least 2 meters apart to preclude airflow interference. Calibration, sampling, and analysis must be the same for both collocated samplers and the same as for all other samplers in the network.

3.3.4 For each pair of collocated samplers, designate one sampler as the primary sampler whose samples will be used to report air quality for the site, and designate the other as the duplicate sampler. Each duplicate sampler must be operated concurrently with its associated routine sampler at least once per week. The operation schedule should be selected so that the sampling days are distributed evenly over the year and over the seven days of the week. A six-day sampling schedule is required. Report the measurements from both samplers at each collocated sampling site. The calculations for evaluating precision between the two collocated samplers are described in section 5.3 of this Appendix.

3.4 Accuracy of Manual Methods Excluding $PM_{2.5}$. The accuracy of manual sampling methods is assessed by auditing a portion of the measurement process.

3.4.1 Procedures for PM_{10} and TSP.

3.4.1.1 Procedures for flow rate audits for PM_{10}. Each calendar quarter, audit the flow rate of at least 25 percent of the PM_{10} samplers such that each PM_{10} sampler is audited at least once per year. If there are fewer than four PM_{10} samplers within a reporting organization, randomly reaudit one or more samplers so that one sampler is audited each calendar quarter. Audit each sampler at its normal operating flow rate, using a flow rate transfer standard certified in accordance with section 2.3.3 of this Appendix. The flow rate standard used for auditing must not be the same flow rate standard used to calibrate the sampler. However, both the calibration standard and the audit standard may be referenced to the same primary flow rate standard. The flow audit should be scheduled so as to avoid interference with a scheduled sampling period. Report the audit (actual) flow rate and the corresponding flow rate indicated by the sampler's normally used flow indicator. The percent differences between these flow rates are used to calculate accuracy and bias as described in section 5.4.1 of this Appendix.

3.4.1.2 Great care must be used in auditing high-volume particulate matter samplers having flow regulators because the introduction of resistance plates in the audit flow standard device can cause abnormal flow patterns at the point of flow sensing. For this reason, the flow audit standard should be used with a normal filter in place and without resistance plates in auditing flow-regulated high-volume samplers, or other steps should be taken to assure that flow patterns are not perturbed at the point of flow sensing.

3.4.2 SO_2 Methods.

3.4.2.1 Prepare audit solutions from a working sulfite-tetrachloromercurate (TCM) solution as described in section 10.2 of the SO_2 Reference Method (40 CFR part 50, Appendix A). These audit samples must be prepared independently from the standardized sulfite solutions used in the routine calibration procedure. Sulfite-TCM audit samples must be stored between 0 and 5 °C and expire 30 days after preparation.

3.4.2.2 Prepare audit samples in each of the concentration ranges of 0.2-0.3, 0.5-0.6, and 0.8-0.9 μg SO_2/ml. Analyze an audit sample in each of the three ranges at least once each day that samples are analyzed and at least twice per calendar quarter. Report the audit concentrations (in μg SO_2/ml) and the corresponding indicated concentrations (in μg SO_2/ml). The percent differences between these concentrations are used to calculate accuracy as described in section 5.4.2 of this Appendix.

3.4.3 NO_2 Methods. Prepare audit solutions from a working sodium nitrite solution as described in the appropriate equivalent method (see Reference 8 of this Appendix). These audit samples must be prepared independently from the standardized nitrite solutions used in the routine calibration procedure. Sodium nitrite audit samples expire in 3 months after preparation. Prepare audit samples in each of the concentration ranges of 0.2-0.3, 0.5-0.6, and 0.8-0.9 μg NO_2/ml. Analyze an audit sample in each of the three ranges at least once each day that samples are analyzed and at least twice per calendar quarter. Report the audit concentrations (in μg NO_2/ml) and the corresponding indicated concentrations (in μg NO_2/ml). The percent differences between these concentrations are used to calculate accuracy as described in section 5.4.2 of this Appendix.

3.4.4 Pb Methods.

3.4.4.1 For the Pb Reference Method (40 CFR part 50, Appendix G), the flow rates of the high-volume Pb samplers shall be audited as part of the TSP network using the same procedures described in section 3.4.1 of this Appendix. For agencies operating both TSP and Pb networks, 25 percent of the total number of high-volume samplers are to be audited each quarter.

3.4.4.2 Each calendar quarter, audit the Pb Reference Method analytical procedure using

glass fiber filter strips containing a known quantity of Pb. These audit sample strips are prepared by depositing a Pb solution on unexposed glass fiber filter strips of dimensions 1.9 cm by 20.3 cm (3/4 inch by 8 inch) and allowing them to dry thoroughly. The audit samples must be prepared using batches of reagents different from those used to calibrate the Pb analytical equipment being audited. Prepare audit samples in the following concentration ranges:

Range	Pb Concentration, µg/Strip	Equivalent Ambient Pb Concentration, µg/m³ [1]
1	100–300	0.5–1.5
2	600–1000	3.0–5.0

[1] Equivalent ambient Pb concentration in µg/m³ is based on sampling at 1.7 m³/min for 24 hours on a 20.3 cm×25.4 cm (8 inch×10 inch) glass fiber filter.

3.4.4.3 Audit samples must be extracted using the same extraction procedure used for exposed filters.

3.4.4.4 Analyze three audit samples in each of the two ranges each quarter samples are analyzed. The audit sample analyses shall be distributed as much as possible over the entire calendar quarter. Report the audit concentrations (in µg Pb/strip) and the corresponding measured concentrations (in µg Pb/strip) using unit code 77. The percent differences between the concentrations are used to calculate analytical accuracy as described in section 5.4.2 of this Appendix.

3.4.4.5 The accuracy of an equivalent Pb method is assessed in the same manner as for the reference method. The flow auditing device and Pb analysis audit samples must be compatible with the specific requirements of the equivalent method.

3.5 Measurement Uncertainty for Automated and Manual $PM_{2.5}$ Methods. The goal for acceptable measurement uncertainty has been defined as 10 percent coefficient of variation (CV) for total precision and ± 10 percent for total bias (Reference 14 of this Appendix).

3.5.1 Flow Rate Audits.

3.5.1.1 Automated methods for $PM_{2.5}$. A one-point precision check must be performed at least once every 2 weeks on each automated analyzer used to measure $PM_{2.5}$. The precision check is made by checking the operational flow rate of the analyzer. If a precision flow rate check is made in conjunction with a flow rate adjustment, it must be made prior to such flow rate adjustment. Randomization of the precision check with respect to time of day, day of week, and routine service and adjustments is encouraged where possible.

3.5.1.1.1 Standard procedure: Use a flow rate transfer standard certified in accordance with section 2.3.3 of this Appendix to check the analyzer's normal flow rate. Care should be used in selecting and using the flow rate measurement device such that it does not alter the normal operating flow rate of the analyzer. Report the actual analyzer flow rate measured by the transfer standard and the corresponding flow rate measured, indicated, or assumed by the analyzer.

3.5.1.1.2 Alternative procedure: It is permissible to obtain the precision check flow rate data from the analyzer's internal flow meter without the use of an external flow rate transfer standard, provided that the flow meter is audited with an external flow rate transfer standard at least every 6 months; records of at least the three most recent flow audits of the instrument's internal flow meter over at least several weeks confirm that the flow meter is stable, verifiable and accurate to ±4%; and the instrument and flow meter give no indication of improper operation. With suitable communication capability, the precision check may thus be carried out remotely. For this procedure, report the set-point flow rate as the actual flow rate along with the flow rate measured or indicated by the analyzer flow meter.

3.5.1.1.3 For either procedure, the differences between the actual and indicated flow rates are used to assess the precision of the monitoring data as described in section 5.5 of this Appendix.

3.5.1.2 Manual methods for $PM_{2.5}$. Each calendar quarter, audit the flow rate of each SLAMS $PM_{2.5}$ analyzer. The audit is made by measuring the analyzer's normal operating flow rate, using a flow rate transfer standard certified in accordance with section 2.3.3 of this Appendix. The flow rate standard used for auditing must not be the same flow rate standard used to calibrate the analyzer. However, both the calibration standard and the audit standard may be referenced to the same primary flow rate or volume standard. Great care must be used in auditing the flow rate to be certain that the flow measurement device does not alter the normal operating flow rate of the analyzer. Report the audit (actual) flow rate and the corresponding flow rate indicated or assumed by the sampler. The procedures used to calculate measurement uncertainty $PM_{2.5}$ are described in section 5.5 of this Appendix.

3.5.2 Measurement of Precision using Collocated Procedures for Automated and Manual Methods of $PM_{2.5}$.

(a) For $PM_{2.5}$ sites within a reporting organization each EPA designated Federal reference method (FRM) or Federal equivalent method (FEM) must:

(1) Have 25 percent of the monitors collocated (values of .5 and greater round up).

(2) Have at least 1 collocated monitor (if the total number of monitors is less than 4). The first collocated monitor must be a designated FRM monitor.

(b) In addition, monitors selected must also meet the following requirements:

(1) A monitor designated as an EPA FRM shall be collocated with a monitor having the same EPA FRM designation.

(2) For each monitor designated as an EPA FEM, 50 percent of the designated monitors shall be collocated with a monitor having the same method designation and 50 percent of the monitors shall be collocated with an FRM monitor. If there are an odd number of collocated monitors required, the additional monitor shall be an FRM. An example of this procedure is found in Table A-2 of this Appendix.

(c) For $PM_{2.5}$ sites during the initial deployment of the SLAMS network, special emphasis should be placed on those sites in areas likely to be in violation of the NAAQS. Once areas are initially determined to be in violation, the collocated monitors should be deployed according to the following protocol:

(1) Eighty percent of the collocated monitors should be deployed at sites with concentrations ≥ ninety percent of the annual $PM_{2.5}$ NAAQS (or 24–hour NAAQS if that is affecting the area); one hundred percent if all sites have concentrations above either NAAQS, and each area determined to be in violation should be represented by at least one collocated monitor.

(2) The remaining 20 percent of the collocated monitors should be deployed at sites with concentrations < ninety percent of the annual $PM_{2.5}$ NAAQS (or 24–hour NAAQS if that is affecting the area)

(3) If an organization has no sites at concentration ranges ≥ ninety percent of the annual $PM_{2.5}$ NAAQS (or 24–hour NAAQS if that is affecting the area), 60 percent of the collocated monitors should be deployed at those sites with the annual mean $PM_{2.5}$ concentrations (or 24–hour NAAQS if that is affecting the area) among the highest 25 percent for all $PM_{2.5}$ sites in the network.

3.5.2.1 In determining the number of collocated sites required for $PM_{2.5}$, monitoring networks for visibility should not be treated independently from networks for particulate matter, as the separate networks may share one or more common samplers. However, for class I visibility areas, EPA will accept visibility aerosol mass measurement instead of a $PM_{2.5}$ measurement if the latter measurement is unavailable. Any $PM_{2.5}$ monitoring site which does not have a monitor which is an EPA federal reference or equivalent method is not required to be included in the number of sites which are used to determine the number of collocated monitors.

3.5.2.2 The two collocated samplers must be within 4 meters of each other, and particulate matter samplers must be at least 2 meters apart to preclude airflow interference. Calibration, sampling, and analysis must be the same for both collocated samplers and the same as for all other samplers in the network.

3.5.2.3 For each pair of collocated samplers, designate one sampler as the primary sampler whose samples will be used to report air quality for the site, and designate the other as the duplicate sampler. Each duplicate sampler must be operated concurrently with its associated primary sampler. The operation schedule should be selected so that the sampling days are distributed evenly over the year and over the 7 days of the week and therefore, a 6-day sampling schedule is required. Report the measurements from both samplers at each collocated sampling site. The calculations for evaluating precision between the two collocated samplers are described in section 5.5 of this Appendix.

3.5.3 Measurement of Bias using the FRM Audit Procedures for Automated and Manual Methods of $PM_{2.5}$.

3.5.3.1 The FRM audit is an independent assessment of the total measurement system bias. These audits will be performed under the National Performance Audit Program

(section 2.4 of this Appendix) or a comparable program. Twenty-five percent of the SLAMS monitors within each reporting organization will be assessed with an FRM audit each year. Additionally, every designated FRM or FEM within a reporting organization must:

(a) Have at least 25 percent of each method designation audited, including collocated sites (even those collocated with FRM instruments), (values of .5 and greater round up).

(b) Have at least one monitor audited.

(c) Be audited at a frequency of four audits per year.

(d) Have all FRM or FEM samples subject to an FRM audit at least once every 4 years. Table A-2 illustrates the procedure mentioned above.

3.5.3.2 For $PM_{2.5}$ sites during the initial deployment of the SLAMS network, special emphasis should be placed on those sites in areas likely to be in violation of the NAAQS. Once areas are initially determined to be in violation, the FRM audit program should be implemented according to the following protocol:

(a) Eighty percent of the FRM audits should be deployed at sites with concentrations ≥ ninety percent of the annual $PM_{2.5}$ NAAQS (or 24–hour NAAQS if that is affecting the area); one hundred percent if all sites have concentrations above either NAAQS, and each area determined to be in violation should implement an FRM audit at a minimum of one monitor within that area.

(b) The remaining 20 percent of the FRM audits should be implemented at sites with concentrations < ninety percent of the annual $PM_{2.5}$ NAAQS (or 24–hour NAAQS if that is affecting the area).

(c) If an organization has no sites at concentration ranges ≥ ninety percent of the annual $PM_{2.5}$ NAAQS (or 24–hour NAAQS if that is affecting the area), 60 percent of the FRM audits should be implemented at those sites with the annual mean $PM_{2.5}$ concentrations (or 24–hour NAAQS if that is affecting the area) among the highest 25 percent for all $PM_{2.5}$ sites in the network. Additional information concerning the FRM audit program is contained in Reference 7 of this Appendix. The calculations for evaluating bias between the primary monitor and the FRM audit are described in section 5.5.

4. *Reporting Requirements.*

(a) For each pollutant, prepare a list of all monitoring sites and their AIRS site identification codes in each reporting organization and submit the list to the appropriate EPA Regional Office, with a copy to AIRS-AQS. Whenever there is a change in this list of monitoring sites in a reporting organization, report this change to the Regional Office and to AIRS-AQS.

4.1 Quarterly Reports. For each quarter, each reporting organization shall report to AIRS-AQS directly (or via the appropriate EPA Regional Office for organizations not direct users of AIRS) the results of all valid precision, bias and accuracy tests it has carried out during the quarter. The quarterly reports of precision, bias and accuracy data must be submitted consistent with the data reporting requirements specified for air quality data as set forth in § 58.35(c). EPA strongly encourages early submittal of the QA data in order to assist the State and Local agencies in controlling and evaluating the quality of the ambient air SLAMS data. Each organization shall report all QA/QC measurements. Report results from invalid tests, from tests carried out during a time period for which ambient data immediately prior or subsequent to the tests were invalidated for appropriate reasons, and from tests of methods or analyzers not approved for use in SLAMS monitoring networks under Appendix C of this part. Such data should be flagged so that it will not be utilized for quantitative assessment of precision, bias and accuracy.

4.2 Annual Reports.

4.2.1 When precision, bias and accuracy estimates for a reporting organization have been calculated for all four quarters of the calendar year, EPA will calculate and report the measurement uncertainty for the entire calendar year. These limits will then be associated with the data submitted in the annual SLAMS report required by § 58.26.

4.2.2 Each reporting organization shall submit, along with its annual SLAMS report, a listing by pollutant of all monitoring sites in the reporting organization.

5. *Calculations for Data Quality Assessment.*

(a) Calculations of measurement uncertainty are carried out by EPA according to the following procedures. Reporting organizations should report the data for individual precision, bias and accuracy tests as specified in sections 3 and 4 of this Appendix even though they may elect to perform some or all of the calculations in this section on their own.

5.1 Precision of Automated Methods Excluding $PM_{2.5}$. Estimates of the precision of automated methods are calculated from the results of biweekly precision checks as specified in section 3.1 of this Appendix. At the end of each calendar quarter, an integrated precision probability interval for all SLAMS analyzers in the organization is calculated for each pollutant.

5.1.1 Single Analyzer Precision.

5.1.1.1 The percent difference (d_i) for each precision check is calculated using equation 1, where Y_i is the concentration indicated by the analyzer for the I-th precision check and X_i is the known concentration for the I-th precision check, as follows:

Equation 1

$$d_i = \frac{Y_i - X_i}{X_i} \times 100$$

5.1.1.2 For each analyzer, the quarterly average (d_j) is calculated with equation 2, and the standard deviation (S_j) with equation 3, where n is the number of precision checks on the instrument made during the calendar quarter. For example, n should be 6 or 7 if precision checks are made biweekly during a quarter. Equation 2 and 3 follow:

Equation 2

$$d_j = \frac{1}{n} \sum_{i=1}^{n} d_i$$

Equation 3

$$S_j = \sqrt{\frac{1}{n-1}\left[\sum_{i=1}^{n} d_i^2 - \frac{1}{n}\left(\sum_{i=1}^{n} d_i\right)^2\right]}$$

5.1.2 Precision for Reporting Organization.

5.1.2.1 For each pollutant, the average of averages (D) and the pooled standard deviation (S_a) are calculated for all analyzers audited for the pollutant during the quarter, using either equations 4 and 5 or 4a and 5a, where k is the number of analyzers audited within the reporting organization for a single pollutant, as follows:

Equation 4

$$D = \frac{1}{k} \sum_{j=1}^{k} d_j$$

Equation 4a

$$D = \frac{n_1 d_1 + n_2 d_2 + \ldots + n_j d_j + \ldots + n_k d_k}{n_1 + n_2 + \ldots + n_j + \ldots + n_k}$$

Equation 5

$$S_a = \sqrt{\frac{1}{k}\sum_{j=1}^{k} S_j^2}$$

Equation 5a

$$S_a = \sqrt{\frac{(n_1 - 1)S_1^2 + (n_2 - 1)S_2^2 + \ldots + (n_j - 1)S_j^2 + \ldots + (n_k - 1)S_k^2}{n_1 + n_2 + \ldots + n_j + \ldots + n_k - k}}$$

5.1.2.2 Equations 4 and 5 are used when the same number of precision checks are made for each analyzer. Equations 4a and 5a are used to obtain a weighted average and a weighted standard deviation when different numbers of precision checks are made for the analyzers.

5.1.2.3 For each pollutant, the 95 Percent Probability Limits for the precision of a reporting organization are calculated using equations 6 and 7, as follows:

Equation 6

$$\text{Upper 95 Percent Probability Limit} = D + 1.96\ S_a$$

Equation 7

$$\text{Lower 95 Percent Probability Limit} = D - 1.96\ S_a$$

5.2 Accuracy of Automated Methods Excluding $PM_{2.5}$. Estimates of the accuracy of automated methods are calculated from the results of independent audits as described in section 3.2 of this Appendix. At the end of each calendar quarter, an integrated accuracy probability interval for all SLAMS analyzers audited in the reporting organization is calculated for each pollutant. Separate probability limits are calculated for each audit concentration level in section 3.2 of this Appendix.

5.2.1 Single Analyzer Accuracy. The percentage difference (d_i) for each audit concentration is calculated using equation 1, where Y_i is the analyzer's indicated concentration measurement from the I-th audit check and X_i is the actual concentration of the audit gas used for the I-th audit check.

5.2.2 Accuracy for Reporting Organization.

5.2.2.1 For each audit concentration level of a particular pollutant, the average (D) of the individual percentage differences (d_i) for all n analyzers audited during the quarter is calculated using equation 8, as follows:

Equation 8

$$D = \frac{1}{n} \sum_{i=1}^{n} d_i$$

5.2.2.2 For each concentration level of a particular pollutant, the standard deviation (S_a) of all the individual percentage differences for all n analyzers audited during the quarter is calculated, using equation 9, as follows:

Equation 9

$$S_a = \sqrt{\frac{1}{n-1}\left[\sum_{i=1}^{n} d_i^2 - \frac{1}{n}\left(\sum_{i=1}^{n} d_i\right)^2\right]}$$

5.2.2.3 For reporting organizations having four or fewer analyzers for a particular pollutant, only one audit is required each quarter. For such reporting organizations, the audit results of two consecutive quarters are required to calculate an average and a standard deviation, using equations 8 and 9. Therefore, the reporting of probability limits shall be on a semiannual (instead of a quarterly) basis.

5.2.2.4 For each pollutant, the 95 Percent Probability Limits for the accuracy of a reporting organization are calculated at each audit concentration level using equations 6 and 7.

5.3 Precision of Manual Methods Excluding $PM_{2.5}$. Estimates of precision of manual methods are calculated from the results obtained from collocated samplers as described in section 3.3 of this Appendix. At the end of each calendar quarter, an integrated precision probability interval for all collocated samplers operating in the reporting organization is calculated for each manual method network.

5.3.1 Single Sampler Precision.

5.3.1.1 At low concentrations, agreement between the measurements of collocated samplers, expressed as percent differences, may be relatively poor. For this reason, collocated measurement pairs are selected for use in the precision calculations only when both measurements are above the following limits:

(a) TSP: 20 $\mu g/m^3$.
(b) SO_2: 45 $\mu g/m^3$.
(c) NO_2: 30 $\mu g/m^3$.
(d) Pb: 0.15 $\mu g/m^3$.
(e) PM_{10}: 20 $\mu g/m^3$.

5.3.1.2 For each selected measurement pair, the percent difference (d_i) is calculated, using equation 10, as follows:

Equation 10

$$d_i = \frac{Y_i - X_i}{(Y_i + X_i)/2} \times 100$$

where:
Y_i is the pollutant concentration measurement obtained from the duplicate sampler; and
X_i is the concentration measurement obtained from the primary sampler designated for reporting air quality for the site.

(a) For each site, the quarterly average percent difference (d_j) is calculated from equation 2 and the standard deviation (S_j) is calculated from equation 3, where n= the number of selected measurement pairs at the site.

5.3.2 Precision for Reporting Organization.

5.3.2.1 For each pollutant, the average percentage difference (D) and the pooled standard deviation (S_a) are calculated, using equations 4 and 5, or using equations 4a and 5a if different numbers of paired measurements are obtained at the collocated sites. For these calculations, the k of equations 4, 4a, 5 and 5a is the number of collocated sites.

5.3.2.2 The 95 Percent Probability Limits for the integrated precision for a reporting organization are calculated using equations 11 and 12, as follows:

Equation 11

$$\text{Upper 95 Percent Probability Limit} = D + 1.96\ S_a$$

Equation 12

$$\text{Lower 95 Percent Probability Limit} = D - 1.96\ S_a$$

5.4 Accuracy of Manual Methods Excluding $PM_{2.5}$. Estimates of the accuracy of manual methods are calculated from the results of independent audits as described in section 3.4 of this Appendix. At the end of each calendar quarter, an integrated accuracy probability interval is calculated for each manual method network operated by the reporting organization.

5.4.1 Particulate Matter Samplers other than $PM_{2.5}$ (including reference method Pb samplers).

5.4.1.1 Single Sampler Accuracy. For the flow rate audit described in section 3.4.1 of this Appendix, the percentage difference (d_i) for each audit is calculated using equation 1, where X_i represents the known flow rate and Y_i represents the flow rate indicated by the sampler.

5.4.1.2 Accuracy for Reporting Organization. For each type of particulate matter measured (e.g., TSP/Pb), the average (D) of the individual percent differences for all similar particulate matter samplers audited during the calendar quarter is calculated using equation 8. The standard deviation (S_a) of the percentage differences for all of the similar particulate matter samplers audited during the calendar quarter is calculated using equation 9. The 95 Percent Probability Limits for the integrated accuracy for the reporting organization are calculated using equations 6 and 7. For reporting organizations having four or fewer particulate matter samplers of one type, only one audit is required each quarter, and the audit results of two consecutive quarters are required to calculate an average and a standard deviation. In that case, probability limits shall be reported semi-annually rather than quarterly.

5.4.2 Analytical Methods for SO_2, NO_2, and Pb.

5.4.2.1 Single Analysis-Day Accuracy. For each of the audits of the analytical methods for SO_2, NO_2, and Pb described in sections 3.4.2, 3.4.3, and 3.4.4 of this Appendix, the percentage difference (d_j) at each concentration level is calculated using equation 1, where X_j represents the known value of the audit sample and Y_j represents the value of SO_2, NO_2, or Pb indicated by the analytical method.

5.4.2.2 Accuracy for Reporting Organization. For each analytical method, the average (D) of the individual percent differences at each concentration level for all audits during the calendar quarter is calculated using equation 8. The standard deviation (S_a) of the percentage differences at each concentration level for all audits during the calendar quarter is calculated using equation 9. The 95 Percent Probability Limits for the accuracy for the reporting organization are calculated using equations 6 and 7.

5.5 Precision, Accuracy and Bias for Automated and Manual $PM_{2.5}$ Methods.

(a) Reporting organizations are required to report the data that will allow assessments of the following individual quality control checks and audits:

(1) Flow rate audit.
(2) Collocated samplers, where the duplicate sampler is not an FRM device.
(3) Collocated samplers, where the duplicate sampler is an FRM device.
(4) FRM audits.

(b) EPA uses the reported results to derive precision, accuracy and bias estimates according to the following procedures.

5.5.1 Flow Rate Audits. The reporting organization shall report both the audit standard flow rate and the flow rate indicated by the sampling instrument. These results are

used by EPA to calculate flow rate accuracy and bias estimates.

5.5.1.1 Accuracy of a Single Sampler - Single Check (Quarterly) Basis (d_i). The percentage difference (d_i) for a single flow rate audit d_i is calculated using Equation 13, where X_i represents the audit standard flow rate (known) and Y_i represents the indicated flow rate, as follows:

Equation 13

$$d_i = \frac{Y_i - X_i}{X_i} \times 100$$

5.5.1.2 Bias of a Single Sampler - Annual Basis (D_j). For an individual particulate sampler j, the average (D_j) of the individual percentage differences (d_i) during the calendar year is calculated using Equation 14, where n_j is the number of individual percentage differences produced for sampler j during the calendar year, as follows:

Equation 14

$$D_j = \frac{1}{n_j} \times \sum_{i=1}^{n_j} d_i$$

5.5.1.3 Bias for Each EPA Federal Reference and Equivalent Method Designation Employed by Each Reporting Organization - Quarterly Basis ($D_{k,q}$). For method designation k used by the reporting organization, quarter q's single sampler percentage differences (d_i) are averaged using Equation 16, where $n_{k,q}$ is the number of individual percentage differences produced for method designation k in quarter q, as follows:

Equation 15

$$D_{k,q} = \frac{1}{n_{k,q}} \times \sum_{i=1}^{n_{k,q}} d_i$$

5.5.1.4 Bias for Each Reporting Organization - Quarterly Basis (D_q). For each reporting organization, quarter q's single sampler percentage differences (d_i) are averaged using Equation 16, to produce a single average for each reporting organization, where n_q is the total number of single sampler percentage differences for all federal reference or equivalent methods of samplers in quarter q, as follows:

Equation 16

$$D_q = \frac{1}{n_q} \times \sum_{i=1}^{n_q} d_i$$

5.5.1.5 Bias for Each EPA Federal Reference and Equivalent Method Designation Employed by Each Reporting Organization - Annual Basis (D_k). For method designation k used by the reporting organization, the annual average percentage difference, D_k, is derived using Equation 17, where $D_{k,q}$ is the average reported for method designation k during the qth quarter, and $n_{k,q}$ is the number of the method designation k's monitors that were deployed during the qth quarter, as follows:

Equation 17

$$D_k = \frac{\sum_{q=1}^{4} \left(n_{k,q} D_{k,q}\right)}{\sum_{q=1}^{4} n_{k,q}}$$

5.5.1.6 Bias for Each Reporting Organization - Annual Basis (D). For each reporting organization, the annual average percentage difference, D, is derived using Equation 18, where D_q is the average reported for the reporting organization during the qth quarter, and n_q is the total number monitors that were deployed during the qth quarter. A single annual average is produced for each reporting organization. Equation 18 follows:

Equation 18

$$D = \frac{\sum_{q=1}^{4} \left(n_q D_q\right)}{\sum_{q=1}^{4} n_q}$$

5.5.2 Collocated Samplers, Where the Duplicate Sampler is not an FRM Device. (a) At low concentrations, agreement between the measurements of collocated samplers may be relatively poor. For this reason, collocated measurement pairs are selected for use in the precision calculations only when both measurements are above the following limits:

$PM_{2.5}$: 6 $\mu g/m^3$

(b) Collocated sampler results are used to assess measurement system precision. A collocated sampler pair consists of a primary sampler (used for routine monitoring) and a duplicate sampler (used as a quality control check). Quarterly precision estimates are calculated by EPA for each pair of collocated samplers and for each method designation employed by each reporting organization. Annual precision estimates are calculated by EPA for each primary sampler, for each EPA Federal reference method and equivalent method designation employed by each reporting organization, and nationally for each EPA Federal reference method and equivalent method designation.

5.5.2.1 Percent Difference for a Single Check (d_i). The percentage difference, d_i, for each check is calculated by EPA using Equation 19, where X_i represents the concentration produced from the primary sampler and Y_i represents concentration reported for the duplicate sampler, as follows:

Equation 19

$$d_i = \frac{Y_i - X_i}{\left(Y_i + X_i\right)/2} \times 100$$

5.5.2.2 Coefficient of Variation (CV) for a Single Check (CV_i). The coefficient of variation, CV_i, for each check is calculated by EPA by dividing the absolute value of the percentage difference, d_i, by the square root of two as shown in Equation 20, as follows:

Equation 20

$$CV_i = \frac{|d_i|}{\sqrt{2}}$$

5.5.2.3 Precision of a Single Sampler - Quarterly Basis ($CV_{j,q}$).

(a) For particulate sampler j, the individual coefficients of variation ($CV_{j,q}$) during the quarter are pooled using Equation 21, where $n_{j,q}$ is the number of pairs of measurements from collocated samplers during the quarter, as follows:

Equation 21

$$CV_{j,q} = \sqrt{\frac{\sum_{i=1}^{n_j} CV_i^2}{n_{j,q}}}$$

(b) The 90 percent confidence limits for the single sampler's CV are calculated by EPA using Equations 22 and 23, where $X^2_{0.05,df}$ and $X^2_{0.95,df}$ are the 0.05 and 0.95 quantiles of the chi-square (X^2) distribution with $n_{j,q}$ degrees of freedom, as follows:

Equation 22

$$\text{Lower Confidence Limit} = CV_{j,q}\sqrt{\frac{n_{j,q}}{\chi^2_{0.95,\ n_{j,q}}}}$$

Equation 23

$$\text{Upper Confidence Limit} = CV_{j,q}\sqrt{\frac{n_{j,q}}{\chi^2_{0.05,\ n_{j,q}}}}$$

5.5.2.4 Precision of a Single Sampler - Annual Basis. For particulate sampler j, the individual coefficients of variation, CV_i, produced during the calendar year are pooled using Equation 21, where n_j is the number of checks made during the calendar year. The 90 percent confidence limits for the single sampler's CV are calculated by EPA using Equations 22 and 23, where $X^2_{0.05,df}$ and $X^2_{0.95,df}$ are the 0.05 and 0.95 quantiles of the chi-square (X^2) distribution with n_j degrees of freedom.

5.5.2.5 Precision for Each EPA Federal Reference Method and Equivalent Method Designation Employed by Each Reporting Organization - Quarterly Basis ($CV_{k,q}$).

(a) For each method designation k used by the reporting organization, the quarter's single sampler coefficients of variation, $CV_{j,q}$s, obtained from Equation 21, are pooled using Equation 24, where $n_{k,q}$ is the number of collocated primary monitors for the designated method (but not collocated with FRM samplers) and $n_{j,q}$ is the number of degrees of freedom associated with $CV_{j,q}$, as follows:

Equation 24

$$CV_{k,q} = \sqrt{\frac{\sum_{j=1}^{n_{k,q}} \left(CV_{j,q}^2 n_{j,q}\right)}{\sum_{j=1}^{n_{k,q}} n_{j,q}}}$$

(b) The number of method CVs produced for a reporting organization will equal the number of different method designations having more than one primary monitor employed by the organization during the quarter. (When exactly one monitor of a specified designation is used by a reporting organization, it will be collocated with an FRM sampler.)

5.5.2.6 Precision for Each Method Designation Employed by Each Reporting Organization- Annual Basis (CV_k). For each method designation k used by the reporting organization, the quarterly estimated coefficients of variation, $CV_{k,q}$, are pooled using Equation 25, where $n_{k,q}$ is the number of collocated primary monitors for the designated method during the qth quarter and also the number of degrees of freedom associated with the quarter's precision estimate for the method designation, $CV_{k,q}$, as follows:

Equation 25

$$CV_k = \sqrt{\frac{\sum_{q=1}^{4} \left(CV_{k,q}^2 n_{k,q}\right)}{\sum_{q=1}^{4} n_{k,q}}}$$

5.5.3 Collocated Samplers, Where the Duplicate Sampler is an FRM Device. At low concentrations, agreement between the measurements of collocated samplers may be relatively poor. For this reason, collocated measurement pairs are selected for use in the precision calculations only when both measurements are above the following limits: $PM_{2.5}$: 6 μg/m³. These duplicate sampler results are used to assess measurement system bias. Quarterly bias estimates are calculated by EPA for each primary sampler and for each method designation employed by each reporting organization. Annual precision estimates are calculated by EPA for each primary monitor, for each method designation employed by each reporting organization, and nationally for each method designation.

5.5.3.1 Accuracy for a Single Check (d'_i). The percentage difference, d'_i, for each check is calculated by EPA using Equation 26, where X_i represents the concentration produced from the FRM sampler taken as the true value and Y_i represents concentration reported for the primary sampler, as follows:

Equation 26

$$d'_i = \frac{Y_i - X_i}{X_i} \times 100\%$$

5.5.3.2 Bias of a Single Sampler - Quarterly Basis ($D'_{j,q}$).

(a) For particulate sampler j, the average of the individual percentage differences during the quarter q is calculated by EPA using Equation 27, where $n_{j,q}$ is the number of checks made for sampler j during the calendar quarter, as follows:

Equation 27

$$D'_{j,q} = \frac{1}{n_{j,q}} \times \sum_{i=1}^{n_{j,q}} d'_i$$

(b) The standard deviation, $s'_{j,q}$, of sampler j's percentage differences for quarter q is calculated using Equation 28, as follows:

Equation 28

$$s'_{j,q} = \sqrt{\frac{1}{n_{j,q}-1} \times \left[\left(\sum_{i=1}^{n_{j,q}} d_i'^2\right) - \left(n_{j,q} D_{j,q}'^2\right)\right]}$$

(c) The 95 Percent Confidence Limits for the single sampler's bias are calculated using Equations 29 and 30 where $t_{0.975,df}$ is the 0.975 quantile of Student's t distribution with df = $n_{j,q}$-1 degrees of freedom, as follows:

Equation 29

$$\text{Lower Confidence Limit} = D'_{j,q} - t_{0.975,df} \times s'_{j,q}$$

Equation 30

$$\text{Upper Confidence Limit} = D'_{j,q} - t_{0.975,df} \times s'_{j,q}$$

5.5.3.3 Bias of a Single Sampler - Annual Basis (D'_j).

(a) For particulate sampler j, the mean bias for the year is derived from the quarterly bias estimates, $D'_{j,q}$, using Equation 31, where the variables are as defined for Equations 27 and 28, as follows:

Equation 31

$$D'_j = \frac{\sum_{q=1}^{4} \left(n_{j,q} D'_{j,q}\right)}{\sum_{q=1}^{4} n_{j,q}}$$

(b) The standard error of the above estimate, se_j' is calculated using Equation 32, as follows:

Equation 32

$$se'_j = \sqrt{\frac{\sum_{q=1}^{4} \left[s'_{j,q}\ 2 \times \left(n_{j,q} - 1\right)\right]}{\sum_{q=1}^{4} \left(n_{j,q} - 1\right) \sum_{q=1}^{4} \left(n_{j,q}\right)}}$$

(c) The 95 Percent Confidence Limits for the single sampler's bias are calculated using Equations 33 and 34, where $t_{0.975,df}$ is the 0.975 quantile of Student's t distribution with df=($n_{j,1}$+$n_{j,2}$+$n_{j,3}$+$n_{j,4}$-4) degrees of freedom, as follows:

Equation 33

$$\text{Lower Confidence Limit} = D'_j - t_{0.975,df} \times se'_j$$

Equation 34

$$\text{Upper Confidence Limit} = D'_j - t_{0.975,df} \times se'_j$$

5.5.3.4 Bias for a Single Reporting Organization (D') - Annual Basis. The reporting organizations mean bias is calculated using Equation 35, where variables are as defined in Equations 31 and 32, as follows:

Equation 35

$$D' = \frac{1}{n_j} \times \sum_{i=1}^{n_j} D'_j$$

5.5.4 FRM Audits. FRM Audits are performed once per quarter for selected samplers. The reporting organization reports concentration data from the primary sampler. Calculations for FRM Audits are similar to those for collocated samplers having FRM samplers as duplicates. The calculations differ because only one check is performed per quarter.

5.5.4.1 Accuracy for a Single Sampler, Quarterly Basis (d_i). The percentage difference, d_i, for each check is calculated using Equation 26, where X_i represents the concentration produced from the FRM sampler and Y_i represents the concentration reported for the primary sampler. For quarter q, the bias estimate for sampler j is denoted $D_{j,q}$.

5.5.4.2 Bias of a Single Sampler - Annual Basis (D'_j). For particulate sampler j, the mean bias for the year is derived from the quarterly bias estimates, $D_{j,q}$, using Equation 31, where $n_{j,q}$ equals 1 because one FRM audit is performed per quarter.

5.5.4.3. Bias for a Single Reporting Organization - Annual Basis (D'). The reporting organizations mean bias is calculated using Equation 35, where variables are as defined in Equations 31 and 32.

References in Appendix A of Part 58

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Systems for Environmental Data Collection and Environmental Technology Programs. ANSI/ASQC E4-1994. January 1995. Available from American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, WI 53202.

(3) EPA Requirements for Quality Management Plans. EPA QA/R-2. August 1994. Available from U.S. Environmental Protection Agency, ORD Publications Office, Center for Environmental Research Information (CERI), 26 W. Martin Luther King Drive, Cincinnati, OH 45268.

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Tables to Appendix A of Part 58

TABLE A–1.—MINIMUM DATA ASSESSMENT REQUIREMENTS

Method	Assessment Method	Coverage	Minimum Frequency	Parameters Reported
Precision:				
Automated Methods for SO_2, NO_2, O_3, and CO	Response check at concentration between .08 and .10 ppm (8 & 10 ppm for CO)[2]	Each analyzer	Once per 2 weeks	Actual concentration[2] and measured concentration[3]
Manual Methods: All methods except $PM_{2.5}$	Collocated samplers	1 site for 1–5 sites 2 sites for 6–20 sites 3 sites >20 sites (sites with highest conc.)	Once every six days	Particle mass concentration indicated by sampler and by collocated sampler
Accuracy:				
Automated Methods for SO_2, NO_2, O_3, and CO	Response check at .03–.08 ppm[1,2] .15–.20 ppm[1,2] .35–.45 ppm[1,2] 80–.90 ppm[1,2] (if applicable)	1. Each analyzer 2. 25% of analyzers (at least 1)	1. Once per year 2. Each calendar quarter	Actual concentration[2] and measured (indicated) concentration[3] for each level
Manual Methods for SO_2, and NO_2	Check of analytical procedure with audit standard solutions	Analytical system	Each day samples are analyzed, at least twice per quarter	Actual concentration and measured (indicated) concentration for each audit solution
TSP, PM_{10}	Check of sampler flow rate	1. Each sampler 2. 25% of samplers (at least 1)	1. Once per year 2. Each calendar quarter	Actual flow rate and flow rate indicated by the sampler
Lead	1. Check of sample flow rate as for TSP 2. Check of analytical system with Pb audit strips	1. Each sampler 2. Analytical system	1. Include with TSP 2. Each quarter	1. Same as for TSP 2. Actual concentration and measured (indicated) concentration of audit samples (µg Pb/strip)
$PM_{2.5}$				

TABLE A–1.—MINIMUM DATA ASSESSMENT REQUIREMENTS—Continued

Method	Assessment Method	Coverage	Minimum Frequency	Parameters Reported
Manual and Automated Methods-Precision.	Collocated samplers	25% of SLAMS (monitors with Conc affecting NAAQS violation status)	Once every six days	1. Particle mass concentration indicated by sampler and by collocated sampler 2. 24-hour value for automated methods
Manual and Automated Methods-Accuracy and Bias	1. Check of sampler flow rate 2. Audit with reference method	25% of SLAMS (monitors with Conc affecting NAAQS violation status)	1. Minimum of every calendar quarter, 4 checks per year 2. Minimum 4 measurements per year	1. Actual flow rate and flow rate indicated by sampler 2. Particle mass concentration indicated by sampler and by audit reference sampler

[1] Concentration times 100 for CO.
[2] Effective concentration for open path analyzers.
[3] Corrected concentration, if applicable, for open path analyzers.

TABLE A-2.—SUMMARY OF $PM_{2.5}$ COLLOCATION AND AUDITS PROCEDURES AS AN EXAMPLE OF A TYPICAL REPORTING ORGANIZATION NEEDING 43 MONITORS, HAVING PROCURED FRMS AND THREE OTHER EQUIVALENT METHOD TYPES

Method Designation	Total # of Monitors	Total # Collocated	# of Collocated FRMs	# of Collocated Monitors of Same Type	# of Independent FRM Audits
FRM	25	6	6	n/a	6
Type A	10	3	2	1	3
Type C	2	1	1	0	1
Type D	6	2	1	1	2

m. Appendix C is amended by revising section 2.2 and adding sections 2.2.1 and 2.2.2, adding sections 2.4 through 2.5, revising section 2.7.1, and adding section 2.9 and references 4 through 6 to section 6.0 to read as follows:

Appendix C—Ambient Air Quality Monitoring Methodology

* * * * *

2.2 *Substitute* PM_{10} samplers.

2.2.1 For purposes of showing compliance with the NAAQS for particulate matter, a high volume TSP sampler described in 40 CFR part 50, Appendix B, may be used in a SLAMS in lieu of a PM_{10} monitor as long as the ambient concentrations of particles measured by the TSP sampler are below the PM_{10} NAAQS. If the TSP sampler measures a single value that is higher than the PM_{10} 24–hour standard, or if the annual average of its measurements is greater than the PM_{10} annual standard, the TSP sampler operating as a substitute PM_{10} sampler must be replaced with a PM_{10} monitor. For a TSP measurement above the 24–hour standard, the TSP sampler should be replaced with a PM_{10} monitor before the end of the calendar quarter following the quarter in which the high concentration occurred. For a TSP annual average above the annual standard, the PM_{10} monitor should be operating by June 30 of the year following the exceedance.

2.2.2 In order to maintain historical continuity of ambient particulate matter trends and patterns for PM_{10} NAMS that were previously TSP NAMS, the TSP high volume sampler must be operated concurrently with the PM_{10} monitor for a one-year period beginning with the PM_{10} NAMS start-up date. The operating schedule for the TSP sampler must be at least once every 6 days regardless of the PM_{10} sampling frequency.

* * * * *

2.4 Approval of non-designated $PM_{2.5}$ methods operated at specific individual sites. A method for $PM_{2.5}$ that has not been designated as a reference or equivalent method as defined in § 50.1 of this chapter may be approved for use for purposes of section 2.1 of this Appendix at a particular SLAMS under the following stipulations.

2.4.1 The method must be demonstrated to meet the comparability requirements (except as provided in this section 2.4.1) set forth in § 53.34 of this chapter in each of the four seasons at the site at which it is intended to be used. For purposes of this section 2.4.1, the requirements of § 53.34 of this chapter shall apply except as follows:

2.4.1.1 The method shall be tested at the site at which it is intended to be used, and there shall be no requirement for tests at any other test site.

2.4.1.2 For purposes of this section 2.4, the seasons shall be defined as follows: Spring shall be the months of March, April, and May; summer shall be the months of June, July, and August; fall shall be the months of September, October, and November; and winter shall be the months of December, January, and February; when alternate seasons are approved by the Administrator.

2.4.1.3 No PM_{10} samplers shall be required for the test, as determination of the $PM_{2.5}/PM_{10}$ ratio at the test site shall not be required.

2.4.1.4 The specifications given in Table C-4 of part 53 of this chapter for Class I methods shall apply, except that there shall be no requirement for any minimum number of sample sets with Rj greater than 40 $\mu g/m^3$ for 24–hour samples or greater than 15 $\mu g/m_3$ average concentration collected over a 48-hour period.

2.4.2 The monitoring agency wishing to use the method must develop and implement appropriate quality assurance procedures for the method.

2.4.3 The monitoring agency wishing to use the method must develop and implement appropriate procedures for assessing and reporting the precision and accuracy of the method comparable to the procedures set forth in Appendix A of this part for designated reference and equivalent methods.

2.4.4 The assessment of network operating precision using collocated measurements with reference method ''audit'' samplers required under section 3 of Appendix A of this part shall be carried out semi-annually rather than annually (i.e., monthly audits with assessment determinations each 6 months).

2.4.5 Requests for approval under this section 2.4 must meet the general submittal requirements of sections 2.7.1 and 2.7.2.1 of this Appendix and must include the requirements in sections 2.4.5.1 through 2.4.5.7 of this Appendix.

2.4.5.1 A clear and unique description of the site at which the method or sampler will be used and tested, and a description of the nature or character of the site and the particulate matter that is expected to occur there.

2.4.5.2 A detailed description of the method and the nature of the sampler or analyzer upon which it is based.

2.4.5.3 A brief statement of the reason or rationale for requesting the approval.

2.4.5.4 A detailed description of the quality assurance procedures that have been developed and that will be implemented for the method.

2.4.5.5 A detailed description of the procedures for assessing the precision and accuracy of the method that will be implemented for reporting to AIRS.

2.4.5.6 Test results from the comparability tests as required in section 2.4.1 through 2.4.1.4 of this Appendix.

2.4.5.7 Such further supplemental information as may be necessary or helpful to support the required statements and test results.

2.4.6 Within 120 days after receiving a request for approval of the use of a method at a particular site under this section 2.4 and such further information as may be requested for purposes of the decision, the Administrator will approve or disapprove the method by letter to the person or agency requesting such approval.

2.5 Approval of non-designated methods under § 58.13(f). An automated (continuous) method for $PM_{2.5}$ that is not designated as either a reference or equivalent method as defined in § 50.1 of this chapter may be approved under § 58.13(f) for use at a SLAMS for the limited purposes of § 58.13(f). Such an analyzer that is approved for use at a SLAMS under § 58.13(f), identified as correlated acceptable continuous (CAC) monitors, shall not be considered a reference or equivalent method as defined in § 50.1 of this chapter by virtue of its approval for use under § 58.13(f), and the $PM_{2.5}$ monitoring data obtained from such a monitor shall not be otherwise used for purposes of part 50 of this chapter.

* * * * *

2.7.1 Requests for approval under sections 2.4, 2.6.2, or 2.8 of this Appendix must be submitted to: Director, National Exposure Assessment Laboratory, Department E, (MD-77B), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

* * * * *

2.9 Use of IMPROVE Samplers at a SLAMS. ''IMPROVE'' samplers may be used in SLAMS for monitoring of regional background and regional transport concentrations of fine particulate matter. The IMPROVE samplers were developed for use in the Interagency Monitoring of Protected Visual Environments (IMPROVE) network to characterize all of the major components and many trace constituents of the particulate matter that impair visibility in Federal Class I Areas. These samplers are routinely operated at about 70 locations in the United States. IMPROVE samplers consist of four sampling modules that are used to collect twice weekly 24–hour duration simultaneous samples. Modules A, B, and C collect $PM_{2.5}$ on three different filter substrates that are compatible with a variety of analytical techniques, and module D collects a PM_{10} sample. $PM_{2.5}$ mass and elemental concentrations are determined by analysis of the 25mm diameter stretched Teflon filters from module A. More complete descriptions of the IMPROVE samplers and the data they collect are available elsewhere (References 4, 5, and 6 of this Appendix).

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6.0 *References.*

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n. Appendix D is amended by revising in the table of contents the entries for 2.8, 3.7, 4., and 5. and adding an entry for 6., by revising the first three paragraphs and Table 1 of section 1., revising the second paragraph in section 2. and adding a new paragraph to the end of the section before section 2.1, revising section 2.8 and adding sections 2.8.0.1 through 2.8.2.3, revising the third and fifth paragraphs in section 3., revising section 3.7 and adding sections 3.7.1 through 3.7.7.4, revising the sixth paragraph in section 4.2 and redesignating Figures 1 and 2 as Figures 5 and 6 respectively, and revising the redesignated figures, revising footnote 3 of Table 2 of section 4.4, revising section 5. and reference 18 in section 6. to read as follows:

Appendix D—Network Design for State and Local Air Monitoring Stations (SLAMS), National Air Monitoring Stations (NAMS), and Photochemical Assessment Monitoring Stations (PAMS)

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2.8 Particulate Matter Design Criteria for SLAMS

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3.7 Particulate Matter Design Criteria for NAMS

4. Network Design for Photochemical Assessment Monitoring Stations (PAMS)

5. Summary

6. References

1. *SLAMS Monitoring Objectives and Spatial Scales.*

The purpose of this Appendix is to describe monitoring objectives and general criteria to be applied in establishing the State and Local Air Monitoring Stations (SLAMS) networks and for choosing general locations for new monitoring stations. It also describes criteria for determining the number and location of National Air Monitoring Stations (NAMS), Photochemical Assessment Monitoring Stations (PAMS), and core Stations for $PM_{2.5}$. These criteria will also be used by EPA in evaluating the adequacy of the SLAMS/NAMS/PAMS and core $PM_{2.5}$ networks.

The network of stations that comprise SLAMS should be designed to meet a minimum of six basic monitoring objectives. These basic monitoring objectives are:

(1) To determine highest concentrations expected to occur in the area covered by the network.

(2) To determine representative concentrations in areas of high population density.

(3) To determine the impact on ambient pollution levels of significant sources or source categories.

(4) To determine general background concentration levels.

(5) To determine the extent of Regional pollutant transport among populated areas; and in support of secondary standards.

(6) To determine the welfare-related impacts in more rural and remote areas (such as visibility impairment and effects on vegetation).

It should be noted that this Appendix contains no criteria for determining the total number of stations in SLAMS networks, except that a minimum number of lead SLAMS and $PM_{2.5}$ are prescribed and the minimal network introduced in § 58.20 is explained. The optimum size of a particular SLAMS network involves trade offs among data needs and available resources that EPA believes can best be resolved during the network design process.

* * * * *

TABLE 1.—RELATIONSHIP AMONG MONITORING OBJECTIVES AND SCALE OF REPRESENTATIVENESS

Monitoring Objective	Appropriate Siting Scales
Highest concentration	Micro, Middle, neighborhood (sometimes urban[1])
Population	Neighborhood, urban
Source impact	Micro, middle, neighborhood
General/background	Neighborhood, urban, regional
Regional transport	Urban/regional
Welfare-related impacts.	Urban/regional

[1] Urban denotes a geographic scale applicable to both cities and rural areas

* * * * *

2. *SLAMS Network Design Procedures.*

* * * * *

The discussion of scales in sections 2.3 through 2.8 of this Appendix does not include all of the possible scales for each pollutant. The scales that are discussed are those that are felt to be most pertinent for SLAMS network design.

* * * * *

Information such as emissions density, housing density, climatological data, geographic information, traffic counts, and the results of modeling will be useful in designing regulatory networks. Air pollution control agencies have shown the value of

screening studies, such as intensive studies conducted with portable samplers, in designing networks. In many cases, in selecting sites for core $PM_{2.5}$ or carbon monoxide SLAMS, and for defining the boundaries of $PM_{2.5}$ optional community monitoring zones, air pollution control agencies will benefit from using such studies to evaluate the spatial distribution of pollutants.

* * * * *

2.8 *Particulate Matter Design Criteria for SLAMS.*

As with other pollutants measured in the SLAMS network, the first step in designing the particulate matter network is to collect the necessary background information. Various studies in References 11, 12, 13, 14, 15, and 16 of section 6 of this Appendix have documented the major source categories of particulate matter and their contribution to ambient levels in various locations throughout the country.

2.8.0.1 Sources of background information would be regional and traffic maps, and aerial photographs showing topography, settlements, major industries and highways. These maps and photographs would be used to identify areas of the type that are of concern to the particular monitoring objective. After potentially suitable monitoring areas for particulate matter have been identified on a map, modeling may be used to provide an estimate of particulate matter concentrations throughout the area of interest. After completing the first step, existing particulate matter stations should be evaluated to determine their potential as candidates for SLAMS designation. Stations meeting one or more of the six basic monitoring objectives described in section 1 of this Appendix must be classified into one of the five scales of representativeness (micro, middle, neighborhood, urban and regional) if the stations are to become SLAMS. In siting and classifying particulate matter stations, the procedures in references 17 and 18 of section 6 of this Appendix should be used.

2.8.0.2 The most important spatial scales to effectively characterize the emissions of particulate matter from both mobile and stationary sources are the middle scales for PM_{10} and neighborhood scales for both PM_{10} and $PM_{2.5}$. For purposes of establishing monitoring stations to represent large homogenous areas other than the above scales of representativeness and to characterize regional transport, urban or regional scale stations would also be needed. Most $PM_{2.5}$ monitoring in urban areas should be representative of a neighborhood scale.

2.8.0.3 Microscale—This scale would typify areas such as downtown street canyons and traffic corridors where the general public would be exposed to maximum concentrations from mobile sources. In some circumstances, the microscale is appropriate for particulate stations; core SLAMS on the microscale should, however, be limited to urban sites that are representative of long-term human exposure and of many such microenvironments in the area. In general, microscale particulate matter sites should be located near inhabited buildings or locations where the general public can be expected to be exposed to the concentration measured. Emissions from stationary sources such as primary and secondary smelters, power plants, and other large industrial processes may, under certain plume conditions, likewise result in high ground level concentrations at the microscale. In the latter case, the microscale would represent an area impacted by the plume with dimensions extending up to approximately 100 meters. Data collected at microscale stations provide information for evaluating and developing hot spot control measures. Unless these sites are indicative of population-oriented monitoring, they may be more appropriately classified as SPMs.

2.8.0.4 Middle Scale—Much of the measurement of short-term public exposure to coarse fraction particles (PM_{10}) is on this scale and on the neighborhood scale; for fine particulate, much of the measurement is on the neighborhood scale. People moving through downtown areas, or living near major roadways, encounter particles that would be adequately characterized by measurements of this spatial scale. Thus, measurements of this type would be appropriate for the evaluation of possible short-term exposure public health effects of particulate matter pollution. In many situations, monitoring sites that are representative of micro-scale or middle-scale impacts are not unique and are representative of many similar situations. This can occur along traffic corridors or other locations in a residential district. In this case, one location is representative of a neighborhood of small scale sites and is appropriate for evaluation of long-term or chronic effects. This scale also includes the characteristic concentrations for other areas with dimensions of a few hundred meters such as the parking lot and feeder streets associated with shopping centers, stadia, and office buildings. In the case of PM_{10}, unpaved or seldom swept parking lots associated with these sources could be an important source in addition to the vehicular emissions themselves.

2.8.0.5 Neighborhood Scale—Measurements in this category would represent conditions throughout some reasonably homogeneous urban subregion with dimensions of a few kilometers and of generally more regular shape than the middle scale. Homogeneity refers to the particulate matter concentrations, as well as the land use and land surface characteristics. Much of the $PM_{2.5}$ exposures are expected to be associated with this scale of measurement. In some cases, a location carefully chosen to provide neighborhood scale data would represent not only the immediate neighborhood but also neighborhoods of the same type in other parts of the city. Stations of this kind provide good information about trends and compliance with standards because they often represent conditions in areas where people commonly live and work for periods comparable to those specified in the NAAQS. In general, most $PM_{2.5}$ monitoring in urban areas should have this scale. A $PM_{2.5}$ monitoring location is assumed to be representative of a neighborhood scale unless the monitor is adjacent to a recognized $PM_{2.5}$ emissions source or is otherwise demonstrated to be representative of a smaller spatial scale by an intensive monitoring study. This category also may include industrial and commercial neighborhoods especially in districts of diverse land use where residences are interspersed.

2.8.0.6 Neighborhood scale data could provide valuable information for developing, testing, and revising models that describe the larger-scale concentration patterns, especially those models relying on spatially smoothed emission fields for inputs. The neighborhood scale measurements could also be used for neighborhood comparisons within or between cities. This is the most likely scale of measurements to meet the needs of planners.

2.8.0.7 Urban Scale—This class of measurement would be made to characterize the particulate matter concentration over an entire metropolitan or rural area ranging in size from 4 to 50 km. Such measurements would be useful for assessing trends in area-wide air quality, and hence, the effectiveness of large scale air pollution control strategies. Core $PM_{2.5}$ SLAMS may have this scale.

2.8.0.8 Regional Scale—These measurements would characterize conditions over areas with dimensions of as much as hundreds of kilometers. As noted earlier, using representative conditions for an area implies some degree of homogeneity in that area. For this reason, regional scale measurements would be most applicable to sparsely populated areas with reasonably uniform ground cover. Data characteristics of this scale would provide information about larger scale processes of particulate matter emissions, losses and transport. Especially in the case of $PM_{2.5}$, transport contributes to particulate concentrations and may affect multiple urban and State entities with large populations such as in the Eastern United States. Development of effective pollution control strategies requires an understanding at regional geographical scales of the emission sources and atmospheric processes that are responsible for elevated $PM_{2.5}$ levels and may also be associated with elevated ozone and regional haze.

2.8.1 *Specific Design Criteria for $PM_{2.5}$.*

2.8.1.1 Monitoring Planning Areas.

Monitoring planning areas (MPAs) shall be used to conform to the community-oriented monitoring approach used for the $PM_{2.5}$ NAAQS given in part 50 of this chapter. MPAs are required to correspond to all metropolitan statistical areas (MSAs) with population greater than 200,000, and all other areas determined to be in violation of the $PM_{2.5}$ NAAQS.[1] MPAs for other designated parts of the State are optional. All MPAs shall be defined on the basis of existing, delineated mapping data such as State boundaries, county boundaries, zip codes, census blocks, or census block groups.

2.8.1.2 $PM_{2.5}$ Monitoring Sites within the State's PM Monitoring Network Description.

2.8.1.2.1 The minimum required number, type of monitoring sites, and sampling

[1]The boundaries of MPAs do not have to necessarily correspond to those of MSAs and existing intra or interstate air pollution planning districts may be utilized.

requirements for $PM_{2.5}$ are based on monitoring planning areas described in the PM monitoring network description and proposed by the State in accordance with § 58.20.

2.8.1.2.2 Comparisons to the $PM_{2.5}$ NAAQS may be based on data from SPMs in addition to SLAMS (including NAMS, core SLAMS and collocated $PM_{2.5}$ sites at PAMS), that meet the requirements of § 58.13 and Appendices A, C and E of this part, that are included in the PM monitoring network description. For comparison to the annual NAAQS, the monitors should be neighborhood scale community-oriented locations. Special purpose monitors that meet part 58 requirements will be exempt from NAAQS comparisons with the $PM_{2.5}$ NAAQS for the first 2 calendar years of their operation to encourage $PM_{2.5}$ monitoring initially. After this time, however, any SPM that records a violation of the $PM_{2.5}$ NAAQS must be seriously considered as a potential SLAMS site during the annual SLAMS network review in accordance with § 58.25. If such SPMs are not established as a SLAMS, the agency must document in its annual report the technical basis for excluding it as a SLAMS.

2.8.1.2.3 The health-effects data base that served as the basis for selecting the new $PM_{2.5}$ standards relied on a spatial average approach that reflects average community-oriented area-wide PM exposure levels. Under this approach, the most effective way to reduce total population risk is by lowering the annual distributions of ambient 24–hour $PM_{2.5}$ concentrations, as opposed to controlling peak 24–hour concentrations on individual days. The annual standard selected by EPA will generally be the controlling standard for lowering both short- and long-term $PM_{2.5}$ concentrations on an area-wide basis and will achieve this result. In order to be consistent with this rationale, therefore, $PM_{2.5}$ data collected from SLAMS and special purpose monitors that are representative, not of area-wide but rather, of relatively unique population-oriented microscale, or localized hot spot, or unique population-oriented middle-scale impact sites are only eligible for comparison only to the 24–hour $PM_{2.5}$ NAAQS. However, in instances where certain population-oriented micro- or middle-scale $PM_{2.5}$ monitoring sites are determined by the EPA Regional Administrator to collectively identify a larger region of localized high ambient $PM_{2.5}$ concentrations, data from these population-oriented sites would be eligible for comparison to the annual NAAQS.

2.8.1.2.4 Within each MPA, the responsible air pollution control agency shall install core SLAMS, other required SLAMS and as many $PM_{2.5}$ stations judged necessary to satisfy the SLAMS requirements and monitoring objectives of this Appendix.

2.8.1.3 Core Monitoring Stations for $PM_{2.5}$.

Core monitoring stations or sites are a subset of the SLAMS network for $PM_{2.5}$ that are sited to represent community-wide air quality. These core sites include sites to be collocated at PAMS.

2.8.1.3.1 Within each monitoring planning area, the responsible air pollution control agency shall install the following core $PM_{2.5}$ SLAMS:

(a) At least two core $PM_{2.5}$ SLAMS per MSA with population greater than 500,000 sampling everyday, unless exempted by the Regional Administrator, including at least one station in a population-oriented area of expected maximum concentration and at least one station in an area of poor air quality and at least one additional core monitor collocated at a PAMS site if the MPA is also a PAMS area[2].

(b) At least one core $PM_{2.5}$ SLAMS per MSA with population greater than 200,000 and less than or equal to 500,000 sampling every third day.

(c) Additional core $PM_{2.5}$ SLAMS per MSA with population greater than 1 million, sampling every third day, as specified in the following table:

TABLE 1.—REQUIRED NUMBER OF CORE SLAMS ACCORDING TO MSA POPULATION

MSA Population	Minimum Required No. of Core Sites[1]
>1 M	3
>2 M	4
>4 M	6
>6 M	8
>8 M	10

[1]Core SLAMS at PAMS are in addition to these numbers.

2.8.1.3.2 The site situated in the area of expected maximum concentration is analogous to NAMS ''category a.'' [3] This will henceforth be termed a category a core SLAMS site. The site located in the area of poor air quality with high population density or representative of maximum population impact is analogous to NAMS, ''category b.'' This second site will be called a category b core SLAMS site.

2.8.1.3.3 Those MPAs that are substantially impacted by several different and geographically disjoint local sources of fine particulate should have separate core sites to monitor each influencing source region.

2.8.1.3.4 Within each monitoring planning area, one or more required core SLAMS may be exempted by the Regional Administrator. This may be appropriate in areas where the highest concentration is expected to occur at the same location as the area of maximum or sensitive population impact, or areas with low concentrations (e.g., highest concentrations are less than 80 percent of the NAAQS). When only one core monitor for $PM_{2.5}$ is included in a MPA or optional CMZ, however, a ''category a'' core site is strongly preferred to determine community-oriented $PM_{2.5}$ concentrations in areas of high average $PM_{2.5}$ concentration.

2.8.1.3.5 More than the minimum number of core SLAMS should be deployed as necessary in all MPAs. Except for the core SLAMS described in section 2.8.1.3.1 of this Appendix, the additional core SLAMS must only comply with the minimum sampling frequency for SLAMS specified in § 58.13(e).

2.8.1.3.6 A subset of the core $PM_{2.5}$ SLAMS shall be designated NAMS as discussed in section 3.7 of this Appendix. The selection of core monitoring sites in relation to MPAs and CMZs is discussed further in section 2.8.3 of this Appendix.

2.8.1.3.7 Core monitoring sites shall represent neighborhood or larger spatial scales. A monitor that is established in the ambient air that is in or near a populated area, and meets appropriate 40 CFR part 58 criteria (i.e., meets the requirements of § 58.13 and § 58.14, Appendices A, C, and E of this part) can be presumed to be representative of at least a neighborhood scale, is eligible to be called a core site and shall produce data that are eligible for comparison to both the 24–hour and annual $PM_{2.5}$ NAAQS. If the site is adjacent to a dominating local source or can be shown to have average 24–hour concentrations representative of a smaller spatial scale, then the site would only be compared to the 24–hour $PM_{2.5}$ NAAQS.

2.8.1.3.8 Continuous fine particulate monitoring at core SLAMS. At least one continuous fine particulate analyzer (e.g., beta attenuation analyzer; tapered-element, oscillating microbalance (TEOM); transmissometer; nephelometer; or other acceptable continuous fine particulate monitor) shall be located at a core monitoring $PM_{2.5}$ site in each metropolitan area with a population greater than 1 million. These analyzers shall be used to provide improved temporal resolution to better understand the processes and causes of elevated $PM_{2.5}$ concentrations and to facilitate public reporting of $PM_{2.5}$ air quality and will be in accordance with appropriate methodologies and QA/QC procedures approved by the Regional Administrator.

2.8.1.4 Other $PM_{2.5}$ SLAMS Locations.

In addition to the required core sites described in section 2.8.1.3 of this Appendix, the State shall also install and operate on an every third day sampling schedule at least one SLAMS to monitor for regional background and at least one SLAMS to monitor regional transport. These monitoring stations may be at a community-oriented site and their requirement may be satisfied by a corresponding SLAMS monitor in an area having similar air quality in another State. The State shall also be required to establish additional SLAMS sites based on the total population outside the MSA(s) associated with monitoring planning areas that contain required core SLAMS. There shall be one such additional SLAMS for each 200,000 people. The minimum number of SLAMS may be deployed anywhere in the State to satisfy the SLAMS monitoring objectives including monitoring of small scale impacts which may not be community-oriented or for regional transport as described in section 1

[2]The core monitor to be collocated at a PAMS site shall not be considered a part of the PAMS as described in section 4 of this Appendix, but shall instead be considered to be a component of the particular MPA $PM_{2.5}$ network.

[3]The measured maximum concentrations at core population-oriented sites should be consistent with the averaging time of the NAAQS. Therefore, sites only with high concentrations for shorter averaging times (say 1-hour) should not be category ''a'' core SLAMS monitors.

of this Appendix. Other SLAMS may also be established and are encouraged in a State $PM_{2.5}$ network.

2.8.1.5 Additional $PM_{2.5}$ Analysis Requirements.

(a) Within 1 year after September 16, 1997, chemical speciation will be required at approximately 25 $PM_{2.5}$ core sites collocated at PAMS sites (1 type 2 site per PAMS area) and at approximately 25 other core sites for a total of approximately 50 sites. The selection of these sites will be performed by the Administrator in consultation with the Regional Administrator and the States. Chemical speciation is encouraged at additional sites. At a minimum, chemical speciation to be conducted will include analysis for elements, selected anions and cations, and carbon. Samples for required speciation will be collected using appropriate monitoring methods and sampling schedule in accordance with procedures approved by the Administrator.

(b) Air pollution control agencies shall archive $PM_{2.5}$ filters from all other SLAMS sites for a minimum of one year after collection. These filters shall be made available for supplemental analyses at the request of EPA or to provide information to State and local agencies on the composition for $PM_{2.5}$. The filters shall be archived in accordance with procedures approved by the Administrator.

2.8.1.6 Community Monitoring Zones.

2.8.1.6.1 The CMZs describe areas within which two or more core monitors may be averaged for comparison with the annual $PM_{2.5}$ NAAQS. This averaging approach as specified in 40 CFR part 50, Appendix N, is directly related to epidemiological studies used as the basis for the $PM_{2.5}$ NAAQS. A CMZ should characterize an area of relatively similar annual average air quality (i.e., the average concentrations at individual sites shall not exceed the spatial average by more than 20 percent) and exhibit similar day to day variability (e.g., the monitoring sites should not have low correlations, say less than 0.6). Moreover, the entire CMZ should principally be affected by the same major emission sources of $PM_{2.5}$.

2.8.1.6.2 Each monitoring planning area may have at least one CMZ, that may or may not cover the entire MPA. In metropolitan statistical areas (MSAs) for which MPAs are required, the CMZs may completely cover the entire MSA. When more than one CMZ is described within an MPA, CMZs shall not overlap in their geographical coverage. All areas in the ambient air may become a CMZ.

2.8.1.6.3. As $PM_{2.5}$ networks are first established, core sites would be used individually for making comparisons to the annual $PM_{2.5}$ NAAQS. As these networks evolve, individual monitors may not be adequate by themselves to characterize the annual average community wide air quality. This is especially true for areas with sharp gradients in annual average air quality. Therefore, CMZs with multiple core SLAMS or other eligible sites as described in accordance with section 2.8.1.2 to this Appendix, may be established for the purposes of providing improved estimates of community wide air quality and for making comparisons to the annual NAAQS. This CMZ approach is subject to the constraints of section 2.8.1.6.1 to this Appendix.

2.8.1.6.4 The spatial representativeness of individual monitoring sites should be considered in the design of the network and in establishing the boundaries of CMZs. Communities within the MPA with the highest $PM_{2.5}$ concentrations must have a high priority for $PM_{2.5}$ monitoring. Until a sufficient number of monitoring stations or CMZs are established, however, the monitored air quality in all parts of the MPA may not be precisely known. It would be desirable, however, to design the placement of monitors so that those portions of the MPAs without monitors could be characterized as having average concentrations less than the monitored portions of the network.

2.8.1.7 Selection of Monitoring Locations Within MPAs or CMZs.

2.8.1.7.1 Figure 1 of this Appendix illustrates a hypothetical monitoring planning area and shows the location of monitors in relation to population and areas of poor air quality. Figure 2 of this Appendix shows the same hypothetical MPA as Figure 1 of this Appendix and illustrates potential community monitoring zones and the location of core monitoring sites within them. Figure 3 of this Appendix illustrates which sites within the CMZs of the same MPA may be used for comparison to the $PM_{2.5}$ NAAQS.

2.8.1.7.2 In Figure 1 of this Appendix, a hypothetical monitoring planning area is shown representing a typical Eastern US urban areas. The ellipses represent zones with relatively high population and poor air quality, respectively. Concentration isopleths are also depicted. The highest population density is indicated by the urban icons, while the area of worst air quality is presumed to be near the industrial symbols. The monitoring area should have at least one core monitor to represent community wide air quality in each sub-area affected by different emission sources. Each monitoring planning area with population greater than 500,000 is required to have at least two core population-oriented monitors that will sample everyday (with PAMS areas requiring three) and may have as many other core SLAMS, other SLAMS, and SPMs as necessary. All SLAMS should generally be population-oriented, while the SPMs can focus more on other monitoring objectives, e.g., identifying source impacts and the area boundaries with maximum concentration. C_a denotes ''category a'' core SLAMS site (community-oriented site in area of expected maximum concentration); it is shown within the populated area and closest to the area with highest concentration. C_b denotes a ''category b'' core SLAMS site (area of poor air quality with high population density or representative of maximum population impact); it is shown in the area of poor air quality, closest to highest population density. S denotes other SLAMS sites (monitoring for any objective: Max concentration, population exposure, source-oriented, background, or regional transport or in support of secondary NAAQS). P denotes a Special Purpose Monitor (a specialized monitor that, for example, may use a non-reference sampler). Finally, note that all SPMs would be subject to the 2-year moratorium against data comparison to the NAAQS for the first 2 complete calendar years of its operation.

2.8.1.7.3 A Monitoring Planning Area may have one or more community monitoring zones (CMZ) for aggregation of data from eligible SLAMS and SPM sites for comparison to the annual NAAQS. The planning area has large gradients of average air quality and, as shown in Figure 2 may be assigned three CMZs: An industrial zone, a downtown central business district (CBD), and a residential area. (If there is not a large difference between downtown concentrations and other residential areas, a separate CBD zone would not be appropriate).

Figure 1. Hypothetical Monitoring Planning Area

Eastern Urban Model - showing location of monitors in relation to population and area of poor air quality

C=Core site S=other SLAMS site p=Special Purpose Monitor

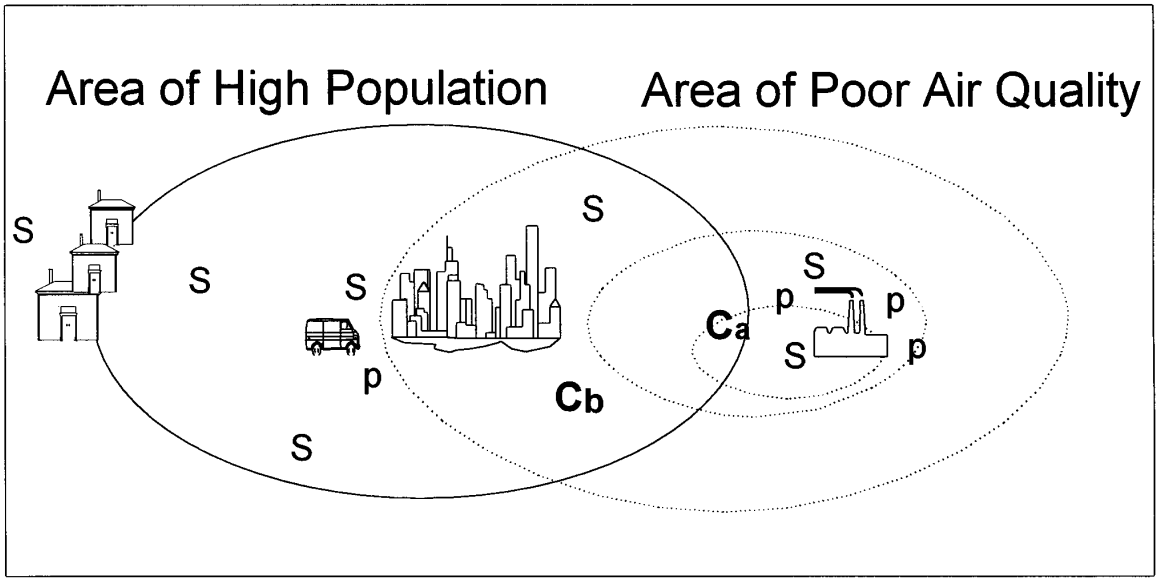
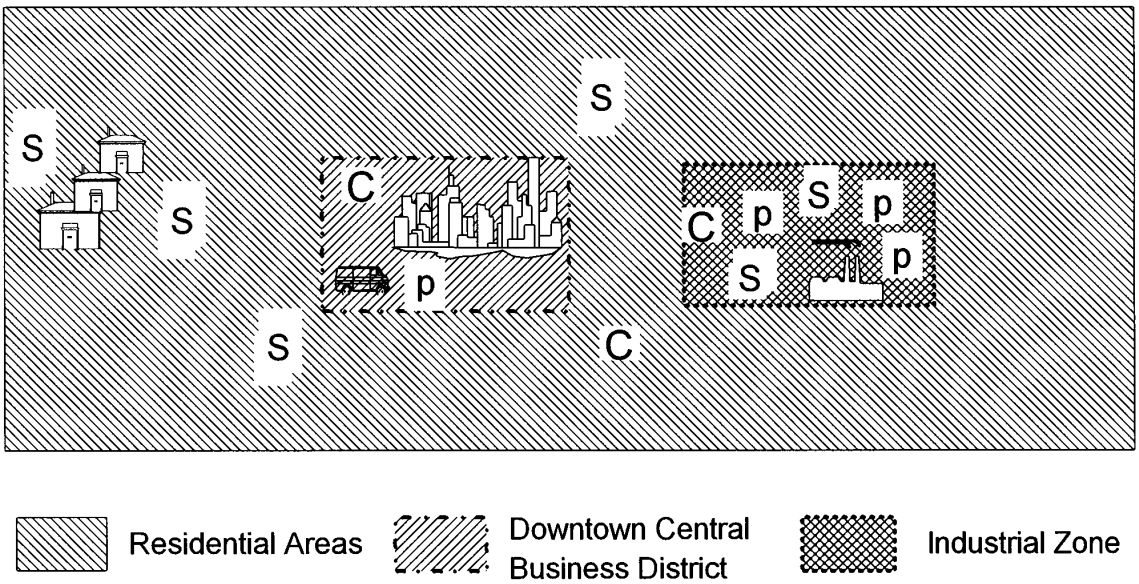


Figure 2. Hypothetical Monitoring Planning Area

Potential Community Monitoring Zones

C=Core site S=other SLAMS site p=Special Purpose Monitor

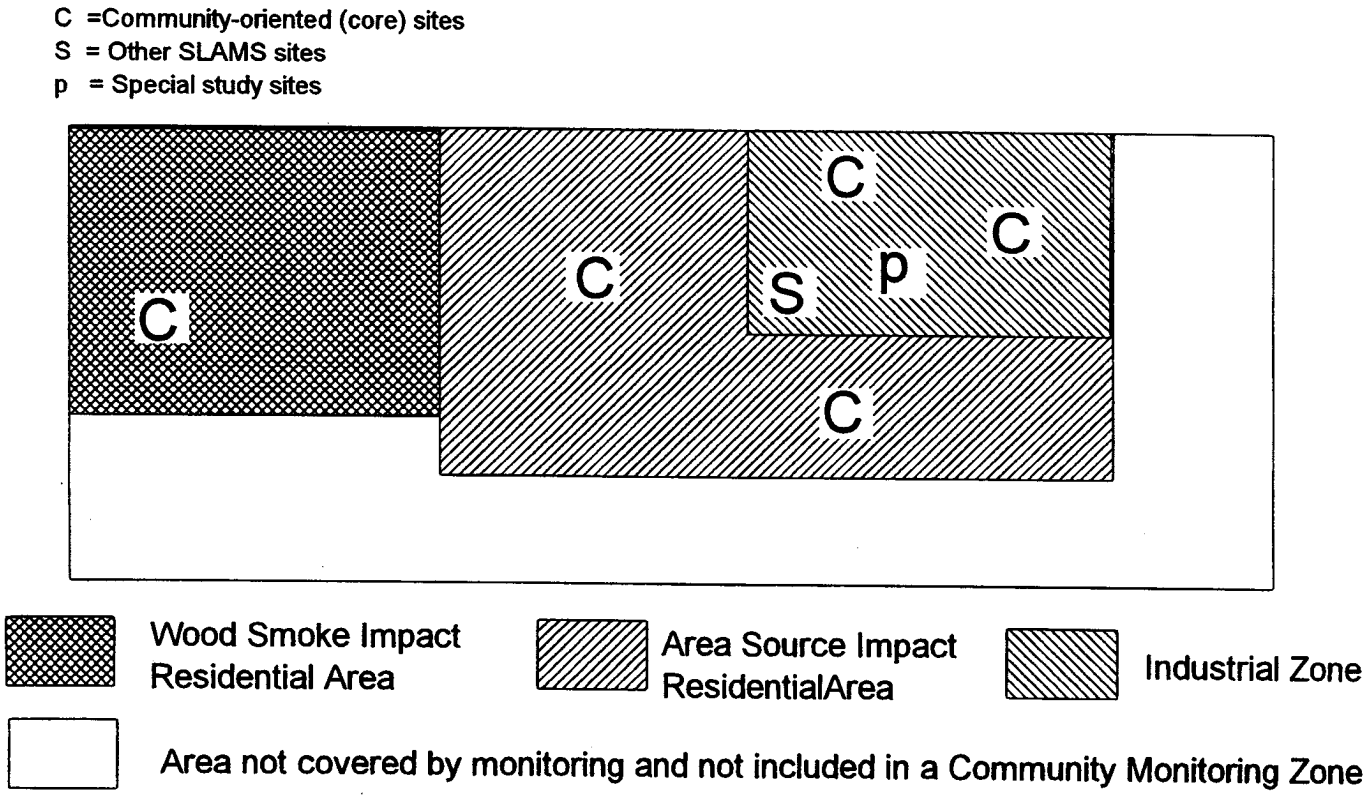


2.8.1.7.4 Figure 3 of this Appendix illustrates how CMZs and $PM_{2.5}$ monitors might be located in a hypothetical MPA typical of a Western State. Western States with more localized sources of PM and larger geographic area could require a different mix

of SLAMS and SPM monitors and may need more total monitors. As the networks are deployed, the available monitors may not be sufficient to completely represent all geographic portions of the Monitoring Planning Area. Due to the distribution of pollution and population and because of the number and spatial representativeness of monitors, the MPAs and CMZs may not cover the entire State.

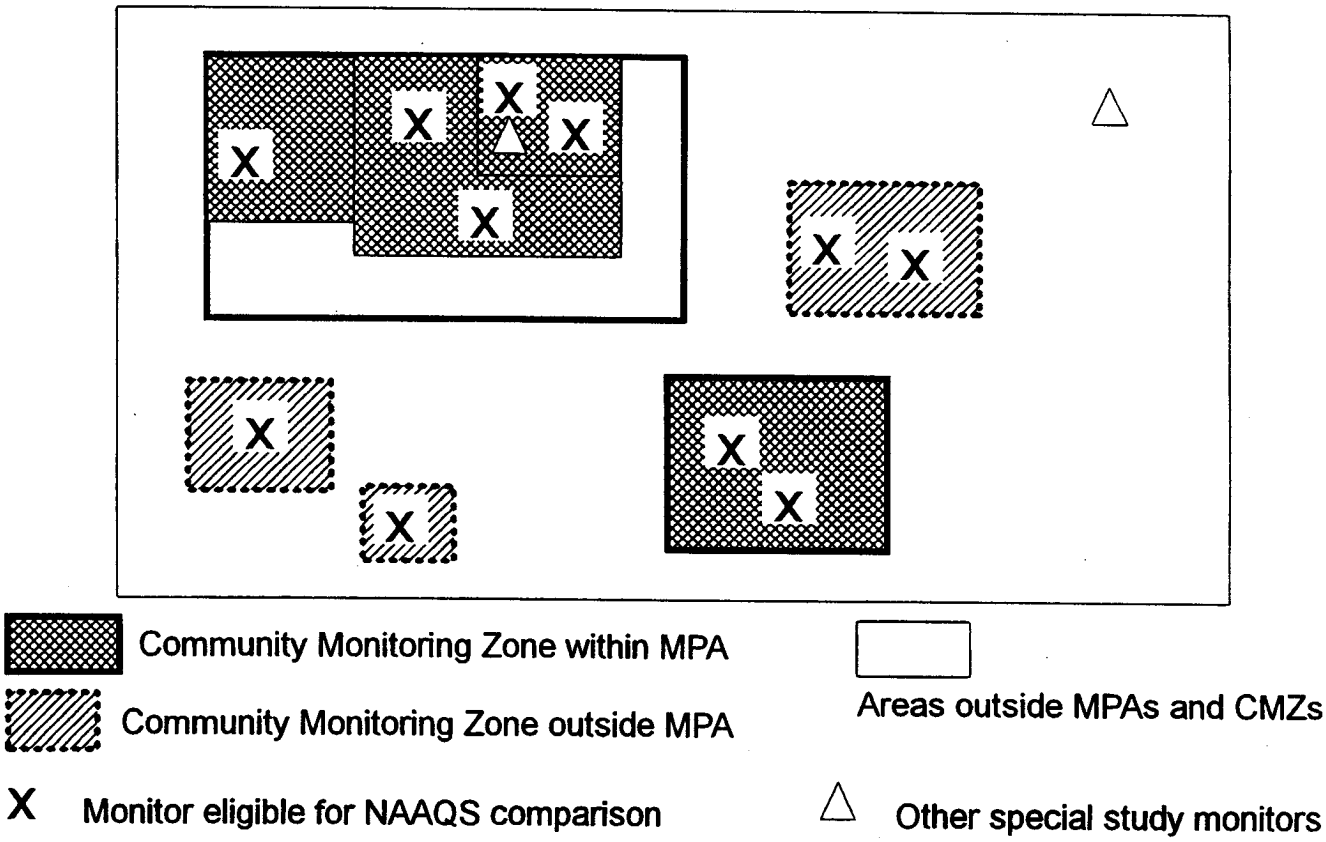
Figure 3. Hypothetical Monitoring Planning Area

Potential Community Monitoring Zones in Western MPA



2.8.1.7.5 Figure 4 of this Appendix shows how the MPAs, CMZs, and $PM_{2.5}$ monitors might be distributed within a hypothetical State. Areas of the State included within MPAs are shown within heavy solid lines. Two MPAs are illustrated. Areas in the State outside the MPAs will also include monitors, but this monitoring coverage may be limited. This portion of the State may also be represented by CMZs (shown by areas enclosed within dotted lines). The monitors that are intended for comparison to the NAAQS are indicated by X. Furthermore, eligible monitors within a CMZ could be averaged for comparison to the annual NAAQS or examined individually for comparison to both NAAQS. Both within the MPAs and in the remainder of the State, some special study monitors might not satisfy applicable 40 CFR part 58 requirements and will not be eligible for comparison to the NAAQS.

Figure 4. MPAs and CMZs in Hypothetical State



2.8.2 *Substitute PM Monitoring Sites.*

2.8.2.1 Section 2.2 of Appendix C of this part describes conditions under which TSP samplers can be used as substitutes for PM_{10}. This provision is intended to be used when PM_{10} concentrations are expected to be very low and substitute TSP samplers can be used to satisfy the minimum number of PM_{10} samplers needed for an adequate PM_{10} network.

2.8.2.2 If data produced by substitute PM samplers exceed the concentration levels described in Appendix C of this part, then the need for this sampler to be converted to a PM_{10} or $PM_{2.5}$ sampler, shall be considered in the PM monitoring network review. If the State does not believe that a PM_{10} or $PM_{2.5}$ sampler should be sited, the State shall submit documentation to EPA as part of its annual PM report to justify this decision. If a PM site is not designated as a substitute site in the PM monitoring network description, then high concentrations at this site would not necessarily cause this site to become a $PM_{2.5}$ or PM_{10} site, whichever is indicated.

2.8.2.3 Consistent with § 58.1, combinations of SLAMS PM_{10} or $PM_{2.5}$ monitors and other monitors may occupy the same structure without any mutual effect on the regulatory definition of the monitors.

3. *Network Design for National Air Monitoring Stations (NAMS).*

* * * * *

Category (a): Stations located in area(s) of expected maximum concentrations, generally microscale for CO, microscale or middle scale for Pb, middle scale or neighborhood scale for population-oriented particulate matter, urban or regional scale for Regional transport $PM_{2.5}$, neighborhood scale for SO2, and NO2, and urban scale for O_3.

* * * * *

For each MSA where NAMS are required, both categories of monitoring stations must be established. In the case of SO_2 if only one NAMS is needed, then category (a) must be used. The analysis and interpretation of data from NAMS should consider the distinction between these types of stations as appropriate.

* * * * *

3.7 *Particulate Matter Design Criteria for NAMS.*

3.7.1 Table 4 indicates the approximate number of permanent stations required in MSAs to characterize national and regional PM_{10} air quality trends and geographical patterns. The number of PM_{10} stations in areas where MSA populations exceed 1,000,000 must be in the range from 2 to 10 stations, while in low population urban areas, no more than two stations are required. A range of monitoring stations is specified in Table 4 because sources of pollutants and local control efforts can vary from one part of the country to another and therefore, some flexibility is allowed in selecting the actual number of stations in any one locale.

3.7.2 Through promulgation of the NAAQS for $PM_{2.5}$, the number of PM_{10} SLAMS is expected to decrease, but requirements to maintain PM_{10} NAMS remain in effect. The PM_{10} NAMS are retained to provide trends data, to support national assessments and decisions, and in some cases to continue demonstration that a NAAQS for PM_{10} is maintained as a requirement under a State Implementation Plan.

3.7.3 The $PM_{2.5}$ NAMS shall be a subset of the core $PM_{2.5}$ SLAMS and other SLAMS intended to monitor for regional transport. The $PM_{2.5}$ NAMS are planned as long-term monitoring stations concentrated in metropolitan areas. A target range of 200 to 300 stations shall be designated nationwide. The largest metropolitan areas (those with a population greater than approximately one million) shall have at least one $PM_{2.5}$ NAMS stations.

3.7.4 The number of total $PM_{2.5}$ NAMS per Region will be based on recommendations of the EPA Regional Offices, in concert with

their State and local agencies, in accordance with the network design goals described in sections 3.7.5 through 3.7.7 of this Appendix. The selected stations should represent the range of conditions occurring in the Regions and will consider factors such as total number or type of sources, ambient concentrations of particulate matter, and regional transport.

3.7.5 The approach for $PM_{2.5}$ NAMS is intended to give State and local agencies maximum flexibility while apportioning a limited national network. By advancing a range of monitors per Region, EPA intends to balance the national network with respect to geographic area and population. Table 5 presents the target number of $PM_{2.5}$ NAMS per Region to meet the national goal of 200 to 300 stations. These numbers consider a variety of factors such as Regional differences in metropolitan population, population density, land area, sources of particulate emissions, and the numbers of PM_{10} NAMS.

3.7.6 States will be required to establish approximately 50 NAMS sites for routine chemical speciation of $PM_{2.5}$. These sites will include those collocated at approximately 25 PAMS sites and approximately 25 other core SLAMS sites to be selected by the Administrator. After 5 years of data collection, the Administrator may exempt some sites from collecting speciated data. The number of NAMS sites at which speciation will be performed each year and the number of samples per year will be determined by the Administrator.

3.7.7 Since emissions associated with the operation of motor vehicles contribute to urban area particulate matter levels, consideration of the impact of these sources must be included in the design of the NAMS network, particularly in MSAs greater than 500,000 population. In certain urban areas particulate emissions from motor vehicle diesel exhaust currently is or is expected to be a significant source of particulate matter ambient levels. The actual number of NAMS and their locations must be determined by EPA Regional Offices and the State agencies, subject to the approval of the Administrator as required by § 58.32. The Administrator's approval is necessary to ensure that individual stations conform to the NAMS selection criteria and that the network as a whole is sufficient in terms of number and location for purposes of national analyses.

TABLE 4.—PM_{10} NATIONAL AIR MONITORING STATION CRITERIA

[Approximate Number of Stations per MSA][1]

Population Category	High Concentration[2]	Medium Concentration[3]	Low Concentration[4]
>1,000,000	6–10	4–8	2–4
500,000–1,000,000	4–8	2–4	1–2
250,000–500,000	3–4	1–2	0–1
100,000–250,000	1–2	0–1	0

[1] Selection of urban areas and actual number of stations per area will be jointly determined by EPA and the State agency.
[2] High concentration areas are those for which ambient PM_{10} data show ambient concentrations exceeding either PM_{10} NAAQS by 20 percent or more.
[3] Medium concentration areas are those for which ambient PM_{10} data show ambient concentrations exceeding 80 percent of the PM_{10} NAAQS.
[4] Low concentration areas are those for which ambient PM_{10} data show ambient concentrations less than 80 percent of the PM_{10} NAAQS.

3.7.7.1 Selection of urban areas and actual number of stations per area will be jointly determined by EPA and the State agency.

3.7.7.2 High concentration areas are those for which: Ambient PM_{10} data show ambient concentrations exceeding either PM_{10} NAAQS by 20 percent or more.

3.7.7.3 Medium concentration areas are those for which: Ambient PM_{10} data show ambient concentrations exceeding either 80 percent of the PM_{10} NAAQS.

3.7.7.4 Low concentration areas are those for which: Ambient PM_{10} data show ambient concentrations less than 80 percent of the PM_{10} NAAQS.

TABLE 5.—GOALS FOR NUMBER OF $PM_{2.5}$ NAMS BY REGION

EPA Region	Number of NAMS[1]	Percent of National Total
1	15 to 20	6 to 8
2	20 to 30	8 to 12
3	20 to 25	8 to 10
4	35 to 50	14 to 20
5	35 to 50	14 to 20
6	25 to 35	10 to 14
7	10 to 15	4 to 6
8	10 to 15	4 to 6
9	25 to 40	10 to 16
10	10 to 15	4 to 6
Total	205–295	100

[1] Each region will have one to three NAMS having the monitoring of regional transport as a primary objective.

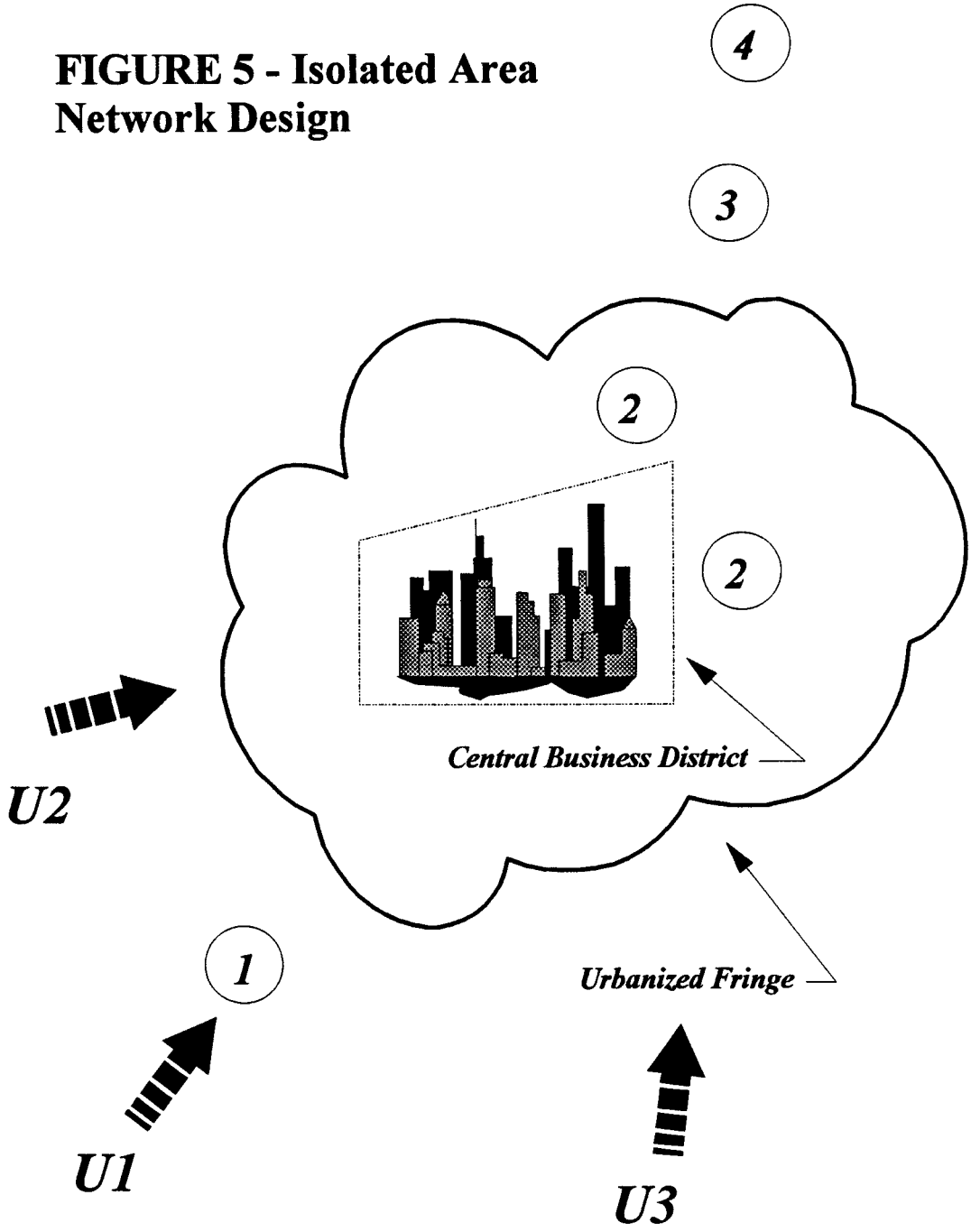
* * * * *

4.2 *PAMS Monitoring Objectives.*

* * * * *

States choosing to submit an individual network description for each affected nonattainment area, irrespective of its proximity to other affected areas, must fulfill the requirements for isolated areas as described in section 4 of this Appendix, as an example, and illustrated by Figure 5. States containing areas which experience significant impact from long-range transport or are proximate to other nonattainment areas (even in other States) should collectively submit a network description which contains alternative sites to those that would be required for an isolated area. Such a submittal should, as a guide, be based on the example provided in Figure 6, but must include a demonstration that the design satisfies the monitoring data uses and fulfills the PAMS monitoring objectives described in sections 4.1 and 4.2 of this Appendix.

FIGURE 5 - Isolated Area Network Design



LEGEND:

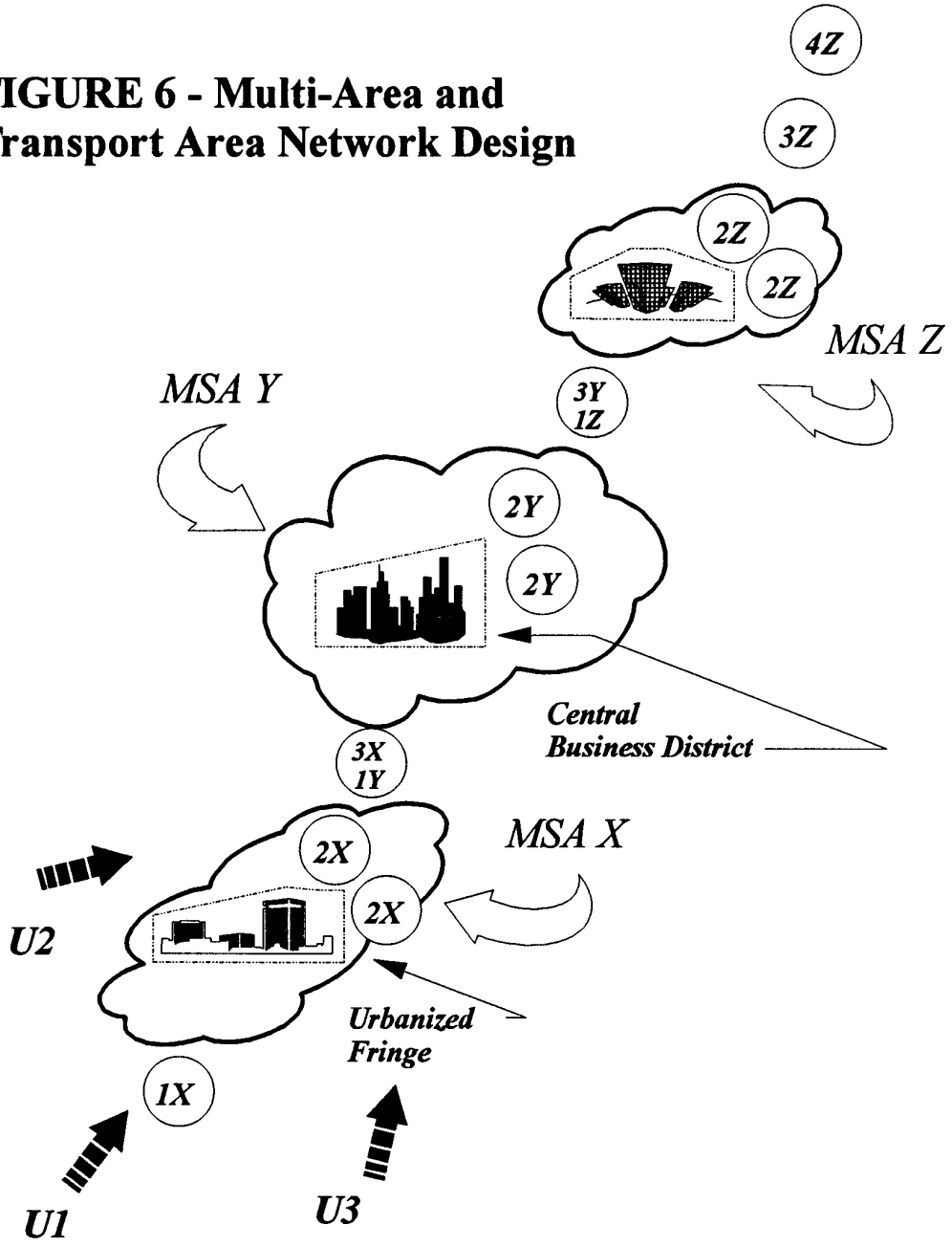
(1) - A circle denotes a PAMS Site. The number inside describes the Site number.

U1 - High ozone day predominant morning wind direction

U2 - Second most predominant high ozone day morning wind direction

U3 - High ozone day predominant afternoon wind direction

FIGURE 6 - Multi-Area and Transport Area Network Design



LEGEND:

(1X) - A circle denotes a PAMS Site. The number inside describes the Site number and the letter indicates the associated MSA/CMSA, e.g., a circle with 1X indicates a Site #1 for MSA X. Since PAMS can serve multiple purposes for more than one MSA/CMSA, Sites with mutiple associations are identified with multiple number and letter identifiers.

U1 - High ozone day predominant morning wind direction

U2 - Second most predominant high ozone day morning wind direction

U3 - High ozone day predominant afternoon wind direction

* * * * *

4.4 *Minimum Monitoring Network Requirements.*

* * * * *

Table 2 * * *

[3]See Figure 5.

* * * * *

5. *Summary.*

Table 6 of this Appendix shows by pollutant, all of the spatial scales that are applicable for SLAMS and the required spatial scales for NAMS. There may also be some situations, as discussed later in Appendix E of this part, where additional scales may be allowed for NAMS purposes.

TABLE 6.—SUMMARY OF SPATIAL SCALES FOR SLAMS AND REQUIRED SCALES FOR NAMS

Spatial Scale	Scales Applicable for SLAMS						
	SO_2	CO	O_3	NO_2	Pb	PM_{10}	$PM_{2.5}$
Micro		✔			✔	✔	✔
Middle	✔	✔	✔	✔	✔	✔	✔
Neighborhood	✔	✔	✔	✔	✔	✔	✔
Urban	✔		✔	✔	✔	✔	✔
Regional	✔		✔		✔	✔	✔
	Scales Required for NAMS						
Micro		✔			✔	✔	✔[1]
Middle					✔	✔	✔[1]
Neighborhood	✔	✔	✔	✔	✔	✔	✔
Urban			✔	✔			✔[2]
Regional							✔[2]

[1] Only permitted if representative of many such micro-scale environments in a residential district (for middle scale, at least two).
[2] Either urban or regional scale for regional transport sites.

6. *References.*

* * * * *

18. Watson et al. Guidance for Network Design and Optimum Site Exposure for $PM_{2.5}$ and PM_{10}. Prepared for U.S. Environmental Protection Agency, Research Triangle Park, NC.

o. Appendix E is amended by revising the entry for 8. in the table of contents, by revising the heading to section 8., adding a sentence at the end of the first paragraph of section 8.1, and in section 8.3 removing the term ''PM_{10}'' wherever it appears and adding in its place ''PM'' to read as follows:

Appendix E—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring

* * * * *

8. Particulate Matter (PM_{10} and $PM_{2.5}$)

* * * * *

8. *Particulate Matter (PM_{10} and $PM_{2.5}$).*

8.1 Vertical Placement * * * Although microscale or middle scale stations are not the preferred spatial scale for $PM_{2.5}$ sites, there are situations where such sites are representative of several locations within an area where large segments of the population may live or work (e.g., central business district of Metropolitan area). In these cases, the sampler inlet for such microscale $PM_{2.5}$ stations must also be 2-7 meters above ground level.

* * * * *

p. Appendix F is amended by revising in the table of contents the entry for 2.7.3 and adding a new entry for 2.7.4, by redesignating section 2.7.3 as section 2.7.4 and adding a new section 2.7.3 to read as follows:

Appendix F—Annual SLAMS Air Quality Information

* * * * *

2.7.3 Annual Summary Statistics

2.7.4 Episode and Other Unscheduled Sampling Data

* * * * *

2.7.3 Annual Summary Statistics. Annual arithmetic mean (μg/m³) as specified in 40 CFR part 50, Appendix N. All daily PM-fine values above the level of the 24–hour PM-fine NAAQS and dates of occurrence. Sampling schedule used such as once every 6 days, everyday, etc. Number of 24–hour average concentrations in ranges:

Range	Number of Values
0 to 15 (μg/m³)	
16 to 30	
31 to 50	
51 to 70	
71 to 90	
91 to 110	
Greater than 110	

[FR Doc. 97–18579 Filed 7–17–97; 8:45 am]

BILLING CODE 6560–50–F

federal register

Friday
July 18, 1997

Part V

Environmental Protection Agency

40 CFR Part 50

National Ambient Air Quality Standards for Ozone; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[ADA–95–58; FRL–5725–3]

RIN–2060–AE57

National Ambient Air Quality Standards for Ozone

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This document describes EPA's decision to revise the national ambient air quality standards (NAAQS) for ozone (O_3) based on its review of the available scientific evidence linking exposures to ambient O_3 to adverse health and welfare effects at levels allowed by the current O_3 standards. The current 1–hour primary standard is replaced by an 8–hour standard at a level of 0.08 parts per million (ppm) with a form based on the 3–year average of the annual fourth-highest daily maximum 8–hour average O_3 concentrations measured at each monitor within an area. The new primary standard will provide increased protection to the public, especially children and other at-risk populations, against a wide range of O_3-induced health effects, including decreased lung function, primarily in children active outdoors; increased respiratory symptoms, particularly in highly sensitive individuals; hospital admissions and emergency room visits for respiratory causes, among children and adults with pre-existing respiratory disease such as asthma; inflammation of the lung, and possible long-term damage to the lungs. The current 1–hour secondary standard is replaced by an 8–hour standard identical to the new primary standard. The new secondary standard will provide increased protection to the public welfare against O_3-induced effects on vegetation, such as agricultural crop loss, damage to forests and ecosystems, and visible foliar injury to sensitive species.

EFFECTIVE DATE: This rule is effective September 16, 1997.

ADDRESSES: A docket containing information relating to the EPA's review of the O_3 primary and secondary standards (Docket No. A–95–58) is available for public inspection in the Central Docket Section of the U.S. Environmental Protection Agency, South Conference Center, Room 4, 401 M St., SW., Washington, DC. This docket incorporates the docket from the previous review of the O_3 standards (Docket No. A–92–17) and the docket established for the air quality criteria document (Docket No. ECAO–CD–92–0786). The docket may be inspected between 8 a.m. and 3 p.m. on weekdays, and a reasonable fee may be charged for copying. The information in the docket constitutes the complete basis for the decision announced in this final rule. For the availability of related information, see ''SUPPLEMENTARY INFORMATION.''

FOR FURTHER INFORMATION CONTACT: David McKee, MD–15, Air Quality Standards and Strategies Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone: (919) 541–5288; e-mail: mckee.dave@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Availability of Related Information

Certain documents are available from the U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. Available documents include:

(1) Air Quality Criteria for O_3 and Other Photochemical Oxidants (''Criteria Document'') (three volumes, EPA/600/P–93–004aF through EPA/600/P–93–004cF, July 1996, NTIS # PB–96–185574, $169.50 paper copy, $58.00 microfiche).

(2) The Review of the National Ambient Air Quality Standards for O_3: Assessment of Scientific and Technical Information (''Staff Paper'')(EPA–452/R–96–007, June 1996, NTIS # PB–96–203435, $67.00 paper copy and $21.50 microfiche). (Add a $3.00 handling charge per order.)

A limited number of copies of other documents generated in connection with this standard review, such as documents pertaining to human exposure and health risk assessments, and vegetation exposure, risk, and benefits analyses can be obtained from: U.S. Environmental Protection Agency Library (MD–35), Research Triangle Park, NC 27711, telephone (919) 541–2777. These and other related documents are also available for inspection and copying in the EPA docket identified under ''ADDRESSES''.

Electronic Availability

The Staff Paper and human exposure and health risk assessment support documents are now available on the Agency's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) Bulletin Board System (BBS) in the Clean Air Act Amendments area, under Title I, Policy/Guidance Documents. To access the bulletin board, a modem and communications software are necessary. To dial up, set your communications software to 8 data bits, no parity and one stop bit. Dial (919) 541–5742 and follow the on-screen instructions to register for access. After registering, proceed to choice ''<T> Gateway to TTN Technical Areas'', then choose ''<E> CAAA BBS''. From the main menu, choose ''<1> Title I: Attain/Maint of NAAQS'', then ''<P> Policy Guidance Documents.'' To access these documents through the World Wide Web, click on ''TTN BBSWeb'', then proceed to the Gateway to TTN Technical areas, as above. If assistance is needed in accessing the system, call the help desk at (919) 541–5384 in Research Triangle Park, NC.

Implementation Strategy for Revised Air Quality Standards

On Wednesday, July 16, 1997, President Clinton signed a memorandum to the Administrator specifying his goals for the implementation of the O_3 and PM standards. Attached to the President's memorandum is a strategy prepared by an interagency Administration group outlining the next steps that would be necessary for implementing these standards. The EPA will prepare guidance and proposed rules consistent with the President's memorandum. Copies of the Presidential document are available in paper copy by contacting the U.S. Environmental Protection Agency Library at the address under ''Availability of Related Information'' and in electronic form as discussed above in ''Electronic Availability.''

The following topics are discussed in this preamble:

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I. Background

A. Legislative Requirements

Two sections of the Act govern the establishment, review, and revision of NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify certain pollutants which ''may reasonably be anticipated to endanger public health or welfare'' and to issue air quality criteria for them. These air quality criteria are to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air ***.''

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate ''primary'' and ''secondary'' NAAQS for pollutants identified under section 108. Section 109(b)(1) defines a primary standard as one ''the attainment and maintenance of which in the judgment of the Administrator, based on [the] criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' The margin of safety requirement was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting, as well as to provide a reasonable degree of protection against hazards that research has not yet identified. Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, by selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that she finds may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The Act does not require the Administrator to establish a primary NAAQS at a zero-risk level but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association* v. *EPA*. (647 F.2d 1130, 1161–62 (D.C. Cir. 1980)).

A secondary standard, as defined in section 109(b)(2), must ''specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on [the] criteria, [are] requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.'' Welfare effects as defined in section 302(h) (42 U.S.C. 7602(h)) include, but are not limited to, ''effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

Section 109(d)(1) of the Act requires periodic review and, if appropriate, revision of existing air quality criteria and NAAQS. Section 109(d)(2) requires appointment of an independent scientific review committee to review criteria and standards and recommend new standards or revisions of existing criteria and standards, as appropriate. The committee established under section 109(d)(2) is known as the Clean Air Scientific Advisory Committee (CASAC), a standing committee of EPA's Science Advisory Board.

B. Related Control Requirements

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the Act (42 U.S.C. 7410) and related provisions, States are to submit, for EPA approval, State implementation plans (SIP's) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with EPA, also administer the prevention of significant deterioration programs (42 U.S.C. 7470–7479) for these pollutants. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants under Title II of the Act (42 U.S.C. 7521–7574), which involves controls for automobile, truck, bus, motorcycle, nonroad engine, and aircraft emissions; the new source performance standards under section 111 (42 U.S.C. 7411); and the national emission standards for hazardous air pollutants under section 112 (42 U.S.C. 7412).

C. Review of Air Quality Criteria and Standards for O_3

The last review of O_3 air quality criteria and standards was completed in March 1993 with notice of a final decision not to revise the existing primary and secondary standards (58 FR 13008). The current primary and secondary standards are each set at a level of 0.12 ppm, with a 1–hour averaging time and a 1-expected-exceedance form, such that the standards are attained when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm is equal to or less than 1, averaged over 3 years (as determined by 40 CFR part 50, Appendix H).[1]

The EPA initiated this current review of the air quality criteria and standards in August 1992 with the development of a revised Air Quality Criteria Document for O_3 and Other Photochemical Oxidants, henceforth the ''Criteria Document.'' Several workshops were held by EPA's National Center for Environmental Assessment (NCEA) to discuss health and welfare effects information during the summer and fall of 1993. An external review draft of the Criteria Document made available to the public and to the CASAC in the spring of 1994 was reviewed at a public CASAC meeting held on July 20–21, 1994. Based on comments made at the meeting, NCEA staff prepared a second external review draft, which was reviewed at a public CASAC meeting on March 21–22, 1995. At the same meeting, the CASAC also reviewed draft portions of a staff paper prepared by the OAQPS, Review of National Ambient Air Quality Standards for O_3: Assessment of Scientific and Technical Information (henceforth, the ''Staff Paper''), focusing on health effects and the primary NAAQS.[2] Taking into account CASAC and public comments, staff revised both documents and made new drafts available for public and CASAC review during the summer of 1995. The OAQPS staff also prepared and made available draft portions of the Staff Paper focusing on welfare effects and the secondary standard.

[1] A more complete history of the O_3 NAAQS is presented in section II.B. of the Office of Air Quality Planning and Standards Staff Paper, Review of National Ambient Air Quality Standards for O_3: Assessment of Scientific and Technical Information (U.S. EPA, 1996b).

[2] The Staff Paper evaluates policy implications of the key studies and scientific information in the Criteria Document, identifies critical elements that EPA staff believes should be considered, and presents staff conclusions and recommendations of suggested options for the Administrator's consideration.

A public CASAC meeting was held on September 19–20, 1995, at which time CASAC came to closure in its review of the draft Criteria Document and the primary standard sections of the draft Staff Paper. In a November 28, 1995 letter from the CASAC chair to the Administrator, CASAC advised that the final draft Criteria Document ''provides an adequate review of the available scientific data and relevant studies of O_3 and related photochemical oxidants'' (Wolff, 1995a). Further, in a November 30, 1995 letter, CASAC advised the Administrator that the primary standard portion of the draft Staff Paper ''provides an adequate scientific basis for making regulatory decisions concerning a primary O_3 standard'' (Wolff, 1995b). The final Criteria Document (U.S. EPA, 1996a) reflects CASAC and public comments received at and subsequent to the September 1995 CASAC meeting.

Based on comments on the Staff Paper from the September 1995 CASAC meeting, revisions were made to the secondary standard sections of the Staff Paper, which were reviewed at a public CASAC meeting held on March 21, 1996. At that meeting and in a subsequent letter to the Administrator, CASAC concluded that the secondary standard sections of the draft Staff Paper ''provide an appropriate scientific basis for making regulatory decisions concerning a secondary O_3 standard'' (Wolff, 1996). The final Staff Paper (U.S. EPA, 1996b) reflects CASAC and public comments received at and subsequent to the September 1995 and March 1996 meetings on the primary standard and secondary standard sections, respectively.

On November 27, 1996 EPA announced its proposed decision to revise the NAAQS for O_3 (61 FR 65716, December 13, 1996, hereinafter ''proposal'') as well as its proposed decision to revise the NAAQS for particulate matter (PM). In the proposal, EPA identified proposed revisions, based on the air quality criteria for O_3, and solicited public comments on alternative primary and secondary standards and on the proposed forms of the standards.

To ensure the broadest possible public input on the O_3 and PM proposals, EPA took extensive and unprecedented steps to facilitate the public comment process beyond the normal process of providing an opportunity to request a hearing and receiving written comments submitted to the rulemaking docket. The EPA established a national toll-free telephone hotline to facilitate public comments on the proposed revisions to the O_3 and PM NAAQS, and on related notices dealing with the implementation of revised O_3 and PM standards, as well as a system for the public to submit comments on the proposals electronically via the Internet. Over 14,000 calls and over 4,000 electronic mail messages were received through these channels. The public could also access key supporting documents (including the Criteria Document, Staff Paper, related technical documents and fact sheets) via the Internet.

The EPA also held several public hearings and meetings across the country to provide direct opportunities for public comment on the proposed revisions to the O_3 and PM NAAQS and to disseminate information to the public about the proposed standard revisions. On January 14 and 15, 1997, EPA held concurrent, 2–day public hearings in Boston, MA, Chicago, IL, and Salt Lake City, UT. A fourth public hearing, which focused primarily on PM monitoring issues, was held in Durham, NC on January 14, 1997. Over 400 citizens and organizations testified during these public hearings. EPA also held two national satellite telecasts to answer questions on the standards and participated in meetings sponsored by the Air and Waste Management Association on the proposed revisions to the standards at more than 10 locations across the country. Beyond that, several EPA regional offices held public meetings and workshops and participated in hearings that States and cities held around the country.

As a result of this intensive effort to solicit public input, over 50,000 written and verbal comments were received on the proposed revisions to the O_3 NAAQS by the close of the public comment period on March 12, 1997. The major issues raised in the comments are discussed throughout the preamble of this final rule. A comprehensive summary of all significant comments, along with EPA's response to such comments (hereafter ''Response to Comments''), can be found in the docket for this rulemaking (Docket No. A–95–58).

The focus of this current review of the air quality criteria and standards for O_3 and related photochemical oxidants is on public health and welfare effects associated with exposure to ambient levels of tropospheric O_3. Tropospheric O_3 is chemically identical to stratospheric O_3, which is produced miles above the earth's surface and provides a protective shield from excess ultraviolet radiation. In contrast, tropospheric O_3 at sufficient concentrations has been associated with harmful effects due to its oxidative properties and its presence in the air that people and plants take up during respiratory processes. Ozone is not emitted directly from mobile or stationary sources but, like other photochemical oxidants, commonly exists in the ambient air as an atmospheric transformation product. Ozone formation is the result of chemical reactions of volatile organic compounds (VOC), nitrogen oxides (NO_x), and oxygen in the presence of sunlight and generally at elevated temperatures. A detailed discussion of atmospheric formation, ambient concentrations, and health and welfare effects associated with exposure to O_3 can be found in the Criteria Document and in the Staff Paper.

D. Summary of Proposed Revisions to the O_3 Standards

For reasons discussed in the proposal, the Administrator proposed to replace the current 1–hour primary standard for O_3 with an 8–hour standard set at 0.08 ppm, which would be met at an ambient air quality monitoring site when the 3–year average of the annual third-highest daily maximum 8–hour average O_3 concentration is less than or equal to 0.08 ppm. The proposal solicited comments on alternative 8–hour standards set at 0.09 ppm, which generally represents the continuation of the present level of protection, and 0.07 ppm, which would be highly precautionary in nature, as well as on retaining the current primary standard. The proposal also solicited comments on alternative forms of the standard, specific data handling and rounding conventions used in determining attainment with the standard, and issues related to the communication of public health information.

With regard to the secondary standard, the Administrator proposed to replace the current 1–hour secondary standard with one of two alternative standards: either one set identical to the proposed primary standard or a new seasonal standard expressed as a sum of hourly O_3 concentrations greater than or equal to 0.06 ppm, cumulated over 12 hours per day during the consecutive 3–month period of maximum concentrations during the O_3 monitoring season, set at a level of 25 ppm-hour. The proposal solicited comments on these two alternatives, as well as on specific issues related to the form of a seasonal standard and on an enhanced rural air quality monitoring network.

II. Rationale for the Primary Standard

A. Introduction

1. *Overview* . This notice presents the Administrator's final decision regarding the need to revise the current primary O_3 standard, and, more specifically, regarding the averaging time, level, and form of a new primary standard to replace the current 1–hour standard. This decision is based on a thorough review, in the Criteria Document, of the scientific information on human health effects associated with exposure to ambient levels of O_3, including evaluation of key studies published through 1995. This decision also takes into account:

(1) Staff Paper assessments of the most policy-relevant information in the Criteria Document and analyses of human exposure and risk, presented in the Staff Paper and supporting technical reports.

(2) CASAC advice and recommendations, as reflected in discussions of drafts of the Criteria Document and Staff Paper at public meetings, in separate written comments, and in CASAC's letters to the Administrator.

(3) Public comments received during the development of these documents, either in connection with CASAC meetings or separately.

(4) Extensive public comments received on the proposal regarding the primary O_3 standard.

After taking this information and comments into account and for the reasons discussed below in this unit, the Administrator concludes that revisions to the current primary standard to provide increased public health protection are appropriate at this time to protect public health with an adequate margin of safety. Further, the Administrator determines that it is appropriate to establish a revised 8–hour, 0.08 ppm primary standard with a form based on the 3–year average of the annual fourth-highest daily maximum 8–hour average O_3 concentrations measured at each monitor within an area.

As discussed more fully below in this unit, the rationale for the final decision regarding the O_3 primary NAAQS includes consideration of:

(1) Health effects information to inform judgments as to the likelihood that exposures to ambient O_3 result in adverse health effects for exposed individuals.

(2) Insights gained from human exposure and risk assessments to provide a broader perspective for judgments about protecting public health from the risks associated with O_3 exposure.

(3) Specific conclusions with regard to the elements of a standard (i.e., averaging time, level, and form) that, taken together, would be appropriate to protect public health with an adequate margin of safety.

(4) Alternative views of the significance of the effects and factors to be considered in policy judgments about the appropriate elements of the standard.

The health effects information and human exposure and risk assessments were summarized in the proposal and are only briefly outlined below. More fully discussed in the following units of this preamble is the Administrator's rationale, in light of key issues raised in public comments, for concluding that it is appropriate to revise the specific elements of the current standard including averaging time (Unit II.B.1.), level (Unit II.B.2.), and form (Unit II.B.3.). Finally, the related subject of the communication of public health information, and the public comments received on this subject, are summarized in Unit II.C.

2. *Health effects information*. The last review of the air quality criteria for O_3 included an evaluation of key studies published through early 1989 and was the basis for EPA's 1993 decision not to revise the primary standard at that time. However, in recognition of the large number of new studies, particularly on 6– to 8–hour exposures to O_3, that had become available since early 1989 but had not undergone rigorous assessment and review by CASAC, the EPA made clear in the 1993 final decision notice that it would proceed with the next review as rapidly as possible to consider this new information. Thus, the current review of health effects information focused on a large body of information published since 1989 that would lead to a more informed decision than was possible in 1993 as to whether an O_3 primary standard with a longer averaging time was appropriate to protect public health.

The proposal reviewed the human health effects associated with exposure to ambient levels of O_3 based on an integrative assessment of human clinical, epidemiological, and animal toxicological studies available through 1995, as assessed in the Criteria Document and Staff Paper. Based on this information, an array of health effects has been attributed to short-term (1 to 3 hours), prolonged (6 to 8 hours), and long-term (months to years) exposures to O_3.

Acute health effects[3] are induced by short-term exposures to O_3 (observed at concentrations as low as 0.12 ppm), generally while individuals are engaged in moderate or heavy exertion, and by prolonged exposures to O_3 (observed at concentrations as low as 0.08 ppm), typically while individuals are engaged in moderate exertion. Moderate exertion levels are more frequently experienced by individuals than heavy exertion levels. The acute health effects include transient pulmonary function responses, transient respiratory symptoms, effects on exercise performance, increased airway responsiveness, increased susceptibility to respiratory infection, increased hospital admissions and emergency room visits, and transient pulmonary inflammation. Based in particular on new information available since the last review of the air quality criteria for O_3 was completed, such acute health effects have been observed following prolonged exposures at moderate levels of exertion at concentrations of O_3 as low as 0.08 ppm. Groups at increased risk of experiencing such effects include active children and outdoor workers who regularly engage in outdoor activities and individuals with preexisting respiratory disease (e.g., asthma, chronic obstructive lung disease). Further, it is recognized that some individuals are unusually responsive to O_3 and may experience much greater functional and symptomatic effects from exposure to O_3 than the average individual.

With regard to chronic health effects[4], the collective data from studies of laboratory animals and human populations have many ambiguities, but provide suggestive evidence of such effects in humans. It is clear from toxicological data that O_3-induced lung injury is roughly similar across species (including monkeys, rats, and mice) with responses that are concentration dependent. The currently available information provides at least a biologically plausible basis for considering the possibility that repeated inflammation associated with exposure to O_3 over a lifetime may result in sufficient damage to respiratory tissue such that individuals later in life may experience a reduced quality of life,

[3] ''Acute health effects'' of O_3 are defined as those effects induced by short-term and prolonged exposures to O_3. Examples of these effects are functional, symptomatic, biochemical, and physiologic changes.

[4] ''Chronic health effects'' of O_3 are defined as those effects induced by long-term exposures to O_2. Examples of these effects are structural damage to lung tissue and accelerated decline in baseline lung function.

although such relationships remain highly uncertain.

EPA's consideration of this health effects information necessarily included judgments with respect to when these physiological effects become so significant that they should be regarded as adverse to the health of individuals experiencing the effects. In making these judgments, the Administrator looked to guidelines published by the American Thoracic Society (1985) and the advice of CASAC. The proposal summarized the criteria and reasoning for EPA's judgments on this issue, upon which the CASAC panel expressed a consensus view that these ''criteria for the determination of an adverse physiological response was reasonable'' (Wolff, 1995b). The criteria take into account the degree of severity of the effects; the likelihood that the effects would interfere with normal activity for individuals with impaired respiratory systems or active healthy individuals; the likelihood that the effects would result in additional or more frequent use of medication, medical treatment, or emergency room visits for individuals with impaired respiratory systems; and the implications of single or repeated occurrences of the effects for an individual.

Some commenters raised concerns regarding the criteria used by EPA to make determinations as to when effects become adverse, citing CASAC's closure letter (Wolff, 1995b) stating that ''there was considerable concern that the criteria for grading physiological and clinical responses to O_3 was confusing if not misleading.'' These concerns with the draft criteria were discussed at length during a public CASAC meeting, resulting in very specific agreements as to how to revise the draft criteria so as to be consistent with CASAC's advice (Transcript of CASAC meeting, September 19–20, 1995, pp. 242–248). Having reached such specific agreement, CASAC advised that further review of the final version of these criteria, subsequently incorporated in both the final Criteria Document and Staff Paper, was unnecessary.

Other commenters have questioned whether judgments made in this review are consistent with those made in the last review with regard to when physiological and clinical effects become adverse to individuals experiencing such effects. Specifically, the commenters focused on the judgment stated in the 1993 final decision notice (58 FR 13008, March 9, 1993) that ''lesser effects associated with [1– to 3–hour] exposure to O_3 in the range of 0.12 ppm to 0.15 ppm observed in the controlled human studies did not constitute adverse effects for purposes of section 109 of the Act.'' The ''lesser effects'' referred to in that notice involved responses of a maximum decrease in lung function [as measured by forced expiratory volume in 1 second (FEV_1)] of from 9 percent to 16 percent for the most sensitive individuals exposed in this range, with few, if any, symptoms. The EPA notes that this judgment is, in fact, consistent with judgments presented in the 1996 proposal, which identify moderate and large lung function decrements (as reflected in EPA's risk assessment by FEV_1 decreases of ≥ 15 percent and ≥ 20 percent, respectively, with the most sensitive individuals experiencing FEV_1 decreases as large as 40 percent to 50 percent at 6– to 8–hour exposures in the range of 0.08 ppm to 0.10 ppm in controlled human studies), and moderate to severe symptoms as being adverse.

3. *Exposure and risk assessments*. To put judgments about health effects that are adverse for individuals into a broader public health context, EPA conducted quantitative assessments to estimate O_3 exposures and related risks for the general population and two at-risk groups, ''outdoor children'' and ''outdoor workers,'' living in nine representative U.S. urban areas. This broader context included consideration, to the extent possible, of the size of the particular population groups identified as at risk for various effects, the estimated number of people within at-risk groups likely to experience O_3-related adverse effects, the estimated number of occurrences of such effects, and the estimated number of people who would experience exposures of concern[5] associated with various air quality scenarios representing attainment of the current and alternative 8–hour standards. Consideration was also given to the kind and degree of uncertainties inherent in assessing such exposures and risks. Such considerations provided a basis for judgments discussed in the proposal about the levels of exposure and risk associated with the current and alternative standards, which helped inform judgments about the adequacy of public health protection afforded by the current and alternative standards.

Risk estimates were developed for those effects for which sufficient concentration-response information was available from studies evaluated in the Criteria Document, including adverse lung function and respiratory symptom responses. In a separate analysis, excess respiratory hospital admissions for individuals with asthma associated with attainment of alternative standards were also estimated, using a risk model for this health endpoint based on the results of an epidemiological study in New York City (Thurston et al., 1992) for which adequate air quality information was available to assess population risk[6]. These quantitative risk estimates (for that subset of O_3-related effects for which information is sufficient to conduct such quantitative analyses) add to our understanding of the broader array of health effects that are associated with exposure to O_3 but for which quantitative risk estimates could not be developed.

The methodology, results, and key observations from these assessments were presented in the proposal. The EPA believes, and CASAC concurred, that the models selected to estimate exposure and risk were appropriate and that the methods used to conduct the health risk assessment for adverse lung function and respiratory symptom responses represent the state of the art. Nevertheless, the Administrator and CASAC recognized that there are many uncertainties inherent in such analyses, and that not all uncertainties inherent in such analyses could be quantified and reflected in ranges of risk estimates (Wolff, 1995b), as discussed in the proposal and the referenced technical support documents.

The exposure and risk assessments available at the time of proposal had been conducted to evaluate the O_3 exposures and risks associated with attainment of the current 1–hour standard and various alternative 8–hour standards under consideration early in the standards review process when the assessments were initiated. The EPA and CASAC recognized at that time that additional alternative standards might need to be analyzed later in the review process. Upon deciding to propose a standard with a concentration-based form in the Fall of 1996, EPA staff initiated supplemental analyses to estimate exposures and risks[7] for the

[5] ''Exposures of concern'' refer throughout to exposures at and above 0.08 ppm, 8–hour average, at which a range of health effects have been observed in controlled human studies, but for which data were too limited to allow for quantitative risk assessment.

[6] This study is one of several studies, mainly conducted in the northeastern portion of the United States and southeastern Canada, reporting excess daily respiratory-related hospital admissions associated with elevated O_3 levels within the general population and, more specifically, for individuals with asthma.

[7] The analyses were conducted for the at-risk population of outdoor children, the group with the highest exposures and risks. Outdoor children are the subset of children between the ages of 6 and 18 years old who tend to be active outdoors, and include approximately over 30 percent to 45

specific standard to be proposed and alternative standards on which the proposal solicited comment. In conducting these supplemental analyses, several technical changes were made based on insights gained from the initial analyses.[8] The supplemental assessment (Richmond, 1997) was placed in the docket and on the TTN on February 12, 1997, and its availability was announced in the **Federal Register** notice extending the public comment period on the proposal, providing the public the opportunity to comment on the supplemental assessment (61 FR 7743, February 20, 1997).

Key observations and results from the initial and supplemental exposure and risk assessments that are most pertinent to the decision to revise the current primary standard are highlighted in the following unit, together with discussion of the key issues raised in public comments on the methodology and public health implications of these assessments.

B. Elements of the Primary Standard

In selecting a primary standard for O_3, the Administrator must specify: Averaging time, O_3 concentration (i.e., level), and form (i.e., the air quality statistic to be used as a basis for determining compliance with the standard).[9] All three of these elements are necessary to define a standard and to determine the degree of public health protection afforded by the standard. The proposal outlined the key factors considered in selecting each of these elements for the proposed standard, as well as the range of options for each element on which the EPA solicited comment. The factors reflect an integration of information on acute and chronic health effects associated with exposure to ambient O_3; expert judgments on the adversity of such effects for individuals; and policy judgments, informed by air quality and exposure analyses and quantitative risk assessment when possible, as to the point at which risks would be reduced sufficiently to achieve protection of public health with an adequate margin of safety.

This approach to selecting a primary standard was endorsed by CASAC (Wolff, 1995b), particularly through its advice to the Administrator that ''EPA's risk assessments must play a central role in identifying an appropriate level'' and its recognition that ''the selection of a specific level and [form] is a policy judgment.'' Further, it was the consensus view of CASAC that the ranges of 8–hour average levels (0.07 to 0.09 ppm) and forms (concentration-based forms that generally allow for 1 to 5 exceedances) on which the proposal solicited comment were appropriate.

The following discussion focuses primarily on those considerations that were most influential in the Administrator's final decisions on these elements, taking into account the comments received on the range of options identified in the proposal.

1. *Averaging time*. In proposing to change the averaging time of the primary standard from 1 to 8 hours, the Administrator was concurring with the unanimous recommendation of CASAC (Wolff, 1995b) ''that the present 1–hour standard be eliminated and replaced with an 8–hour standard,'' and that more research is needed to resolve uncertainties about potential chronic effects before appropriate consideration can be given to establishing a long-term (e.g., seasonal or annual) primary standard. The Administrator's proposed decision was supported by the following key observations and conclusions:

(1) The 1–hour averaging time specified in the current NAAQS was originally selected primarily on the basis of health effects associated with short-term (i.e., 1– to 3–hour) exposures, with qualitative consideration given to preliminary information on potential associations with longer exposure periods.

(2) Substantial new health effects information available for consideration in this review demonstrates associations between a wide range of health effects and prolonged (i.e., 6– to 8–hour) exposures below the level of the current 1–hour NAAQS.

(3) Results from the quantitative risk analyses show that attaining a standard with a 1-hour averaging time reduces the risk of experiencing health effects associated with both 1–hour and 8–hour exposures. Likewise, attaining an 8–hour standard reduces the risk of experiencing health effects associated with both 8–hour and 1–hour exposures. Thus, reductions in risks from both short-term and prolonged exposures can be achieved through a primary standard with an averaging time of either 1 or 8 hours. As a result, establishment of both 1–hour and 8–hour standards would not be necessary to reduce risks associated with the full range of observed acute health effects.

(4) The 8–hour averaging time is more directly associated with health effects of concern at lower O_3 concentrations than is the 1–hour averaging time. It was thus the consensus of CASAC ''that an 8–hour standard was more appropriate for a human health-based standard than a 1–hour standard.'' (Wolff, 1995b)

(5) While there is a large animal toxicology database providing clear evidence of associations between long-term (e.g., from several months to years) exposures and lung tissue damage, with additional evidence of reduced lung elasticity and accelerated loss of lung function, there is no corresponding evidence for humans. Moreover, the state of the science has not progressed sufficiently to permit quantitative extrapolation of the animal-study findings to humans. Thus, the Administrator concluded that consideration of a separate long-term primary O_3 standard is not appropriate at this time. As discussed below, however, the Administrator considered the possibility of long-term effects in selecting the level of an 8–hour standard, which will provide protection against such effects to the extent they may occur in humans, by lowering overall air quality distributions and, thus, reducing cumulative long-term exposures.

The public comments reflect broad support for a standard with an 8–hour averaging time, either alone or in conjunction with a 1–hour standard. This support was typically based on references to:

(1) Evidence of health effects from 6– to 8–hour exposures to O_3 concentrations down to 0.08 ppm, which are lower than those concentrations that have induced such effects after 1– to 3–hour exposures, and which are lower than the 0.12 ppm level of the current standard.

(2) Analyses indicating that an 8–hour standard would limit both 1– and 8–hour exposures.

(3) CASAC's unanimous agreement that the current 1–hour standard should be replaced by an 8–hour standard. In considering the adequacy of the current 1–hour standard alone in light of the health effects evidence, some commenters have highlighted the statement in the Criteria Document that there is ''strong evidence that ambient exposures to O_3 can cause significant exacerbations of preexisting respiratory disease in the general public at concentrations below 0.12 ppm.'' (U.S. EPA, 1996a, p. 7–171)

Commenters expressing support for an 8–hour averaging time included not only those who supported a level of public health protection consistent with

percent of all children in this age group in the nine urban areas analyzed.

[8] These changes primarily focused on the air quality data used in the exposure analysis and on the air quality adjustment procedures used to simulate ambient O_3 concentrations upon attainment of alternative standards.

[9] This review focused only on a standard for O_3, as the most appropriate surrogate for photochemical oxidants.

or greater than that reflected by EPA's proposed standard, but also many who disagreed for various reasons with the need for increased public health protection beyond that provided by the current standard. Of those supporting an 8–hour averaging time but not supporting the need for increased protection, some expressed the view that the averaging time of a health-based standard should be consistent with the exposures of most concern, while others were simply neutral between the choices of retaining the current 1–hour standard and replacing it with an ''equivalent'' 8–hour standard.

The EPA agrees with the considerations raised by those commenters who favor an 8–hour standard. Further, in considering the appropriateness of an 8–hour standard as compared to a 1–hour standard, EPA also notes the results of its exposure and risk assessments which show variability across the nine urban areas analyzed with regard to the extent to which the current 1–hour standard, and alternative 8–hour standards, limit 8–hour exposures of concern and associated risks of adverse health effects. As noted in the proposal and in the supplemental risk assessment, there is much greater variability across urban areas, particularly in looking at the seven current nonattainment areas examined, in the extent to which the current 1–hour standard limits such exposures of concern and risks than for the alternative 8–hour standards. For example, the updated assessment estimates that the current 1–hour standard results in 8–hour exposures of concern at and above 0.08 ppm[10] that vary by almost two orders of magnitude across these areas. In contrast, alternative 8–hour standards at the proposed level of 0.08 ppm result in estimated 8–hour exposures of concern and risks that are much more consistent.[11] In EPA's view, the fact that an averaging time of 8 hours results in a significantly more uniformly protective national standard than the current 1–hour standard is an important public health policy consideration that supports the selection of an 8–hour averaging time.

Those commenters who did not support EPA's proposal for an 8–hour averaging time generally did not support any revision to the current standard. These commenters predominantly focused on two basic points: The generally improving trends in air quality under the current standard and associated air quality management programs, which, commenters argued, suggest that there is no need for EPA to adopt any more stringent standard; and observations made in CASAC's closure letter (Wolff, 1995b) with regard to EPA's risk assessment not demonstrating any ''bright line'' threshold of effects or acceptable risk. With regard to the first issue, EPA agrees that air quality trends are improving as a consequence of ongoing control programs designed to attain the current NAAQS. The EPA does not, however, believe that these trends relieve the Agency of its statutory mandate to review and, if appropriate, revise the NAAQS on the basis of the best available scientific evidence to establish standards that protect public health with an adequate margin of safety. The fact that current control programs are resulting in progress toward improving air quality does suggest that it is important to ensure that such progress is maintained during any transition to a revised standard.

With regard to the second issue, commenters very frequently quoted from the CASAC closure letter (Wolff, 1995b) stating ''that there is no bright line' which distinguishes any of the proposed standards (either the level or the number of allowable exceedances) as being significantly more protective of public health'' and that ''the selection of a specific level and number of allowable exceedances is a policy judgment.'' These commenters have variously interpreted these statements as a CASAC consensus that the differences in the public health protection afforded by any of the alternative standards were too small to be important from a public health perspective, not statistically significantly different, or simply not different at all. Based on these interpretations, the commenters argued that it is not appropriate to revise the standard in any way, because a revised standard would result in disruption to ongoing programs, additional planning requirements, and increased implementation costs, but would provide no or only very little improvement in public health protection.

The EPA believes that these commenters have misconstrued or too narrowly interpreted CASAC's advice to the Administrator by not considering the entire range of views and recommendations included in its closure letter. Specifically, CASAC began its summary of recommendations to the Administrator (Wolff, 1995b) by stating that ''[t]he Panel was in unanimous agreement that the present 1–hour standard be eliminated and replaced with an 8–hour standard.'' This agreement was based on ''the consensus of the Panel that an 8–hour standard was more appropriate for a human health-based standard than a 1–hour standard.'' Thus, CASAC was unequivocal in its advice to the Administrator with regard to which averaging time the health effects evidence more strongly supports. While some commenters have also quoted statements by individual Panel members at CASAC meetings suggesting that choosing between a 1– or 8–hour averaging time is a ''policy'' choice, these individual statements during the course of CASAC's review do not contradict nor supersede the clear and unanimous agreement of CASAC on averaging time as conveyed to the Administrator in its closure letter.

In considering these comments, EPA also believes it is important to put into a public health perspective CASAC's observations about the differences among alternative standards in protecting the public from the health effects that were quantitatively estimated in EPA's risk assessment. In the closure letter (Wolff, 1995b), CASAC observed that ''the differences in the percent of outdoor children *** responding between the present standard and the most stringent proposal *** are small and their ranges overlap for all health endpoints.'' Most importantly, EPA notes that the primary standard would provide protection from a broader array of health effects than it was possible to consider in its quantitative risk assessment. This perspective is clearly shared in particular by those CASAC panel members who personally favored a level or range of levels that included the proposed level of 0.08 ppm, in that the closure letter characterizes their views as reflecting, in part, their ''concern over the evidence for chronic deep lung inflammation from the controlled human and animal exposure studies.'' While the risk of this effect, as well as other effects related to 6– to 8–hour exposures in the Criteria Document and Staff Paper (including increased airway responsiveness, impairment of host

[10] More precisely, exposures at and above 0.08 ppm refers to estimates of exposures to O_3 concentrations ≥ 0.081 ppm from the exposure assessment.

[11] In terms of the percent of outdoor children estimated to be exposed to O_3 concentrations at and above 0.08 ppm while engaged in moderate exertion, the current 1–hour standard results in a range across the seven nonattainment areas of approximately 0.3 percent to 24 percent of such children, whereas alternative 8–hour standards, at the proposed level of 0.08 ppm, result in a significantly more uniform degree of protection, with ranges of approximately 2 percent to 9 percent, third-highest concentration form, and 3 percent to 11 percent, fifth-highest concentration form, across the areas.

defenses suggesting an increased susceptibility to respiratory infection, and increased emergency room visits, doctor visits, and frequency of medication use by individuals with impaired respiratory systems) could not be quantitatively estimated in EPA's risk assessment, EPA believes that consideration of these effects is nevertheless important in making public health policy judgments.

Further, in interpreting CASAC's statements on EPA's risk assessment report (Whitfield et al., 1996) that there is no ''bright line'' which distinguishes any of the standards as being ''significantly'' more protective, and that the ''ranges overlap,'' EPA notes that there are statistically significant differences in the estimated risks for the standards analyzed with 1- and 5-exceedance forms. This information was presented to CASAC at its September 1995 meeting (CASAC meeting transcript, September 19–20, 1995, pp. 108–109). Further, EPA again notes that whether one judges the differences to be significant or small can depend on whether one focuses on percentages, as CASAC's letter did, or on total numbers of times that children or other at-risk individuals experience such effects. The overlap in the ranges of risk referred to in the CASAC letter reflect differences among urban areas used in EPA's risk analysis (e.g., air quality, exposure patterns, environmental factors), not random uncertainties in risk estimates within any given urban area. Thus, the fact that the ranges overlap does not mean that there are no real or statistically significant differences in protection among alternative standards. To the extent that the quoted statements from CASAC's closure letter are read as implying that CASAC considered the differences not to be statistically significant (or that there are no differences at all in the protection afforded by the alternative standards), EPA disagrees with that reading.

Another group of commenters, while supporting an 8–hour standard, specifically opposed replacing the current 1–hour standard with an 8–hour standard, but favored instead both 8–hour and 1–hour standards. These commenters generally felt that a greater degree of public health protection than that provided by the proposed standard was warranted, and that standards based on both averaging times were necessary to provide the requisite protection from 1– and 8–hour exposures of concern. These commenters generally argued that an 8–hour standard alone could still allow for high 1–hour exposures of concern, or that the retention of the current 1–hour standard was critical to maintaining current pollution control measures. As an initial matter, EPA is delaying revocation of the 1–hour standard to ensure an effective transition to the 8–hour standard, as discussed in Unit II.B.4 of this preamble. While EPA agrees that it is possible that an 8–hour standard alone could allow for high 1–hour exposures of concern, at and above 0.12 ppm,[12] EPA's exposure assessments estimate that alternative 8–hour standards, at the proposed level of 0.08 ppm but with different forms, would be very effective in limiting 1–hour exposures, and generally even more effective in limiting 1–hour exposures of concern than is the current 1–hour standard. More specifically, the updated assessment estimates that upon attainment of alternative 8–hour, 0.08 ppm standards, with forms ranging up to the fifth-highest concentration form, less than 0.1 percent of outdoor children are likely to experience any 1–hour exposures greater than 0.12 ppm while at heavy exertion levels in four to seven of the nine urban areas analyzed, whereas this is true for only two of the nine areas upon attainment of the current 1–hour standard. In all nine areas both the current and alternative 8–hour, 0.08 ppm standards are estimated to limit such exposures to less than 1 percent of the outdoor children. Thus, EPA concludes that an 8–hour averaging time does effectively limit both 1– and 8–hour exposures of concern.

For the reasons discussed above in this unit, and after taking into account the range of views expressed in the public comments, the Administrator finds that replacing the current 1–hour standard with an 8–hour standard, in combination with the decisions on level and form described below, is appropriate to provide adequate and more uniform protection of public health from both short-term (1 to 3 hours) and prolonged (6 to 8 hours) exposures to O_3 in the ambient air.

2. *Level.* Taken together, the level and form of the standard, for a given averaging time, determine the degree of public health protection afforded by the standard. Consideration of the level of the standard discussed in this unit of the preamble reflects a recognition of this linkage between level and form (discussed separately below in Unit II.B.3).

The Administrator's decision to propose the level of an 8–hour primary O_3 standard at 0.08 ppm, and to solicit comment on alternative levels, necessarily reflected a recognition, as emphasized by CASAC, that it is likely that ''O_3 may elicit a continuum of biological responses down to background concentrations'' (Wolff, 1995b). Thus, in the absence of any discernible threshold, it is not possible to select a level below which absolutely no effects are likely to occur. Nor does it seem possible, in the Administrator's judgment, to identify a level at which it can be concluded with confidence that no ''adverse'' effects are likely to occur. In such a case, as CASAC has advised, the traditional paradigm for standard-setting cannot be applied in the usual way, and assessments of risk ''must play a central role in identifying an appropriate level'' (Wolff, 1995b). Thus, the Administrator's task became one of attempting to select a standard level that would reduce risks sufficiently to protect public health with an adequate margin of safety, since a zero-risk standard is neither possible nor required by the Act. In this and other NAAQS reviews the CASAC has generally recognized that the selection of specific standards requires that the Administrator make public health policy judgments in addition to determinations of a strictly scientific nature. The Administrator's public health policy judgment on the level of the proposed standard was framed by the considerations discussed above in this unit and informed by the following key observations and conclusions:

(1) During the last review of the O_3 criteria and standards, CASAC concluded that the existing 1–hour standard set at 0.12 ppm O_3 provided ''little, if any, margin of safety,'' and that the upper end of the range of consideration for a 1–hour standard should be 0.12 ppm (McClellan, 1989). In addition, several members of the CASAC panel recommended that consideration should be given to a lower 1–hour level of 0.10 ppm to offer some protection against effects for which there was preliminary information at that time of associations with 8–hour exposures to O_3.

Regarding currently available evidence of O_3-related effects:

(2) Based on a significant body of information available since the last review, there is now clear evidence from human clinical studies that O_3 effects of concern are associated with the 6– to 8–hour exposures tested. Studies were done at 6– to 8–hour exposure levels of 0.12, 0.10, and 0.08 ppm. This includes evidence of the following statistically significant responses at 6– to 8–hour exposures to the lowest concentration evaluated, 0.08 ppm O_3, at moderate

[12] The EPA recognizes this possibility exists especially in the very few areas with unusually ''peaky'' air quality patterns (i.e., in which the ratio of the 1– and 8–hour average design values for the current and proposed standards is greater than 1.5).

exertion: lung function decrements, respiratory symptoms (e.g., cough, pain on deep inspiration), nonspecific bronchial responsiveness, and biochemical indicators of pulmonary inflammation. Field studies provide evidence of similar functional and symptomatic effects at ambient O_3 exposures that are consistent with the clinical findings. Laboratory animal studies provide supporting evidence of O_3-induced biochemical indicators of inflammation and functional changes.

(3) Numerous epidemiological studies have reported excess hospital admissions and emergency department visits for respiratory causes (for asthmatic individuals and the general population) attributed primarily to ambient O_3 exposures, including O_3 concentrations below the level of the current standard, with no discernible threshold at or below this level. The biological plausibility of attributing such effects to ambient O_3 exposures is supported by human studies showing increased nonspecific bronchial responsiveness, laboratory animal studies showing pulmonary changes that decrease the effectiveness of the lung's defenses against bacterial respiratory infections, and the reasonable anticipation that O_3 exposures also increase the risk of respiratory infections in humans, based on the many similarities between animal and human defense mechanisms.

(4) Long-term laboratory animal studies suggest that changes in lung biochemistry and structure may, under certain circumstances, become irreversible, although it is unclear whether long-term exposures to ambient O_3 levels result in similar chronic health effects in humans.

Regarding the types and severity of O_3-induced physiological effects that are considered to be adverse to the health status of individuals experiencing such effects:

(5) With regard to lung function decrements and respiratory symptoms, the Administrator recognized that these O_3-induced effects are transient and reversible, and concluded that the extent to which such effects are adverse to the health status of an individual depends upon the severity, duration, and frequency with which an individual experiences such effects throughout the O_3 season. While group mean responses in clinical studies at the lowest exposure level tested of 0.08 ppm are typically small or mild in nature, responses of some sensitive individuals are sufficiently severe and extended in duration to be considered adverse. This would especially be true to the extent that those individuals likely to experience such effects would, on average, experience them several times a year.

(6) With regard to increased hospital admissions and emergency room visits, the Administrator judged that such effects are clearly adverse to individuals.

(7) With regard to pulmonary inflammation, the Administrator recognized that singular occurrences of inflammation are likely reversible and potentially of little health significance. On the other hand, based on laboratory animal studies, repeated inflammatory responses associated with exposure to O_3 over a lifetime have the potential to result in damage to respiratory tissue such that individuals later in life may experience a reduced quality of life. Furthermore, there is the possibility that repeated pulmonary inflammatory responses could adversely affect asthmatic individuals by resulting in increased medication use, medical treatment, and/or emergency room visits and hospital admission. Such effects in asthmatics are of special concern particularly in light of the growing asthma problem in the United States and the increasing rates of asthma-related mortality and hospitalizations, especially among children in general and black children in particular. While O_3 has not been shown to cause asthma, the available evidence suggests that O_3 may exacerbate asthma. Accordingly, the Administrator judged that repeated exposures to O_3 levels that produce inflammation of the lungs are adverse to individuals likely to experience such exposures over long periods of time.

The Administrator considered the results of the exposure and risk analyses and the following key observations and conclusions from these analyses in putting effects considered to be adverse to individuals into a broader public health perspective and in making judgments about the level of a standard that would reduce risk sufficiently to protect public health with an adequate margin of safety:

(8) The median risk estimates for respiratory functional and symptomatic effects, as well as for excess hospital admissions of asthmatics for respiratory causes, are approximately the same or only marginally smaller for some of the 8–hour, 0.09 ppm standard options evaluated (including those with forms ranging from 1- to 3-expected-exceedances[13]) as compared to the current 1–hour, 0.12 ppm NAAQS (risk estimates are somewhat larger for an 8–hour, 0.09 ppm, 5-expected-exceedance standard as compared to those for the current NAAQS).

(9) Within any given urban area, statistically significant reductions in exposure and risk associated with respiratory functional and symptomatic effects result from alternative 8–hour standards as the level changes from 0.09 ppm to 0.08 ppm to 0.07 ppm. These reductions represent differences of hundreds of thousands of times that children in the nine urban areas included in the analysis would likely experience such effects under the range of alternative standards considered relative to the current standard. There are significant uncertainties in such quantitative estimates, however, and there is no break point or bright line that differentiates between acceptable and unacceptable risks within this range.

(10) Similarly, reductions in hospital admissions for respiratory causes for asthmatic individuals and the general population are estimated to occur with each change in the level of the standard from 0.09 ppm to 0.08 ppm to 0.07 ppm. However, hospital admissions for asthmatic individuals associated with ambient O_3 exposures within the range of standard levels under consideration represent a relatively small fraction of the total respiratory-related hospital admissions for asthmatics over the O_3 season.

(11) Estimated exposures to O_3 concentrations at and above 0.08 ppm (at which increased nonspecific bronchial responsiveness, decreased pulmonary defense mechanisms, and indicators of pulmonary inflammation have been observed in humans) while engaged in moderate exertion are essentially zero at the 0.07 ppm standard level (with a 1-expected-exceedance form) for the seven nonattainment areas evaluated in the exposure analyses for the at-risk population of outdoor children. Such exposures of outdoor children increase to approximately 0 to 1 percent at the 0.08 ppm standard level, while the estimated range at the 0.09 ppm standard level increases to approximately 3 to 7 percent of outdoor children for these areas.

(12) While recognizing that sensitive individuals may experience adverse but transient effects with a standard set at 0.08 ppm, no CASAC panel member supported selection of 0.07 ppm as the level of a primary standard. Of the

[13] The upper end of this range, 3-expected-exceedances, was based on air quality comparisons, since risk estimates were only available at the time of proposal for the 1– and 5-expected-exceedance forms of a 0.09 ppm standard. This range is consistent with the results of the updated risk assessment.

members who expressed their personal views, three indicated a preference for a level of 0.08 ppm, one for a range of 0.08 to 0.09 ppm, three for a level of 0.09 ppm (with one of the three expressing a preference for selecting a form that would result in equivalent protection to the current standard), and one for a range of 0.09 to 0.10 ppm, associated with public advisories for O_3 levels at and above 0.07 ppm. Other CASAC panel members also expressed support for such public notices or advisories reflecting potential effects for extremely sensitive individuals associated with O_3 levels as low as 0.07 ppm.

These observations and conclusions resulted in the Administrator focusing in particular on the alternative levels of 0.08 ppm and 0.09 ppm, having placed great weight on the fact that none of the CASAC panel members expressed support for a standard set below 0.08 ppm. In deciding between these two levels, the Administrator took into account quantitative estimates of the risks associated with attaining standards set at these levels for those effects for which such quantitative risk estimates could be developed. Other factors that were important in the Administrator's proposed decision include:

(1) Quantitative estimates of 8–hour exposures of concern (i.e., at and above 0.08 ppm) associated with these standard levels.

(2) The consistency of the clinical, field, and epidemiological studies, in which effects were seen not only from controlled exposures to 0.08 ppm, but also in ambient environments in which 8–hour average O_3 concentrations ranged from above to below the 0.08 ppm level.

(3) The importance of increased protection for those sensitive individuals who may experience respiratory symptomatic and functional effects at lower O_3 concentrations than the population as a whole.

(4) The uncertainties in considering the potentially more serious but as yet uncertain chronic effects.

As discussed above in Unit II.A.3., EPA completed and made available for public comment supplemental exposure and risk assessments subsequent to the proposal. For any of the alternative standards considered in the assessment, the new estimates of exposures at and above 0.08 ppm are somewhat higher than those available at the time of proposal, while the new estimates of risks, for adverse effects including moderate and large decreases in lung function, moderate to severe respiratory symptoms, and hospital admissions for asthmatics, are lower. However, the relative differences in estimated exposures and risks between alternative standard levels remain about the same as at the time of proposal. Thus, while the Administrator's final decision takes into account the more recent assessments, the differences in the quantitative results between the initial and supplemental assessments do not fundamentally alter the basis for the judgments expressed at the time of proposal.

To aid in comparing the public health protection associated with 8–hour standards at the 0.08 ppm and 0.09 ppm levels, observations from the updated exposure and risk assessments for all nine urban areas evaluated are summarized below (assuming the third-highest concentration form, which was the upper end of the range of consideration for forms for the 0.09 ppm level).

(1) The percentages of outdoor children exposed to O_3 concentrations at and above 0.08 ppm (at which increased nonspecific bronchial responsiveness, decreased pulmonary defense mechanisms, and indicators of pulmonary inflammation have been observed in humans) while engaged in moderate exertion are estimated to be approximately 3 percent at the 0.08 ppm standard level, ranging from approximately 2 percent to 10 percent in the nine areas, increasing to approximately 11 percent at a standard level of 0.09 ppm, ranging from approximately 7 percent to 29 percent in the nine areas.

Updated risk estimates in terms of the percentages[14] and numbers of outdoor children estimated to experience various health effects, and the total numbers of occurrences of these effects in outdoor children, upon attainment of these two alternative standards for all nine urban areas combined[15] are as follows:

(2) For moderate lung function (FEV_1) decreases ≥ 15 percent, approximately 6 percent of outdoor children (180,000 children) would experience this effect one or more times per year (650,000 occurrences) at the 0.08 ppm standard level, increasing to approximately 8 percent of outdoor children (250,000 children and 1,100,000 occurrences) at the 0.09 ppm standard level.

(3) For large lung function (FEV_1) decreases ≥ 20 percent, approximately 2 percent of outdoor children (58,000 children) would experience this effect one or more times per year (100,000 occurrences) at the 0.08 ppm standard level, increasing to approximately 3 percent of outdoor children (97,000 children and 220,000 occurrences) at the 0.09 ppm standard level.

(4) For moderate or severe pain on deep inspiration, approximately 0.9 percent of outdoor children (27,000 children) would experience this effect one or more times per year (120,000 occurrences) at the 0.08 ppm standard level, increasing to over 1 percent of outdoor children (41,000 children and 220,000 occurrences) at the 0.09 ppm standard level.

Many public commenters supported EPA's proposed level of 0.08 ppm for an 8–hour standard, including most public health associations and groups of medical professionals, many citizens, and some States and regional associations. There were also large numbers of commenters who expressed strong views in opposition to the proposed level. Of those who did not support the proposed 8–hour level, almost all commenters representing businesses and industry associations, many local governmental groups and private citizens, and some States either supported no change to the current standard or, if EPA were to replace the current 1–hour standard with an 8–hour standard, supported a level of 0.09 ppm directly or simply one that would be ''equivalent'' to the current standard. On the other hand, environmental groups, many citizens, and some medical professionals and researchers supported a level of 0.07 ppm for an 8–hour standard.

In general, the issues raised by these groups of commenters can be addressed in three categories: Comments on the strength and adequacy of the health effects evidence upon which the proposed decision was based, comments on the quantitative exposure and risk assessments and the extent to which the assessments either over- or under-predict exposures and risks among sensitive populations, and judgments as to whether the differences in public health protection provided by alternative standards are significant from a public health perspective. Each of these categories of key issues is discussed separately below.

With regard to the first category of comments, on the strength and adequacy of the health effects evidence, commenters who did not support the need for any increased protection beyond that provided by the current standard questioned the adequacy or highlighted the limitations of the

[14] These updated risk estimates in terms of the percentage of outdoor children in the nine urban areas are roughly comparable to the range of original estimates presented in Table 1 of the proposal for 1- and 5-expected-exceedance forms of the standards.

[15] Approximately 3.1 million outdoor children reside in these nine urban areas.

various types of health effects studies that have related O_3 exposures to adverse effects. For example, some commenters questioned the controlled human exposure studies, arguing that: Many such studies used patterns of exposures and exercise levels that are not representative of normal population exposures to ambient O_3; some exposure chambers using artificially generated O_3 may have been contaminated with other pollutants that could have accounted for some of the observed effects; and responses to elevated O_3 levels were compared to responses to air with essentially no O_3 rather than to background levels typical of ambient air. Some commenters argued that these flaws in the study designs would result in overestimating responses to non-background levels of ambient O_3 or in erroneous findings of statistical significance. In contrast, others commented that because the chambers did not contain other pollutants and natural pulmonary irritants (e.g., pollens, dust) or a full range of environmental conditions (e.g., high temperatures and humidity) typical of ambient air, the results may underestimate the true impact of O_3 in the ambient air.

Some commenters also questioned the summer camp and other field studies and epidemiological studies reporting increased hospital admissions and emergency room visits, arguing that: The responses in these studies were inherently confounded by exposures to other pollutants, the camp studies did not differentiate activity levels of the participants, and linear regression down to or below background levels was unjustifiably used to analyze the results of the hospital admission studies. These commenters expressed the view that these and other flaws call into question any conclusions about whether the reported associations are causal. In contrast, other commenters argued that the hospital admissions reported in these studies are indicative of a pyramid of adverse health effects, including increased mortality, increased visits to emergency and outpatient departments and physicians, increased numbers of asthma attacks resulting in increased medication use, and increased numbers of restricted activity days and acute respiratory symptom days, that EPA has not adequately taken into account. The EPA notes that these comments are consistent with statistics published by the U.S. Department of Health and Human Services, which indicate that for every hospital admission of an individual with asthma for respiratory causes, there are more than five emergency and outpatient department visits and more than 20 office-based physician visits (U.S. DHHS, 1996).

With regard to studies related to pulmonary inflammation and chronic respiratory damage, some commenters argued that the linkage between repeated inflammatory responses and chronic respiratory damage was merely speculation, and, therefore, should not be considered as part of the basis for decisions on the primary standard. In contrast, others commented that animal studies had demonstrated that repeated pulmonary inflammation leads to degenerative or irreversible lung damage, that these studies are consistent with observations in human exposure studies, and, therefore, that they should be considered in decisions on the standard.

The EPA notes that many of these comments did not reflect an integrative assessment of the evidence—the approach CASAC has historically urged EPA to follow—but rather a piecemeal look at each individual study or type of study, which tends to miss the strength of the entire body of evidence taken together. Other commenters did consider the body of evidence in a more integrative manner, and many of these commenters expressed the view that the body of evidence as a whole provided clear evidence of O_3-related effects at and below O_3 concentrations allowed by the current standard. Some commenters highlighted the large number of studies that demonstrate evidence of effects for prolonged exposures at and below 0.08 ppm, and criticized EPA for giving too little weight to those studies which reported serious effects, but for which the data were not sufficient to do quantitative risk assessments.

With regard to the second category of comments, on the exposure and risk assessments, a number of commenters raised concerns about key aspects of the assessments, including the exposure model, the development of concentration-response functions, the application of the risk model, and the measures of risk used to characterize the results of the assessments. With regard to the exposure model, a number of commenters claimed that: The model overestimates the exertion level that can be achieved by most children and outdoor workers and the fraction of time that these groups spend in moderate or heavy exertion; the model overestimates outdoor ambient exposures because fixed-site monitors overestimate outdoor personal exposures; and the air quality adjustment procedures used to simulate attainment of the standards are inappropriate or highly uncertain. Other commenters expressed concern that the exposure model may be significantly underestimating exposures for children and outdoor workers who repeatedly exercise due to limitations in the available human activity pattern data.

As discussed in the proposal, EPA recognizes that the exposure model necessarily contains many sources of uncertainty, although every effort has been made to account for such uncertainties to the extent possible. In particular, the model incorporates and is sensitive to analytical procedures used to simulate spatial and temporal distributions of O_3 concentrations that would occur as a result of an area just attaining any of the alternative standards addressed in the exposure assessment. These air quality adjustment procedures are based on generalized models intended to reflect the patterns of changes in distributions of O_3 concentrations that have historically been observed in areas implementing control programs designed to attain the O_3 NAAQS. The EPA recognizes that future changes in air quality distributions are area-specific, and will be affected by whatever specific control strategies are implemented in the future to attain the revised NAAQS. Thus, generalized models are expected to be more uncertain for any given area than when exposure results are aggregated across many areas (as was done across the nine urban areas analyzed in EPA's exposure assessment).

Some commenters questioned the specific air quality adjustment procedure used in the initial and supplemental assessment[16], and a few of these commenters recommended revisions or alternative procedures that they believed would be more representative of historical or projected future air quality patterns. As discussed in more detail in the Response to Comments, EPA acknowledges that both procedures used in the assessments result in projections of air quality that deviate to some degree from historical patterns of air quality changes observed in specific urban areas, and that other procedures may be more representative of air quality patterns in specific areas. While EPA will take these comments into account as future refinements are made to the air quality adjustment

[16] The initial risk assessment used both ''Weibull'' and ''proportional'' air quality adjustment procedures, whereas the supplemental risk assessment used a ''proportional'' air quality adjustment procedure for all nine urban areas. In responding to comments on the air quality adjustment procedures, EPA also evaluated an alternative ''quadratic'' procedure (as discussed in the Response to Comments), which generally resulted in risk estimates between those from the Weibull and proportional procedures.

procedures used in the exposure model, EPA believes, and CASAC concurred, that the procedures used in the assessments conducted as part of this review are reasonable given the uncertainties inherent in projecting future changes in air quality patterns.

In commenting on the air quality adjustment procedure used in the supplemental assessment, some commenters particularly focused on the results for two of the nine areas analyzed in which, contrary to results from the initial assessment, lower risks were estimated for the current standard as compared to the proposed standard. As discussed more fully in the Response to Comments, EPA believes that these results for each area cannot be distinguished within the sensitivity of the alternative air quality adjustment procedures used in the initial and supplemental assessments. Further, EPA notes that these two areas have much higher ratios of peak 1–hour to 8–hour O_3 concentrations than the vast majority of areas in which O_3 is monitored[17], and it is thus reasonable to expect that generalized air quality adjustment procedures would be particularly uncertain for such areas.

Comments focusing on the development of concentration- response functions for use in the risk model have included a number of claims. Some commenters claimed that EPA inappropriately selected studies for developing the functions by excluding studies that reported lower response rates and by using only studies conducted by EPA scientists. Some commenters asserted that contaminants in the controlled exposure chambers may be responsible for some of the effects incorporated into the concentration-response functions for O_3. Further, some commenters asserted that it was inappropriate to extrapolate the concentration-response functions to background levels or to develop concentration-response functions for symptomatic responses in children based on studies of such responses in adults.

Of the comments focusing on the application of the risk model, some commenters claimed that the aggregate risk results were overstated because of: Many of the methodological problems noted in the above summary of comments, the failure to take into account the known attenuation of effects, and the assumption of an inappropriately low background concentration in calculating risks attributable to non-background sources of O_3. On the other hand, other commenters claimed that aggregate risk results were understated because of: Methodological problems, noted above, that underestimate exposures, limiting the analyses to only a subset of adverse health effects rather than estimating the full range of effects that have been attributed to O_3, and by focusing only on nine urban areas rather than projecting risk reductions from alternative standards nationally.

While EPA has included comprehensive responses to these comments in the Response to Comments, most of the issues and concerns raised by commenters concerning the health effects evidence and the methods used in the exposure and risk assessments are essentially restatements of concerns raised during the review of the Criteria Document and the development and review of these quantitative assessments as part of the preparation and review of the Staff Paper. EPA presented and the CASAC reviewed in detail the approaches used to assess exposure and health risk, the studies and health effect categories selected for which concentration-response functions were estimated, and the presentation of the exposure and risk results summarized in the Staff Paper. As stated in the proposal, EPA believes and CASAC concurred, that the general models selected to estimate exposure and risk are appropriate and that the methods used to conduct the exposure and risk assessments represent the state of the art. EPA does not believe that the exposure or risk assessments are fundamentally biased in one direction or the other as claimed in some of the comments.

The Administrator and CASAC have recognized, however, that there are many uncertainties inherent in such assessments and that the resulting ranges of quantitative risk estimates do not reflect all of the uncertainties associated with the numerous assumptions inherent in such analyses (Wolff, 1995b). EPA summarized some of the most important caveats and limitations concerning both the exposure analyses and the risk assessments for lung function changes, respiratory symptoms, and hospital admissions in the proposal. A more complete discussion of assumptions and uncertainties is contained in the Staff Paper and technical support documents (Johnson et al., 1996 a,b; Whitfield et al., 1996; Richmond, 1997).

With regard to the third category of comments, reflecting commenters' judgments as to whether the differences in public health protection of alternative standards are significant from a public health perspective, EPA notes that highly divergent judgments were expressed by different groups of commenters. A large number of commenters who expressed the view that the differences in public health protection were not significant or important enough to warrant any standard more stringent than the current standard used CASAC as the basis for their position, as discussed above in Unit II.B.1. on averaging time. Others cited small percentages of outdoor children and other sensitive groups likely to be affected based on EPA's assessment, or even smaller percentages as modified by analyses conducted by the commenter to correct perceived errors in the analyses. In contrast, other commenters cited large total numbers of children likely to be affected, not only for the subset of O_3-related effects and the nine areas analyzed in EPA's assessments, but also for a broader array of related effects projected nationally.

The core issue in this review of the primary O_3 standard, as stated by the Administrator at the time of proposal, is who is to be protected, and from what. Clearly, for pollutants, such as O_3, that have no discernible thresholds for health effects, no standard can be risk-free. The Administrator's task is to select a standard level that will reduce risks sufficiently to protect public health with an adequate margin of safety since a zero-risk standard is neither possible nor required by the Act. As CASAC and the Administrator recognize, the selection of a specific standard level for such pollutants requires public health policy judgments in addition to determinations of a strictly scientific nature.

In making such judgments, the Administrator rejects the notion that because standards cannot be risk-free they should not be revised to provide increased protection for sensitive populations, particularly including children in this case, when available evidence points to greater impacts on public health than had previously been demonstrated. In carefully reassessing both those risks to public health that can be quantified as well as those for which quantitative risk information is more limited, the Administrator has focused on the following comparisons between the degree of public health protection likely to be afforded by an 8–hour standard at the proposed level of 0.08 ppm and an alternative standard set at a level of 0.09 ppm (assuming the same third-highest concentration form):

(1) Based on EPA's updated analyses of estimated moderate or large decreases

[17] The two areas are Houston and parts of Los Angeles county, which are two of only six areas nationwide with peak 1– to 8–hour design value ratios greater than 1.5.

in lung function and moderate to severe pain on deep inspiration in outdoor children in nine urban areas (Richmond, 1997), a standard set at 0.09 ppm would allow approximately 40 percent to 65 percent more outdoor children to experience such effects than would a 0.08 ppm standard, and approximately 70 percent to 120 percent more occurrences of such effects in outdoor children per year.

(2) While only relatively small percentages of outdoor children are estimated to experience such effects, the differences in these percentages between the two standard levels represent tens of thousands more children, and hundreds of thousands more occurrences of adverse effects in these children, in these nine urban areas alone, for a 0.09 ppm standard as compared to a 0.08 ppm standard.

(3) Based on EPA's updated risk assessment of increased hospital admissions in New York City (Richmond, 1997), a standard set at 0.09 ppm would allow approximately 40 more excess hospital admissions of asthmatics within an O_3 season in New York City for respiratory causes as compared to a 0.08 ppm standard, which represents approximately a 40 percent increase in excess O_3-related admissions, but only approximately a 0.3 percent increase in total admissions of asthmatics. The EPA believes that while these numbers of hospital admissions are relatively small from a public health perspective, they are indicative of a pyramid of much larger numbers of related O_3-induced effects, including respiratory-related hospital admissions among the general population, emergency and outpatient department visits, doctors visits, and asthma attacks and related increased use of medication that are important public health considerations.

(4) Based on EPA's exposure analyses in the nine urban areas, a standard set at 0.09 ppm would allow more than three times as many children to experience 8–hour average exposures of concern as would a 0.08 ppm standard, with the number of outdoor children likely to experience such exposures increasing from approximately 100,000 to more than 300,000 in the nine urban areas alone, representing an increase from approximately 3 percent to approximately 11 percent of the outdoor children likely to experience such exposures.

(5) These exposures of concern are judged by EPA to be an important indicator of the public health impacts of those O_3-related effects for which information is too limited to develop quantitative estimates of risk, but which have been observed in humans at a level of 0.08 ppm for 6– to 8–hour exposures. Such effects include the following: increased nonspecific bronchial responsiveness (related, for example, to aggravation of asthma), decreased pulmonary defense mechanisms (suggestive of increased susceptibility to respiratory infection), and indicators of pulmonary inflammation (related to potential aggravation of chronic bronchitis or long-term damage to the lungs).

(6) To put these risks and exposures into broader perspective, EPA notes that approximately 46 million more people, including approximately 13 million more children and 3 million more individuals with asthma, live in areas that would not attain a 0.08 ppm standard compared to a 0.09 ppm standard. The general population as well as children and asthmatics would breathe cleaner air as a direct result of control measures designed to bring areas into attainment with the proposed standard.[18]

While recognizing the inherent uncertainties in these estimates, and after taking into account the range of views and judgments expressed in the public comments, the Administrator finds the public health impacts described in the proposal, as updated above, to be important and sufficiently large as to warrant a standard set at a level of 0.08 ppm, as proposed.

The Administrator recognizes the views of those who argue that similarly large improvements in public health protection would result from a standard set at 0.07 ppm as compared to the proposed standard, such that, based on the same reasoning, the evidence warrants a standard set at 0.07 ppm. In considering these views, the Administrator gives significant weight to the following considerations:

(1) No member of the CASAC panel of experts supported a standard set lower than 0.08 ppm, specifically after considering a range of alternative standards that included 0.07 ppm.

(2) The most certain O_3-related effects, while judged to be adverse, are transient and reversible (particularly at O_3 exposures below 0.08 ppm), and the more serious effects with greater immediate and potential long-term impacts on health are less certain, both as to the percentage of individuals exposed to various concentrations who are likely to experience such effects and as to the long-term medical significance of these effects.

(3) As many commenters have noted, based on information in the Criteria Document with regard to ambient concentrations of O_3 from background sources, an 8–hour standard set at a 0.07 ppm level would be closer to peak background levels that infrequently occur in some areas due to nonanthropogenic sources of O_3 precursors, and thus more likely to be inappropriately targeted in some areas on such sources.

After taking into account the public comments, and for the reasons outlined above, the Administrator finds that a standard set at a level of 0.07 ppm is not requisite to protect public health with an adequate margin of safety.

3. *Form*. The form of the current 1–hour, 0.12 ppm standard is a ''1-expected-exceedance'' form. That is, the current standard is based on the expected[19] number of days per year, on average over 3 years, on which the level of the standard is exceeded, and limits that number of expected exceedances to be less than or equal to 1.0.

In evaluating alternative forms for the primary standard, the adequacy of the public health protection provided was the Administrator's foremost consideration. The Administrator also recognized, however, that concerns have been raised with the current form since it was promulgated in 1979 due to the inherent lack of year-to-year stability in the measure of air quality on which the 1-expected-exceedance form is based.[20] The CASAC specifically took such concerns into account in recommending that the current form be revised and in noting that a more robust, concentration-based form would minimize such instability and provide some insulation from the impacts of extreme meteorological events that are conducive to O_3 formation (Wolff, 1995b). Such instability can have the effect of reducing public health protection by disrupting ongoing implementation plans and associated control programs.

As discussed in the proposal, based on information presented in sections IV. and V.I of the Staff Paper and the advice of CASAC, the Administrator focused her consideration on the following alternatives:

(1) Revising the current 1-expected-exceedance form of the standard to

[18] The EPA anticipates that additional people would be protected through regional measures adopted for purposes of an 8–hour, 0.08 ppm standard.

[19] The term ''expected'' means that the numbers of exceedances per year are averaged over 3 years and may be calculated using specific adjustments to account for missing data.

[20] The 1-expected-exceedance form essentially requires the fourth-highest air quality value in 3 years, based on adjustments for missing data, to be less than or equal to the level of the standard for the standard to be met at an air quality monitoring site.

allow for multiple (up to five) expected exceedances per year, averaged over 3 years. A multiple-exceedance form would be based on a less extreme air quality statistic and, thus, would increase the stability of the expected-exceedance form.

(2) Adopting a concentration-based statistic, such as the 3–year average of the nth-highest daily maximum 8–hour average O_3 concentration, as an alternative to an expected exceedance statistic. Air quality analyses presented in the Staff Paper indicate that the 3–year averages of the annual third-, fourth-, and fifth-highest daily maximum 8–hour concentrations would provide approximately the same health protection as the 3-, 4-, and 5-expected-exceedance forms averaged over the same period, respectively.

It was the consensus of the CASAC Panel that this range of allowable exceedances (i.e., up to 5 exceedances), and the consideration of comparable concentration-based forms, was appropriate. Further, CASAC acknowledged that selecting from within this range of alternative forms is a policy judgment, especially given the nature of the health effects and the absence of a ''bright line'' that clearly differentiates between acceptable and unacceptable risks within this range. All 10 CASAC Panel members who expressed specific opinions on the form of the standard favored one that would allow for multiple exceedances (Wolff, 1995b).

In reaching her proposed decision on the form of an 8–hour standard set at 0.08 ppm, the Administrator had to choose a specific form within the range of up to 5 allowable exceedances or up to the comparable fifth-highest concentration, and either an exceedance-based or a concentration-based form. As discussed in the proposal, in considering possible forms within the range of 1 to 5 exceedances (or their concentration-based counterparts) the Administrator took into consideration aggregate risk estimates for those health effects for which quantitative risk analyses have been done; estimated exposures associated with those effects for which no quantitative risk estimates could be developed; and the magnitude of peak measurements of 8–hour average O_3 concentrations, and the number of days on which the level of the standard would likely be exceeded, based on an analysis of historical air quality data (Freas, 1996). In considering exposure and risk estimates available at the time of proposal for 1– and 5-expected-exceedance forms, the Administrator noted that the level of the standard is a more dominant factor in determining the degree of exposure and risk reductions achieved, with the form being associated with smaller differences in risk estimates within a continuum of risk. In considering air quality comparisons for standards across the range of forms considered, the Administrator focused in particular on the extent to which alternative forms would limit the number of days in which the level of the standard would be exceeded in areas that just attain the standard[21], and the magnitude of peak 8–hour average O_3 concentrations[22] that would occur in such areas.[23] More specifically, the Administrator took into consideration the percentage of monitoring sites just attaining an 8–hour, 0.08 ppm standard that would have 8–hour peak O_3 concentrations above a benchmark level of 0.09 ppm. This benchmark level is the upper end of the range of levels endorsed by CASAC for an 8–hour O_3 standard. The Administrator believes, given the uncertainties associated with this kind of complex health decision, that it is an appropriate goal to limit the percentages of areas experiencing such daily peaks.

In choosing to propose a concentration-based form, the Administrator recognized the advantages of a concentration-based form over an exceedance-based form. As discussed in the proposal, the principal advantage of a concentration-based form is that it is more directly related to the ambient O_3 concentrations that are associated with health effects. That is, given that there is a continuum of effects associated with exposures to varying levels of O_3, the extent to which public health is affected by exposure to ambient O_3 is related to the actual magnitude of the O_3 concentration, not just whether the concentration is above a specified level. With an exceedance-based form, days on which the ambient O_3 concentration is well above the level of the standard are given equal weight to those days on which the O_3 concentration is just above the standard (i.e., each day is counted as 1 exceedance), even though the public health impact on the two days is significantly different. With a concentration-based form, days on which higher O_3 concentrations occur would weigh proportionally more than days with lower O_3 concentrations, since the actual concentrations are used directly in determining whether the standard is attained. A concentration-based form also has greater temporal stability than the expected-exceedance form and, thus, would facilitate the development of more stable implementation programs by the States.

As discussed above in Units II.A.3. and II.B.2., EPA completed and made available for public comment supplemental exposure and risk assessments subsequent to the proposal. These updated assessments, which specifically analyzed the third- and fifth-highest concentration-based forms, aid in comparing the differences in public health protection among alternative concentration-based forms within the range considered in the proposal for 8–hour, 0.08 ppm standards. Based on these updated assessments, the Administrator again notes that the level of the standard is the more dominant factor in determining the degree of risk reduction achieved, with these alternative forms being associated with much smaller differences in risk estimates within a continuum of risk. For example, within the nine urban areas included in the risk assessment, approximately 180,000 outdoor children would experience moderate lung function (FEV_1) decreases ≥ 15 percent upon attainment of an 8–hour, 0.08 ppm standard with a third-highest concentration form, compared to approximately 200,000 outdoor children with a fourth-highest concentration form and 220,000 outdoor children with a fifth-highest concentration form.

The public comments include a large number that specifically addressed the form of the standard. Those commenters who expressed views on the form of the standard can be divided into three groups, according to the level of 8–hour standard and the relative degree of public health protection that the commenter supported. These groups include: Commenters who supported an 8–hour, 0.08 ppm standard to provide increased public health protection relative to the current standard;

[21] Areas that ''just attain the standard'' are defined as those whose design value falls between 0.075 and 0.084 ppm.

[22] Peak 8–hour average concentrations are defined in terms of the fourth-highest daily maximum concentration in 3 years (i.e., the design value for the current 1-expected-exceedance form of the standard).

[23] The results of these air quality analyses are presented in Freas (1996) and summarized in the proposal for the third- and fifth-highest concentration forms and the 3– and 5-expected-exceedance forms. Based on these considerations, and the air quality comparisons in particular, the Administrator judged that the middle of the range of exceedances considered, three expected exceedances, or the comparable third-highest concentration, represented a reasonable policy choice, and proposed the 3–year average of the annual third-highest daily maximum 8–hour average O_3 concentrations as the form of the standard. In recognition of a range of views on the degree of health protection that would be appropriate, she also solicited comment on other concentration-based forms, including the second-, fourth-, and fifth-highest concentration forms.

commenters who supported either an 8–hour, 0.09 ppm standard, or simply an 8–hour standard ''equivalent'' to the current standard; and commenters who supported an 8–hour, 0.07 ppm standard to provide a greater margin of safety than that afforded by the proposed standard.

The first group included many private citizens, some medical professionals and researchers, and some States and local governmental groups. While a number of commenters in the first group specifically supported the proposed third-highest concentration form, generally for the reasons presented in the proposal, others supported either a 1-expected-exceedance form or a concentration-based form in the upper part of the range (i.e., the fourth- or fifth-highest forms). The second group of commenters, which included many local governmental groups and private citizens, some States, and most commenters representing businesses and industry associations, almost exclusively supported a concentration-based form in general, and a form in the upper part of the range (or above the range) in particular. In sharp contrast, the third group of commenters, which included environmental groups, many private citizens, and some medical professionals and researchers, almost exclusively supported a 1-expected-exceedance form in conjunction with an 8–hour, 0.07 ppm standard to provide the largest margin of safety within the range of alternative standards considered.

To the extent that the second and third groups of commenters argued for a different level than the Agency adopts today, the Administrator disagrees with their comments for the reasons set forth in the discussion of the standard level above in Unit II.B.2. To the extent that they argued for more than 5 exceedances (or the concentration-based equivalent), the Administrator disagrees with their views because such forms fall outside the range recommended by CASAC and would provide less public health protection than she deems appropriate. To the extent that the second and third groups of commenters addressed the merits of particular forms within the range of forms considered in the proposal, they raised points similar to those raised by commenters in the first group. These points are discussed below.

Among the commenters in the first group (i.e., those supporting an 8–hour, 0.08 ppm standard to provide increased public health protection), many felt that there was no compelling basis for selecting the third-highest rather than the fourth- or fifth-highest concentration-based form. These commenters frequently quoted CASAC's closure letter (Wolff, 1995b) as stating ''that there is no bright line' which distinguishes any of the proposed standards (either the level or the number of exceedances) as being significantly more protective of public health,'' and that ''the selection of a specific level and number of allowable exceedances is a policy judgment.'' In general, these commenters did not give weight to the air quality comparisons that were a major consideration in the Administrator's decision to propose the third-highest concentration form. Some commenters seem to view such air quality comparisons, particularly with regard to pollutants such as O_3 that have no discernible threshold of effects, as relating more to people's perceptions of how well air pollution is controlled than to any objective measure of actual risks to public health.

These commenters made a number of points in questioning the need to specify an 8–hour, 0.08 ppm standard in terms of the third-highest rather than the fourth- or fifth-highest concentration form. Many noted that a change to an 8–hour averaging time in and of itself would appropriately focus air quality management programs on prolonged exposures of most concern. Further, many noted that a level of 0.08 ppm, regardless of the form within the range of forms considered in the proposal, would provide significantly increased protection from O_3-related risks to public health associated with acute effects (i.e., those resulting from short-term and prolonged exposures) for which they believe there is sufficient evidence to be used as a basis for a standard at this time. Some of these commenters expressed the view that the potential for chronic effects (i.e., those resulting from long-term exposures) would be better addressed through continued research, rather than by adding a greater margin of safety to a revised standard based primarily on effects of short-term and prolonged exposures. Many of these commenters recognized, as did EPA in the proposal, that there is a continuum of risks associated with O_3 exposures, that no standard can therefore be risk-free, and that there are large uncertainties in any estimates of the degree of protection associated with alternative forms. In general, these commenters also noted that, for the same reasons, CASAC advised that the selection of a form from within the range considered in the proposal was a policy judgment, not one that could be decided on the basis of science alone. In essence, these commenters argued that a more restrictive form than the upper part of the range endorsed by CASAC is not requisite to protect public health.

In contrast, other commenters in the first group (i.e., those supporting an 8–hour, 0.08 ppm standard) supported either the proposed third-highest or second-highest concentration form or a 1-expected-exceedance form. These commenters generally gave greater weight to limiting the magnitude of peak O_3 concentrations and the number of days on which the standard level would be exceeded in areas meeting such a standard, and, in some cases, to providing a greater margin of safety to account for potential chronic effects. Such views suggest that limiting the number of days on which the standard level would be exceeded, for example, is an important factor in risk communication and in the public's understanding of the degree to which a standard protects people from exposures to O_3 that may interfere with their ability to engage in normal activities or may result in the need for increased medication or medical treatment, especially for those individuals with asthma or other respiratory diseases. As discussed above in this unit, although some of these commenters felt that the third-highest concentration form would protect public health while also providing increased stability, others expressed concern that public health could be compromised by any form that allowed for multiple exceedances of the standard. The advantages of forms that allow for multiple exceedances, thus providing increased stability as discussed in the proposal, and the views of the CASAC panel members who expressed opinions, all of whom favored such forms, were not given weight by commenters within this group who supported a 1-expected-exceedance form.

The Administrator has carefully reassessed the relative risks to public health of specific forms within the range of the second- to fifth-highest concentration forms or their exceedance-based equivalents, taking into account the public comments summarized above, and the advice from CASAC Panel members that the current form be replaced by a form that allows multiple exceedances. In doing so, the Administrator focused on the following considerations:

(1) The CASAC advised that concentration-based forms, within the range considered up to the fifth-highest concentration form, are appropriate for a health-based primary O_3 standard, and that selection from within this range is a policy judgment that cannot be based

on science alone. This advice reflects CASAC's recognition that O_3 exhibits a continuum of effects, such that there is no discernible threshold above which public health protection requires that no exposures be allowed or below which all risks to public health can be avoided. The CASAC also recognized that a concentration-based form would increase the stability of the standard by providing some insulation from the impacts of extreme meteorological events (Wolff, 1995b).

(2) Estimates of the differences in risk to public health, for those effects that could be considered quantitatively, within a range of alternative forms from the second- to fifth-highest concentrations (for an 8–hour, 0.08 ppm standard) are relatively small compared to the differences between alternative levels. In other words, the choice of level is substantially more important to the degree of public health protection afforded by the standard than the choice of form from within this range of forms.

(3) Measures that distinguish between the alternatives within the range of the second- to fifth-highest forms, based on air quality analyses, reflect considerations related to how some individuals understand the degree to which an air quality standard protects public health. These considerations are a distinct aspect of risk communication to individual citizens even though the days on which exceedances occur are accounted for in EPA's quantitative assessments of risks to public health.

(4) To assess the comparative effect of all forms within the range of the second- to fifth-highest concentration forms, EPA considered air quality comparisons for all such forms (Freas, 1996). These comparisons (based on 1993 to 1995 data) show that 8–hour, 0.08 ppm second- and third-highest concentration standards are very similar in that each standard limits the percent of monitoring sites that would experience peak days above the benchmark level of 0.09 ppm to 1 percent of such sites, and the number of days on which the standards would likely be exceeded in the worst of 3 years would be no more than 6 and 7, respectively. While less restrictive than either of these standards, an 8–hour, 0.08 ppm fourth-highest concentration standard would be significantly more restrictive than a fifth-highest standard. For example, the 8–hour, 0.08 ppm fourth-highest concentration standard would limit the percent of monitoring sites that would experience peak days about the benchmark level of 0.09 ppm to 8 percent of such sites, and the number of days on which the standards would likely be exceeded in the worst of 3 years would be no more than nine. In comparison, the fifth-highest concentration standard would limit the percent of monitoring sites that would experience peak days about the benchmark level of 0.09 ppm to 17 percent of such sites, and the number of days on which the standards would likely be exceeded in the worst of 3 years would be no more than 11.

(5) The extent to which the alternatives within the range of the second- to fifth-highest concentration forms provide protection against the more serious, but less certain effects that have been associated with exposure to O_3, including potential chronic effects, cannot be quantitatively assessed at this time. Given that all such forms would result in significant reductions in exposures to O_3 at and above 0.08 ppm (the level where suggestive evidence of such effects is available), any form within this range would provide some margin of safety against these effects.

Based on these considerations, the available health effects evidence, the quantitative assessments contained in the Criteria Document, Staff Paper, and supplemental analyses and supporting documents, and the range of views and judgments expressed in the public comments on the appropriate form, the Administrator has reconsidered the form of the standard that is requisite to protect public health with an adequate margin of safety. As an initial matter, the Administrator has decided to adopt a concentration-based form which allows for more than one exceedance. While the Adminstrator understands the views of the many citizens who are concerned about a standard that would allow for multiple days on which the level of the standard may be exceeded, the Administrator concludes that such concerns are more relevant for pollutants that exhibit a clear threshold of effects than for pollutants such as O_3 that exhibit a continuum of effects. The Administrator believes that the public health risks associated with such pollutants can be appropriately addressed through a standard that allows for multiple exceedances to provide increased stability, but that also significantly limits both the number of days on which the level may be exceeded and the magnitude of such exceedances. This approach recognizes that exposures associated with such exceedances are already reflected in the exposure and risk assessments that were an important consideration in selecting a 0.08 ppm level for the primary O_3 standard, and that increased stability in the standard is important to avoid disruption to ongoing control programs, and thus to maintain ongoing public health protection.

Having again concluded that a concentration-based O_3 standard that allows for multiple exceedances is appropriate, the Administrator considered the extent to which the form of an 8–hour standard should be selected so as to provide a margin of safety against possible, but uncertain chronic effects. The Administrator carefully considered the views of the many commenters who emphasized the uncertainties in the evidence, primarily from laboratory animal studies, that was available in this review of the criteria and standards to relate long-term exposures to ambient levels of O_3 to possible chronic effects in humans. These commenters, as did CASAC, advised that further research into potential chronic effects in humans should be continued, and the results considered in the next review of the O_3 standard. The Administrator is persuaded that the difference between the margins of safety for these potential chronic effects afforded by the alternatives within the range of the second- to fifth-highest concentration forms is not well enough understood at this time to use as the basis for choosing the most restrictive forms (i.e., the second- or third-highest concentration form). On the other hand, the Administrator also judges that the relatively large percentage of sites that would experience O_3 peaks above a benchmark level of 0.09 ppm even when attaining a fifth-highest concentration standard and the number of days on which the level of a fifth-highest concentration standard may be exceeded argue against choosing that form, which is the least restrictive within the range considered.

For the reasons outlined above, and taking into account the range of views in the public comments, the Administrator concludes that an intermediate form, the fourth-highest concentration form, would serve to appropriately balance these public health considerations in conjunction with the 8–hour averaging time and 0.08 ppm level selected, as discussed above in Units II.B.1. and II.B.2., that are of primary importance in determining the degree of public health protection afforded by the standard. In addition, the Administrator notes that based on an analysis of air quality in counties that would attain an 8–hour, 0.08 ppm fourth-highest concentration standard (based on 1993–1995 data), over 99 percent of such counties would be expected to have four or fewer days on which the level of the standard is exceeded in an average year (Freas,

1997). This number of exceedances is clearly within the range of multiple exceedances that CASAC judged to be appropriate for a health-based primary O_3 standard. Thus, in the Administrator's judgment, based on the information currently available, an 8–hour, 0.08 ppm standard with a fourth-highest concentration form will protect public health with an adequate margin of safety.

In the proposal, which maintained the current approach of using air quality data from the monitor measuring the highest O_3 concentrations in an area to determine whether the primary standard for O_3 is attained, the Administrator solicited comment on the alternative of using some form of averaging across monitors. As discussed in the proposal, EPA recognized that during the review of the Staff Paper, a number of commenters suggested that averaging across monitors might be appropriate to increase the degree to which monitoring data used in determining attainment of the standard reflects population exposure and aggregate population health risk. Further, these commenters suggested that averaging data from multiple monitors in an area would produce a more stable measure of air quality and would take into account broader population exposure patterns across an area than would the current approach of considering data from each monitor independently.

The Administrator did not propose the use of spatial averaging because of concerns outlined in the proposal including: The difficulty in determining an appropriate level for a spatially averaged primary standard given that the bulk of the human health effects evidence supporting a decision on an appropriate O_3 standard is based on controlled human exposure studies that relate known O_3 exposures directly to responses in individuals; and questions as to whether adequate health protection would be provided to individuals within the populations that live or work in communities that routinely experience higher O_3 concentrations within a broad metropolitan area.

To address these two concerns, it would be necessary to define criteria for geographic locations or communities (e.g., spatial averaging zones) within which the use of spatially averaged O_3 data would be acceptable. Such criteria would be important since O_3 air quality concentrations can vary significantly across most urban areas. The lowest concentrations typically occur in the urban center and in locations near O_3 precursor sources, mid-range concentrations in neighborhoods and locations surrounding the urban center, and peak concentrations are typically measured downwind along the outermost suburban regions of the urban area. Also, the location of residences, schools, parks, and other places where individuals might be exposed more frequently to ambient O_3 concentrations of concern would be an important consideration. Unless the O_3 concentration gradients within each spatial averaging zone were relatively homogeneous, there may be significant numbers of sensitive individuals exposed to high O_3 concentrations in areas where the spatial average indicates that the overall air quality is acceptable.

In the proposal, EPA also noted the need to help State and local governments devise different O_3 monitoring networks by revising relevant regulations and guidance, should spatial averaging be adopted. This would likely involve defining general criteria for monitoring network design, siting, and spatial averaging zones in nationally implementable terms, with case-by-case evaluation of each monitoring network. The EPA recognized that this activity would place additional burdens on State and local air quality management districts.

In soliciting comment on whether it would be desirable to adopt some form of spatial air quality averaging for O_3, the Administrator also solicited comment on specific alternative approaches that could be used to address the issues of concern. In particular, the Administrator was interested in analyses that inform questions about monitoring network design, siting requirements, and approaches for specification of spatial averaging zones; the distribution of public health protection that would result from such alternative approaches; and the extent to which the level of the standard would need to be adjusted, if any, to provide public health protection consistent with the level of protection contemplated in the proposal.

The EPA received many comments on the subject of using spatially averaged data to determine when the primary standard for O_3 is attained. Commenters from business and industry associations frequently supported the use of spatially averaged data, as did many local governments and a small number of States, principally because it would provide a more stable air quality indicator and would better represent population exposure and risk. Some of these commenters felt that the use of spatial averaging would be consistent with the use of risk assessment as a policy tool for standard setting. Many of these commenters agreed that the heterogeneity of O_3 concentrations across geographic areas would need to be addressed by network design, with a few expressing the opinion that this would not be an insurmountable problem given that there is continual movement of monitors within existing networks. Some commenters suggested averaging approaches that included the use of population weighting of monitored data, and some supported the use of a public health information system to allow individuals residing in ''hot spot'' areas to reduce their exposures to O_3 concentrations of concern.

In contrast, environmental associations, public health professionals, most States, and many individuals voiced strong concerns that the use of spatially averaged data would routinely allow individuals who live or work in communities with consistently higher O_3 levels than those occurring across the broader urban area to be exposed to concentrations of concern. Many of these commenters raised the issue of environmental equity, expressing the view that communities with consistently higher O_3 concentrations typically are composed predominantly of individuals of lower socioeconomic status, or are composed of a predominantly minority population. The EPA notes that this view is not consistent with the air quality data discussed earlier in this unit, in that O_3 concentrations are typically lower in urban centers than in locations surrounding or downwind of urban centers. Some commenters also raised concerns about the complexity and burdens associated with redesigning existing monitoring networks.

Taking into account the comments received, the Administrator does not find that the issues of concern, as outlined in the proposal and above, have been adequately addressed in this review of the O_3 standard. In particular, while EPA strongly agrees with the importance of public health advisories in addition to adequately protective standards, relying on the use of public health advisories to provide information for at-risk populations who may consistently be exposed to localized O_3 concentrations of concern is considered by the Administrator to be an insufficient approach to protecting public health with an adequate margin of safety. Further, the suggested use of population weighting of monitored data may, in many cases, be insufficiently sensitive to local O_3 variations to ensure adequate protection of these populations from localized O_3 concentrations. Thus, the revised O_3 standard will maintain the current

approach of using air quality data from the monitor measuring the highest O_3 concentrations in an area to determine whether the standard is attained within an area.

The EPA has also considered spatial averaging in the context of the decision to revise the PM NAAQS, in part, by adopting a form of an annual standard for fine particles (i.e., $PM_{2.5}$) that allows for spatial averaging within appropriate criteria. It is important to note that different considerations apply in these two cases. One principal difference is the nature of the health effects evidence for O_3 and $PM_{2.5}$. When considering averaging approaches for O_3, it should be recognized that much of the human health effects evidence supporting the O_3 standard is based on controlled human exposure studies that relate individual O_3 exposures directly to responses in individuals, whereas the health effects evidence supporting the $PM_{2.5}$ standards is from epidemiological studies relating community measures of $PM_{2.5}$ concentrations to population-wide responses. Thus, information available for determining an appropriate level of a standard in these two cases is predominantly individual-oriented in the case of O_3 and community-oriented in the case of $PM_{2.5}$. As a consequence, additional research and exposure and risk assessments beyond those available in this review would be necessary to provide a basis for further consideration of a spatially averaged standard for O_3. The EPA will continue to explore this approach.

Another important difference between the O_3 and PM standards is that the suite of annual and 24–hour $PM_{2.5}$ standards permits the use of the 24–hour $PM_{2.5}$ standard, which would not be spatially averaged, as a backstop to control localized ''hot spots,'' whereas a single O_3 standard does not allow for such a dual approach. Also, EPA notes that the existence of an established, extensive O_3 monitoring network would require substantial redesigning and relocation of monitors for the purpose of spatial averaging, in contrast to the current absence of such a network for $PM_{2.5}$ which can be newly designed to address community-oriented monitoring from the outset.

As discussed in the proposal, the Administrator recognizes that no standard within the range of levels and forms considered in this review, including the selected standard, is risk free, due to the continuum of risk likely posed by exposures to ambient O_3 potentially down to background levels. Accordingly, consistent with CASAC advice, the Administrator solicited comment in the proposal on elements of an enhanced public health advisory system. The Administrator believes that the information that could be made available through such a public health advisory system would be particularly useful to extremely sensitive individuals in making personal decisions about avoiding exposures with the potential to cause transient adverse effects on days when 8–hour average O_3 concentrations are predicted to be at or near the level of the standard. Approaches to developing an enhanced system, and comments received on such approaches, are discussed in Unit II.C. of this preamble.

4. *Final decision on the primary standard.* After carefully considering the information presented in the Criteria Document and the Staff Paper, the advice and recommendations of CASAC, public comments received on the proposal, and for the reasons discussed above, the Administrator is replacing the existing 1–hour, 0.12 ppm primary standard with a new 8–hour, 0.08 ppm primary standard. The new 8–hour standard will become effective September 16, 1997.

The 8–hour, 0.08 ppm primary standard will be met at an ambient air quality monitoring site when the 3–year average of the annual fourth-highest daily maximum 8–hour average O_3 concentration is less than or equal to 0.08 ppm. Data handling conventions are specified in a new Appendix I to 40 CFR part 50 as discussed in Unit VI below.

In the proposal, EPA proposed that the revocation of the existing 1–hour O_3 standard be delayed for certain purposes until EPA had approved State Implementation Plans to implement the new 8–hour O_3 standard. EPA had proposed continuing the applicability of the 1-hour standard in this way in order to facilitate continuity in public health protection during the transition to a new standard. (See Memorandum from John S. Seitz to Mary D. Nichols, November 20, 1996; Docket No. A–95–58, item II–B–3.) Also, at the time of the proposal of the new O_3 standard, EPA had proposed an interpretation of the Act in the proposed Interim Implementation Policy (61 FR 65764, December 13, 1996) under which the provisions of subpart 2 of part D of Title I of the Act would not apply to existing O_3 nonattainment areas once a new O_3 standard becomes effective.

In light of comments received regarding the interpretation proposed in the Interim Implementation Policy, EPA has reconsidered that interpretation and now believes that the Act should be interpreted such that the provisions of subpart 2 continue to apply to O_3 nonattainment areas for purposes of achieving attainment of the current 1–hour standard. As a consequence, the provisions of subpart 2, which govern implementation of the 1–hour O_3 standard in O_3 nonattainment areas, will continue to apply as a matter of law for so long as an area is not attaining the 1–hour standard. Once an area attains that standard, however, the purpose of the provisions of subpart 2 will have been achieved and those provisions will no longer apply. However, the provisions of subpart 1 of part D of Title I of the Act would apply to the implementation of the new 8–hour O_3 standards.

To facilitate the implementation of those provisions and to ensure a smooth transition to the implementation of the new 8–hour standard, the 1–hour standard should remain applicable to areas that are not attaining the 1–hour standard. Therefore, the 1–hour standard will remain applicable to an area until EPA determines that it has attained the 1–hour standard, at which point the 1–hour standard will no longer apply to that area.

C. Communication of Public Health Information

Information on the public health implications of ambient concentrations of criteria pollutants is currently made available primarily through two EPA programs. The first program is designed to prevent ambient pollutant concentrations from reaching the significant harm level (i.e., an exposure level that constitutes an imminent and substantial endangerment to public health). The second program is the Pollutant Standards Index (PSI),[24] which is a health advisory system. The proposal focused on the potentially expanded use of the PSI in regard to allowing sensitive individuals to reduce their risk of exposure. Currently, EPA and local officials use the PSI as a public information tool to advise the public about the general health effects associated with different pollution levels and to describe whatever precautionary steps may need to be taken if air pollution levels rise into the unhealthful range. By notifying the public when a PSI value exceeds 100 (which corresponds to the NAAQS for each criteria pollutant)[25], citizens are given the opportunity to take appropriate steps to avoid exposures of concern. This use of the PSI could be expanded to provide more specific health information for O_3 concentrations

[24] For a discussion of these programs, see the proposal.

[25] Currently, a PSI value of 100 for O_3 corresponds to an ambient concentration of 0.12 ppm, averaged over 1 hour.

close to the level of the primary standard. Given the continuum of risks associated with exposure to O_3, this information, while perhaps of interest to all citizens, would be particularly useful to those individuals who are extremely sensitive to relatively low O_3 concentrations. As an example, the proposal mentioned the possibility of expanding the PSI to include two new descriptive categories in the Index, one including concentrations within a range somewhat below the level of the new primary standard (with a possible descriptor of ''moderately good''), the other including concentrations within a range somewhat above the level of the standard (with a possible descriptor of ''moderately unhealthful''). Such an approach could better reflect the increased understanding of health effects associated with O_3 exposure developed during this review, and would be consistent with the recommendation of a number of CASAC panel members ''that an expanded air pollution warning system be initiated so that sensitive individuals can take appropriate 'exposure avoidance' behavior'' (Wolff, 1995b).

The proposal also discussed the use of forecasting in combination with this expanded use of the PSI. For a health advisory system to be effective, citizens need to be notified as early as possible to be able to avoid exposures of concern. The notice indicated that if the current 1–hour primary NAAQS for O_3 is replaced with an 8–hour standard, there would clearly be increased value in using forecasted O_3 concentrations in providing cautionary statements to the public. Currently, when a health advisory indicates that the 1–hour O_3 PSI value of 100 has been exceeded, citizens generally have time to avoid exposures of concern because O_3 levels tend to remain elevated for several hours during the day. With the new 8–hour standard, however, this would likely not be the case, since by the time a PSI value is reported, the potential for prolonged exposures of concern would likely have passed for that day. Forecasting 8–hour maximum O_3 concentrations would facilitate the risk-reduction function of the PSI by giving citizens more time to limit or avoid exposures of concern.

The EPA did not formally propose revisions to the PSI in the proposal. Instead, the Administrator requested comment, and indicated that the Agency might propose revisions to the PSI in conjunction with future proposals associated with the implementation of a revised NAAQS.

The EPA received a large number of comments from a wide variety of commenters on the usefulness of both an expanded health advisory system and the forecasting of 8–hour ambient O_3 concentrations. Commenters representing State and local agencies, business and industry associations, as well as environmental associations overwhelmingly endorsed the use of an expanded public health advisory system and many noted the importance of forecasting 8–hour O_3 concentrations in conjunction with the PSI, while recognizing a number of issues that would need to be addressed.

Comments from environmental associations endorsed increasing the specificity of warnings with regard to the health effects that could occur as a result of exposure, and noted that citizens are capable of dealing with complex information. These commenters also took exception to describing O_3 levels around the level of the standard that have been shown to result in decreased lung function and increased respiratory symptoms, as ''moderately good,'' stating that this descriptor is misleading and might not be heeded by people who could, if they fully understood the nature of the health risk, take action to minimize their exposures. Other commenters felt that the descriptors ''moderately good'' and ''moderately unhealthful'' were unnecessarily confusing.

Industry commenters were uniformly supportive of enhancing the risk reduction function of the PSI by issuing health advisories with specific health information at and above the level of the standard. Several industry commenters also recommended that the function of the PSI be combined with the function of an O_3 action system, which would recommend voluntary actions to reduce ambient O_3 concentrations when the level of the standard is forecasted to be exceeded. This would result in a system that not only could provide accurate health effects information specific to the members of the population likely to experience effects, but also could help prevent exposures to levels of O_3 at or above the level of the standard.

Commenters from State and local air pollution control authorities strongly endorsed expanding the use of the PSI and the utilization of forecasted 8–hour O_3 concentrations. These commenters encouraged EPA to develop any such approaches to revise the PSI in consultation with State and local agencies, specifically in the areas of sharing real-time O_3 monitoring data among neighboring States, risk communication with the public, and coordination of a national program. States also expressed the need for flexibility in the implementation of such approaches and for guidance from EPA on technical aspects such as forecasting.

The EPA will take all of these comments into consideration when developing a proposal to revise the PSI (40 CFR 58.50) for O_3. The EPA plans to propose these revisions, as well as revisions to the significant harm level program (40 CFR 51.16), at a later date.

III. Rationale for the Secondary O_3 Standard

A. Introduction

1. *Overview*. This notice presents the Administrator's final decision regarding the need to revise the current secondary O_3 standard, and more specifically, to replace the existing 1–hour, 0.12 ppm O_3 secondary NAAQS with a secondary standard equal in form, level, and averaging time to the new 8–hour, 0.08 ppm primary standard. This decision is based on a thorough review of the scientific information on vegetation effects associated with exposure to ambient levels of O_3 as assessed in the Criteria Document. This decision also takes into account:

(1) Staff Paper assessments of the most policy-relevant information in the Criteria Document and staff analyses of air quality, vegetation exposure and risk, and economic values presented in the Staff Paper, upon which staff recommendations for a new O_3 secondary standard were based.

(2) Consideration of the degree of protection to vegetation potentially afforded by the new 8–hour, 0.08 ppm primary standard compared to alternative secondary standards.

(3) CASAC advice and recommendations as reflected in discussion of drafts of the Criteria Document and Staff Paper at public meetings, in separate written comments, and in CASAC's letter to the Administrator (Wolff, 1996).

(4) Public comments received during development of these documents either in conjunction with CASAC meetings or separately.

(5) Extensive public comments received on the proposed decision regarding the secondary O_3 standard. After taking this information into account and for the reasons discussed in this Unit, the Administrator concludes that revisions to the current secondary standard are appropriate at this time to provide increased protection against adverse effects to public welfare, and that it is appropriate to set the new secondary standard identical to the new primary standard.

This review has focused on O_3 effects on vegetation since these public welfare effects are of most concern at O_3

concentrations typically occurring in the United States. By affecting commercial crops and natural vegetation, O_3 may also indirectly affect natural ecosystem components such as soils, water, animals, and wildlife. Based on the scientific literature assessed in the Criteria Document, the Administrator believes it is reasonable to conclude that a secondary standard that protects the public welfare categories of commercial crops and natural vegetation from known or anticipated adverse effects would also afford increased protection to these other related public welfare categories. With regard to O_3 effects on manmade materials and deterioration of property, the scientific literature assessed in the Criteria Document contains little new information since the last review. Accordingly, EPA again concludes for the reasons set forth in 1993 (58 FR 13008, March 9, 1993) that O_3-related effects on materials do not provide a basis for selecting an averaging time and level for a secondary standard. In addition, since the effects of O_3 on personal comfort and well-being (e.g., nose and throat irritation, chest discomfort, and cough) have been accounted for in the review of the primary standard, these effects are not considered in this review of the secondary standard.

The vegetation effects information, exposure and risk assessment, and economic analyses presented in the Staff Paper and proposal are briefly outlined in the remainder of Unit III.A. of this preamble. The key issues raised in public comments with regard to: Whether revisions to the current secondary standard are requisite to protect public welfare from adverse effects and the specific elements of a revised secondary standard are discussed in Unit III.B. along with the Administrator's rationale for concluding that it is appropriate to revise the current secondary standard to be identical to the new primary standard.

2. *Vegetation effects information.* Exposures to O_3 have been associated quantitatively and qualitatively with a wide range of vegetation effects such as visible foliar injury, growth reductions and yield loss in annual crops, growth reductions in tree seedlings and mature trees, and effects that can have impacts at the forest stand and ecosystem level. Summarized below are key findings for each of the above effects categories that are discussed in more detail in the Criteria Document, Staff Paper, and proposal.

Visible foliar injury can represent a direct loss of the intended use of the plant, ranging from reduced yield and/or marketability for some agricultural species to impairment of the aesthetic value of urban ornamental species. On a larger scale, foliar injury is occurring on native vegetation in national parks, forests, and wilderness areas, and may be degrading the aesthetic quality of the natural landscape, a resource important to public welfare.

Ozone can interfere with carbon gain (photosynthesis) and allocation of carbon with or without the presence of visible foliar injury. As a result of decreased carbohydrate availability, remaining carbohydrates may be allocated to sites of injured tissue or employed in other repair or compensatory processes, thus reducing the carbohydrates available for plant growth and/or yield. Growth and yield effects of O_3 have been well documented for numerous species, including commodity crops, fruits and vegetables, and seedlings of both coniferous and deciduous tree species.

Due to a number of differences between seedlings and mature trees in their responses to O_3 exposures, data from tree seedling studies cannot, at this time, be extrapolated to quantify responses to O_3 in mature trees. However, long-term observational studies of mature trees have shown growth reductions in the presence of elevated O_3 concentrations. Where these growth reductions are not attributed to O_3 alone, due to the presence of many other environmental variables, it has been reported that O_3 is a significant contributor that potentially exacerbates the effects of other environmental stresses (e.g., pests). In addition, studies show that sensitivity to O_3 with respect to visible foliar injury and growth and yield effects can vary significantly within and between species for both crops and trees.

Growth reductions can indicate that plant vigor is being compromised such that the plant can no longer compete effectively for essential nutrients, water, light, and space. When many O_3-sensitive individuals make up a population, the whole population may be affected. Changes occurring within sensitive populations, or stands, if they are severe enough, ultimately can change community and ecosystem structure. Structural changes that alter the ecosystem functions of energy flow and nutrient cycling can alter ecosystem succession.

In the CASAC closure letter, all CASAC panel members agreed that ''damage is occurring to vegetation and natural resources at concentrations below the present 1–hour national ambient air quality standard (NAAQS) of 0.12 ppm,'' and the vegetation experts agreed that ''plants appear to be more sensitive to O_3 than humans'' (Wolff, 1996). Further, the CASAC panel agreed ''that a secondary NAAQS, more stringent than the present primary standard, was necessary to protect vegetation from O_3'' (Wolff, 1996). The Administrator concurred in the proposal with the unanimous view of CASAC that the current standard of 0.12 ppm, 1–hour average, does not provide adequate protection to vegetation from the adverse effects of O_3, based on the following specific observations that were taken from key studies and other biological effects information reported in the O_3 Criteria Document and Staff Paper:

(1) O_3 concentrations ≥ 0.10 ppm can be phytotoxic to a large number of plant species, and can produce acute foliar injury responses and reduced crop yield and biomass production.

(2) O_3 concentrations within the range of 0.05 to 0.10 ppm have the potential over a longer duration of creating chronic stress on vegetation that can result in reduced plant growth and yield, shifts in competitive advantages in mixed populations, decreased vigor leading to diminished resistance to pest and pathogens, and injury from other environmental stresses. Some sensitive species can experience foliar injury and growth and yield effects even when concentrations never exceed 0.08 ppm.

The Administrator further concluded that the available scientific information supports the conclusion that a cumulative seasonal exposure index, such as the proposed SUM06 index,[26] is more biologically relevant than a single event or mean index.

3. *Vegetation exposure and risk analyses.* In reaching a judgment in the proposal as to a standard requisite to protect crops and vegetation against the adverse effects of O_3, the Administrator took into account several additional considerations including the extent of exposure of O_3-sensitive species, potential risks of adverse effects to such species, and monetized and nonmonetized categories of increased vegetation protection associated with reductions in O_3 exposures. In so doing, the Administrator recognized that markedly improved air quality, and thus significant reductions in O_3 exposures would result from attainment of the alternative 0.08 ppm, 8–hour primary standards within the range of 1- and 5-expected exceedance forms. Thus, as a matter of policy, the Agency estimated the increased protection from O_3-related

[26] The SUM06 exposure index cumulates over a given time period and diurnal window all hourly O_3 concentrations greater than or equal to 0.06 ppm.

effects on vegetation associated with attainment of alternative 8–hour, 0.08 ppm primary standards, and then considered the incremental protection associated with attainment of a seasonal secondary standard.

The ability of EPA to characterize O_3 air quality in rural and remote sites was limited by the available rural O_3 monitoring network. Therefore, EPA conducted national analyses using geographic information systems (GIS) and data from existing air quality monitoring sites to estimate seasonal O_3 air quality for the year 1990, in terms of the 3–month, 12–hour, SUM06 exposure index. The year 1990 was selected because it was a fairly typical year in terms of O_3 air quality. The estimated 1990 air quality was then used as a baseline from which to roll back O_3 concentrations to project O_3 air quality that would be expected to occur when alternative standards were just attained.

The regulatory scenarios examined included just attaining the existing 1–hour secondary standard, alternative 8–hour primary standards in the range of 0.07 to 0.09 ppm, including standards set at 0.08 ppm, with 1- and 5-expected-exceedance forms, and a range of seasonal standards using the SUM06 index, based on a single year of data. Estimates of air quality associated with alternative 8–hour primary standards with 1- and 5-expected-exceedance forms were used to roughly bound air quality estimates for 8–hour standards with concentration-based forms ranging from the annual second- to the fifth-highest concentration-based forms, and including the proposed third-highest concentration-based form.

By comparing these projected air quality scenarios for alternative standards with maps showing the growing regions for O_3-sensitive crops and tree seedling species, estimates of exposures of concern and risks of adverse effects for various species were developed for alternative standards. Taking into account the body of information concerning O_3 effects on vegetation, as presented in the Criteria Document and Staff Paper and summarized in the proposal, EPA considered both quantifiable risks (when exposure-response functions were available) as well as those risks that could only be qualitatively characterized.

The Administrator concluded in the proposal that attaining a 8–hour, 0.08 ppm primary standard within the range of forms under consideration would provide substantially improved protection of vegetation from seasonal O_3 exposures of concern. The Administrator recognized, however, that some areas may continue to have elevated seasonal exposures, including forested park lands and other natural areas and Class I areas that are federally mandated to preserve certain air quality related values.

In its discussions of uncertainties, described in the proposal, the CASAC Panel members expressed concerns about the use of the GIS methodology to project national O_3 air quality and exposures of O_3-sensitive species. As is the case with other analytic methods (e.g., Krieging, inverse distance weighting), the GIS methodology contains numerous assumptions and uncertainties, and incorporates various databases each with their own set of uncertainties. As noted in the Staff Paper and proposal, the EPA and CASAC recognized that the uncertainties in exposure and risk estimates derived from the GIS methodology are large and unquantifiable, but that the method provides useful information that is appropriate to consider in comparing the relative protection afforded by alternative standards. Further, EPA noted in the Staff Paper and proposal that the GIS-generated air quality estimates compare reasonably well with the limited available O_3 monitoring data. In taking the results from these analyses into account, the Administrator recognized these inherent limitations and primarily considered the comparative results in assessing the degree of protection afforded by alternative standards.

While the analyses discussed above indicated that an 8–hour, 0.08 ppm primary standard within the range of alternatives considered, would provide increased protection for commercial and natural vegetation, it remained uncertain as to the extent to which air quality improvements designed to reduce 8–hour O_3 concentrations would reduce O_3 exposures measured by a seasonal SUM06 index. To further explore this question, EPA also examined the design values for alternative 8–hour, 0.08 ppm standards, within the range of 1- and 5-expected exceedances, averaged over 3 years, and a 3–month, 12–hour SUM06 standard for 581 counties (those having sufficient monitoring data for the period 1991 – 1993). As discussed in the Staff Paper and proposal, this analysis revealed that almost all areas that are within or above a SUM06 range of 25–38 ppm–hours would also have an 8–hour daily maximum design value of greater than 0.08 ppm. Thus, in those areas in which air quality monitoring is being conducted, areas that would likely be of most concern for effects on vegetation, as measured by the SUM06 exposure index, would also be addressed by an 8–hour primary standard set at a 0.08 ppm level.

4. *Monetized estimates of vegetation protection.* As discussed in section VII.F. of the Staff Paper and in the proposal, EPA developed monetized estimates of increased protection associated with several alternative standards for economically important commodity crops nation-wide[27] and for fruit and vegetable crops in California.[28] These analyses were based on the GIS-generated projections of O_3 air quality for various alternative standards. Monetized estimates of increased protection could not be developed for other important categories of vegetation, such as urban ornamentals, Class I areas, and commercial and other forests because of a lack of available concentration-response functions and appropriate economic valuation models. The available data suggested, however, that reductions in ambient O_3 concentrations resulting from attainment of alternative standards would confer increased protection for these categories as well by reducing biomass loss, protecting functional, aesthetic, and existing values, and by preserving biodiversity and native habitats.

As summarized in the proposal, most of the monetized estimates of increased protection would accrue from attainment of an 8–hour, 0.08 ppm primary standard, with a smaller incremental improvement obtained by the addition of a seasonal secondary standard. In contrast, the incremental protection obtained from the addition of a seasonal secondary standard would be considerably more significant when compared to an alternative 8–hour primary standard at a level of 0.09 ppm.

B. Need for Revision of the Current Secondary Standard

Based on the above considerations and the rationale in the proposal, the Administrator proposed and sought comment on two alternative standards, either of which in her judgment would be appropriate to protect public welfare from known or anticipated adverse effects given the available scientific knowledge. The two alternatives were setting the revised secondary standard

[27] Including 15 species, representing approximately 75% of the U.S. sales of agricultural crops, evaluated in the National Crop Loss Assessment Network (NCLAN) studies undertaken in the early to mid-1980's, which provide the largest, most uniform database on the effects of O_3 on agricultural crop species.

[28] These fruit and vegetable crops constitute approximately 50% of the Nation's fruits and vegetable markets.

identical to the proposed 8–hour, 0.08 ppm primary standard, or establishing a 3–month, 12–hour, SUM06 seasonal secondary standard at the level of 25 ppm–hours. The Administrator recognized that it would be a reasonable policy choice to set the revised secondary standard identical to an 0.08, 8–hour ppm primary standard, but also recognized that a SUM06 seasonal standard is more biologically relevant and, therefore, was also appropriate to consider.

In reaching her final decision on a revised secondary standard, the Administrator has taken into account several factors. First, she again concludes based on information presented in the Criteria Document and Staff Paper, and summarized in the proposal and in this preamble, that the existing secondary standard does not provide adequate protection for vegetation against the adverse welfare effects of O_3.

Second, she has considered the comments made by the CASAC Panel members during their reviews of these documents and in CASAC's closure letter, ''that a secondary NAAQS, more stringent than the present primary standard, was necessary to protect vegetation from O_3'' (Wolff, 1996). These statements provide strong support to the Administrator's judgment that the body of scientific evidence on O_3 effects on vegetation provides sufficient and compelling evidence that the current secondary standard is not adequately protective and should be revised.

Third, the Administrator recognizes that significant uncertainties remain with respect to exposure dynamics, air quality relationships, and estimates of increased vegetation protection which are important factors in selecting an appropriate secondary standard, as described more fully in the Criteria Document, Staff Paper and proposal. The CASAC closure letter highlighted key uncertainties that hampered the Panel's ability to make any recommendations as to an appropriate form or level for a secondary standard that would be protective against adverse effects on vegetation from exposure to ambient levels of O_3. The Panel stated that ''agreement on the level and form of such a standard is still elusive'' and ''***there remain important limitations to our understanding of the extent of the response of vegetation to O_3 under field conditions'' (Wolff, 1996). These uncertainties are largely a result of inadequate rural and remote O_3 air quality data that would allow with greater certainty determination of the relationships between O_3-related effects being observed in the field and ambient O_3 exposures. Nevertheless, the alternative standards proposed by the Administrator are consistent with the range of views expressed by the CASAC panel members, and CASAC recognized that choosing between the two alternatives is a policy decision that cannot be based solely on science (Wolff, 1996).

Fourth, the Administrator recognized that just attaining the 8–hour, 0.08 ppm, 1- and 5-expected exceedance alternatives results in markedly improved air quality when compared to just attaining the existing secondary standard, with only slight improvements associated with going from a 5- to 1-expected exceedance form.

Fifth, the Administrator has carefully considered the information and views provided in the public comments. Though these comments yielded no new scientific information relevant to choosing between the two alternative proposed standards, many commenters repeated the CASAC's concerns over the significant uncertainties remaining in the database. Many of these commenters expressed the view that EPA should wait to set a seasonal secondary standard until better rural air quality data were available, which would allow for better characterization of the magnitude of improvements in public welfare protection likely to be afforded by such a standard compared to a revised primary standard.

In sharp contrast, other commenters expressed the view that the available data were sufficient to demonstrate a need to set a seasonal secondary standard to protect vegetation against the adverse effects of O_3, and many such commenters recommended the proposed SUM06 form for such a standard. A significant number of these commenters also made recommendations on the appropriate level for a seasonal SUM06, generally recommending levels lower than the proposed 25 ppm-hours, ranging from 8 to 20 ppm–hours. The key source frequently cited in support of these recommendations is an article by Heck and Cowling (1997) which summarizes the outcome of a consensus-building workshop sponsored by the Southern Oxidant Study group on the secondary standard held in January 1996.

This workshop was attended by 16 scientists with backgrounds in agricultural, managed forest, natural systems, and air quality, all of whom are leaders in their fields and whose research formed the basis of much of the research examined in the Criteria Document. These scientists expressed their judgements on what standard level(s) would provide vegetation with adequate protection from O_3-related adverse effects.

Though the report identified no new data in support of the scientists' recommendations, the Administrator believes that the report lends important support to the view that the current secondary standard is not adequately protective of vegetation. Further, the Administrator believes that the report foreshadows the direction of future scientific research in this area, the results of which could be important in future reviews of the O_3 secondary standard.

As the results of such research become available, EPA will be in a better position to characterize rural air quality and the improvements in vegetation protection that would result from a seasonal secondary standard, and to select a standard level that would provide adequate protection for vegetation. However, given the present limits of the scientific evidence of O_3-related effects and of rural air quality data, as discussed in the Criteria Document, Staff Paper, the proposal, and by CASAC, the Administrator has decided that it is not appropriate to move forward with a seasonal secondary standard at this time for the reasons described below. In coming to this conclusion, the Administrator specifically considered the significant improvements in public welfare protection that are expected to be afforded by the new 8–hour primary standard, as well as the value of obtaining additional information to better characterize O_3-related effects on vegetation under field conditions.

C. Final Decision on the Secondary Standard

Based on the scientific evidence, CASAC advice and recommendations, comments received on the proposal, and the considerations summarized above, the Administrator is replacing the current secondary O_3 standard with an 8–hour standard, set at a level of 0.08 ppm, identical in all respects to the new primary standard. The Administrator judges that this standard will provide substantially improved protection for vegetation from O_3-related adverse effects as compared to that provided by the current 1–hour, 0.12 ppm secondary standard, while allowing time for additional research and the development of a more complete rural monitoring network and air quality database from which to evaluate the elements of an appropriate seasonal secondary standard.

The decision not to set a seasonal secondary standard at this time is based

in large part on the Administrator's recognition that the exposure, risk, and monetized valuation analyses presented in the proposal contain substantial uncertainties, resulting in only rough estimates of the increased public welfare protection likely to be afforded by each of the proposed alternative standards. These uncertainties were discussed in the proposal and the Staff Paper and were noted by CASAC (Wolff, 1996). In light of these uncertainties, the Administrator has decided it is not appropriate at this time to establish a new separate seasonal secondary standard given the potentially small incremental degree of public welfare protection that such a standard may afford. Instead, the Administrator finds it a reasonable policy choice to set a new secondary standard identical to the new primary standard, while focusing additional research on key areas for consideration in the next review of the O_3 criteria and standards.

Continued research on the effects of O_3 on vegetation under field conditions and on better characterizing the relationship between O_3 exposure dynamics and plant response will be important in the next review because:

(1) The available biological database highlights the importance of cumulative, seasonal exposures as a primary determinant of plant responses.

(2) The association between daily maximum 8–hour O_3 concentrations and plant responses has not been specifically examined in field tests.

(3) The impacts of attaining an 8–hour, 0.08 ppm primary standard in upwind urban areas on rural air quality distributions cannot currently be characterized with confidence due to limited monitoring data and air quality modeling in rural and remote areas.

Setting the secondary standard equal to the primary standard will allow EPA the opportunity to evaluate more specifically the improvement in rural air quality and in O_3-related vegetation effects resulting from measures designed to attain the new primary standard. This information in turn will allow for better evaluation of the incremental need for a separate seasonal secondary standard in the next review of the O_3 criteria and standards.

In the proposal, the Administrator solicited comment on the appropriate spatial scale of an expanded rural monitoring network. Relatively few comments were received regarding an expanded rural monitoring network, but those who did submit comments were generally in favor of an expanded network to allow for improved modelling of long-range transport of O_3 and its precursors and for better characterization of O_3 air quality in rural and remote areas. Those comments will serve to inform EPA's development of revised air quality surveillance requirements (40 CFR part 58) that will be proposed at a later date.

With respect to the proposed seasonal secondary standard only, the proposal sought comment on whether O_3 concentrations from several monitors should be spatially integrated when determining compliance with the standard. Only a few comments were received, with some supporting and some opposing spatial integration of O_3 concentrations from several monitors.

In view of the Administrator's decision to replace the current secondary standard with a secondary standard which is identical in form, level, and averaging time to the new 8–hour, 0.08 ppm primary standard, rather than with a seasonal standard, EPA is not adopting the use of spatial averaging for the new secondary standard.

To decrease some of the uncertainties discussed above and to remedy the lack of air quality data in rural and remote areas of commercial or ecological importance for vegetation, the Administrator reiterates her intention, expressed in the proposal, to expand the rural O_3 monitoring network. The EPA will propose revised O_3 air quality surveillance requirements (40 CFR part 58) at a later date. The EPA is exploring opportunities to work with other Federal agencies to develop a coordinated and long-term rural monitoring network.

IV. Other Issues

Several commenters raised key legal and procedural issues that are discussed below. These include: (1) Whether EPA must give consideration to costs and similar factors in setting NAAQS; (2) whether EPA erred in its selection of a methodology for determining the level of a NAAQS that protects public health with an adequate margin of safety; (3) whether EPA committed a procedural error by not extending the comment period; and (4) whether the 1990 amendments to the Act preclude EPA from revising the O_3 NAAQS to establish a new 8–hour standard. Responses to other legal and procedural issues are included in the Response-to-Comments Document.

A. Cost Considerations

For more than a quarter of a century, EPA has interpreted section 109 of the Act as precluding consideration of the economic costs or technical feasibility of implementing NAAQS in setting them. As indicated in the proposal, a number of judicial decisions have confirmed this interpretation. *Natural Resources Defense Council* v. *Administrator*, 902 F.2d 962, 972–73 (D.C. Cir. 1990)(PM NAAQS)(''PM10''), vacated, in part, dismissed, 921 F.2d 326 (D.C. Cir.), certs. dismissed, 498 U.S. 1075, and cert. denied, 498 U.S. 1082 (1991); *Natural Resources Defense Council* v. *EPA*, 824 F.2d 1146, 1157–59 (D.C. Cir. 1987)(en banc)(CAA section 112 standards for vinyl chloride)(''Vinyl Chloride''); *American Petroleum Institute* v. *Costle*, 665 F.2d 1176, 1185–86 (D.C. Cir. 1981)(ozone NAAQS)(''Ozone''), cert. denied, 455 U.S. 1034 (1982); *Lead Industries Ass'n* v. *EPA*, 647 F.2d 1130, 1148–51 (D.C. Cir.)(lead NAAQS)(''Lead Industries''), cert. denied, 449 U.S. 1042 (1980).

Some commenters have argued that costs and similar factors should, nonetheless, be considered, both in this rulemaking and in the rulemaking on proposed revisions to the NAAQS for particulate matter. Although most of the commenters' arguments are inconsistent with the judicial decisions cited above, several commenters have argued that those decisions are not dispositive. For reasons discussed below and in the Response-to-Comments Document, EPA disagrees with these comments and maintains its longstanding interpretation of the Act as precluding consideration of costs and similar factors in setting NAAQS.

1. *Background*. Given the nature of the points raised, a brief review of the issue seems useful before addressing the comments. The requirement that EPA establish national ambient air quality standards for certain pollutants, to be implemented by the States, was enacted in 1970 as part of a set of comprehensive amendments that established the basic framework for Federal, State, and local air pollution control. When EPA promulgated the original NAAQS in 1971, its first Administrator, William D. Ruckelshaus, concluded that costs and similar factors could not be considered in that decision.[29] This conclusion was not challenged in litigation on the original NAAQS. It has been confirmed since then, however, by every judicial decision that has considered the issue.

As discussed below, EPA's interpretation rests primarily on the language, structure, and legislative history of the statutory scheme adopted in 1970. It is also supported by the judicial decisions cited above, as well as by legislative developments since 1970 that reaffirm Congress' original approach to the issue.

[29] 36 FR 8186, Apr. 30, 1971. EPA has maintained this interpretation consistently since then.

Without cataloguing all relevant aspects of the 1970 amendments and their legislative history, several basic points should be noted. Under section 109(b) of the Act, NAAQS are to be ''based on'' the air quality criteria issued under section 108. Under section 108(a)(2), the kind of information EPA is required to include in criteria documents is limited to information about health and welfare effects ''which may be expected from the presence of [a] pollutant in the ambient air ***.'' There is no mention of the costs or difficulty of implementing the NAAQS, nor of ''effects'' that might result from implementing the NAAQS (as opposed to effects of pollution in the air).[30] By contrast, Congress explicitly provided for consideration of costs and similar factors in decisions under other sections of the Act.[31] Moreover, States were permitted to consider economic and technological feasibility in developing plans to implement the NAAQS to the extent such consideration did not interfere with meeting statutory deadlines for attainment of the standards.[32] Finally, the legislative history indicated that Congress had considered the issue and had deliberately chosen to mandate NAAQS that would protect health regardless of concerns about feasibility.[33]

The first judicial decision on the issue came in the Lead Industries case. An industry petitioner argued that EPA should have considered economic and technological feasibility in allowing a ''margin of safety'' in setting primary standards for lead. Based on a detailed review of the language, structure, and legislative history of the statutory scheme, the U.S. Court of Appeals for the District of Columbia Circuit concluded that:

> This argument is totally without merit. [The petitioner] is unable to point to anything in either the language of the Act or its legislative history that offers any support for its claim ***. To the contrary, the statute and its legislative history make clear that economic considerations play no part in the promulgation of ambient air quality standards under section 109.

647 F.2d at 1148.

The Court cited a number of reasons for this conclusion. *Id.* at 1148–50. Among other things, it noted the contrast between section 109(b) and other provisions in which Congress had explicitly provided for consideration of economic and technological feasibility, as well as the requirement that NAAQS be based on air quality criteria defined without reference to such factors. *Id.* at 1148–49 & n.37. The Court also noted that, in developing plans to implement NAAQS, States may consider economic and technological feasibility only to the extent that this does not interfere with meeting the statutory deadlines for attainment of the standards; and that EPA may not consider such factors at all in deciding whether to approve State implementation plans. *Id.* at 1149 n.37 (citing *Union Electric Co. v.* EPA, 427 U.S. 246, 257–58, 266 (1976)).[34]

As to the legislative history of the 1970 amendments, the Court observed that:

> [T]he absence of any provision requiring consideration of these factors was no accident; it was the result of a deliberate decision by Congress to subordinate such concerns to the achievement of health goals.

Id. at 1149. Citing several leading Supreme Court decisions, as well as the Senate report quoted above, the Court noted that Congress had intended a drastic change in approach toward the control of air pollution in the 1970 amendments and was well aware that sections 108–110 imposed requirements of a ''technology-forcing'' character. *Id.*[35]

The Court also noted that Congress had already acted, in further amendments adopted in 1977, to relieve some of the burdens imposed by the 1970 amendments. *Id.* at 1150 n.38. Observing that Congress had, however, declined to amend section 109(b) to provide for consideration of costs and similar factors as requested by industrial interests, *id.* n.39, the Court concluded:

> A policy choice such as this is one which only Congress, not the courts and not EPA, can make. Indeed, the debates on the [1970 amendments] indicate that Congress was quite conscious of this fact***.
>
> *** [I]f there is a problem with the economic or technological feasibility of the lead standards, [the petitioner], or any other party affected by the standards, must take its case to Congress, the only institution with the authority to remedy the problem.

Id. at 1150.

After the decision in Lead Industries, Supreme Court review was sought on the question whether costs and similar factors could be considered in setting NAAQS, among other issues. The Supreme Court declined to review the decision. *Lead Industries Ass'n v. EPA*, 449 U.S. 1042 (1980). The subsequent decisions in Ozone, Vinyl Chloride, and PM_{10}, cited above, strongly reaffirmed the interpretation adopted in Lead Industries.[36] Supreme Court review of the Ozone and PM_{10} decisions was sought but denied. *American Petroleum Institute* v. *Gorsuch*, 455 U.S. 1034 (1984); *American Iron and Steel Institute* v. *EPA*, 498 U.S. 1082 (1991).

The Lead Industries opinion focused largely, though not exclusively, on the 1970 amendments and their legislative history. Perhaps as a result, it did not canvass all the factors that, in fact, supported its conclusions at the time. For example, when Congress enacted major amendments to the Act in 1977, it was clearly aware that some areas of the country had experienced difficulty in attempting to attain some of the NAAQS.[37] It was also aware that there might be no health-effects thresholds for the pollutants involved, and that significant uncertainties are inherent in setting health-based standards under the Act.[38] In response, Congress made

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[30] That consideration of such factors was not intended in NAAQS decisions is also supported by section 109(a)(1). For pollutants for which air quality criteria had been issued prior to the 1970 amendments, that provision required EPA to propose NAAQS within 30 days after enactment and to take final action 90 days later. The criteria issued previously did not include information on costs and similar factors, and it would have been difficult if not impossible for EPA to supplement them in time to include meaningful consideration of such factors in NAAQS proposed 30 days after enactment.

[31] See, e.g., sections 110(e)(1), 111(a)(1), 231(b) (1970 Act); see also, e.g., sections 113(d)(4)(C)(ii), 125(a)(3), 202(a)(3)(C), 317 (1977 Act).

[32] *Union Electric Co.* v. *EPA*, 427 U.S. 246, 257–58 (1976).

[33] The Senate report on the 1970 amendments stated: ''In the Committee discussions, considerable concern was expressed regarding the use of the concept of technical feasibility as the basis of ambient air standards. The Committee determined that (1) the health of people is more important than the question of whether the early achievement of ambient air quality standards protective of health is technically feasible; and, (2) the growth of pollution load in many areas, even with application of available technology, would still be deleterious to public health.''

''Therefore, the Committee determined that existing sources of pollutants either should meet the standard of the law or be closed down ***.''

S. Rep. No. 91–1196, at 2–3 (1970).

[34] These limitations would, of course, make little sense if such factors could be considered in setting the NAAQS themselves.

[35] Such requirements '' 'are expressly designed to force regulated sources to develop pollution control devices that might at the time appear to be economically or technologically infeasible.' '' *Id.* (quoting *Union Electric Co.* v. *EPA*, 427 U.S. at 257).

[36] In the PM_{10} case, for example, the Court considered an argument that EPA should have considered potential health consequences of unemployment that might result from revision of the primary NAAQS for PM:

''This claim is entirely without merit. In three previous cases, this court has emphatically stated that section 109 does not permit EPA to consider such costs in promulgating national ambient air quality standards ***. It is only *health effects relating to pollutants in the air* that EPA may consider . *** Consideration of costs associated with alleged health risks from unemployment would be flatly inconsistent with the statute, legislative history and case law on this point.''

902 F.2d at 973 (emphasis in original; citations omitted).

[37] See, e.g., H.R. Rep. No. 95–294, at 207–17 (l977).

[38] See, e.g., *id.* at 110–12; *id.* at 43–51.

significant changes in the provisions for implementation of the NAAQS, including changes intended to ease the burdens of attainment. It also amended sections 108 and 109 in several ways; for example, by requiring periodic review and, if appropriate, revision of air quality criteria and NAAQS and by establishing a special scientific advisory committee (CASAC) to advise EPA on such reviews. Notably, Congress recognized that implementation of NAAQS could cause ''adverse public health, welfare, social, economic, or energy effects'' and charged CASAC with advising EPA on such matters.[39] Yet it made no changes in sections 109(b) or 108(a)(2); that is, in the substantive criteria for setting or revising NAAQS. In other words, Congress chose to address economic and other difficulties associated with attainment of the NAAQS by adjusting the scheme for their implementation, rather than by changing the instructions for setting them.[40]

Congress enacted major amendments to the Act again in 1990, well after the Lead Industries and Ozone decisions that interpreted section 109 as precluding consideration of costs in NAAQS decisions.[41] In doing so, Congress was clearly aware of intervening developments such as EPA's decision to revise the PM NAAQS in 1987—the result of an elaborate review in which the Administrator strongly underscored the scientific uncertainties involved[42]—and the Vinyl Chloride case drawing a sharp distinction between sections 109 and 112 with regard to consideration of costs and similar factors.[43] Indeed, the legislative history of the 1990 amendments reflects Congress' understanding that primary NAAQS were to be based on protection of health ''without regard to the economic or technical feasibility of attainment.''[44] Again, however, Congress chose to respond to severe, widespread, and persistent problems with attaining the NAAQS by adjusting the scheme for their implementation rather than by changing the basis for setting them. See, e.g., sections 181–192.

2. *Public comments.* As noted previously, a number of commenters have argued that costs and similar factors should be considered in EPA's final decisions on revision of both the ozone and particulate NAAQS. Aside from arguments that are simply inconsistent with the judicial decisions cited above, some of the commenters argue that those decisions are not dispositive for a variety of reasons. One commenter submitted a particularly comprehensive version of this argument in the rulemaking on proposed revisions to the particulate NAAQS; the following discussion focuses primarily on points raised by that commenter, among others.[45]

As a general matter, the commenter acknowledges that Congress intended to preclude consideration of economic costs and similar factors in setting NAAQS. The commenter argues, however, that this is so only when the scientific basis for NAAQS is ''clear and compelling'' or ''unambiguous.'' From that premise, the commenter advances three key assertions:

(1) Where non-threshold pollutants are involved and the health evidence is ambiguous, section 109 must be interpreted to allow consideration of all relevant factors, including the practical consequences of EPA's decisions;

(2) To the extent the judicial decisions cited above are read as precluding this, they rest on a faulty analysis that pre-dates and cannot survive scrutiny under *Chevron, U.S.A.* v. *Natural Resources Defense Council*, 467 U.S. 837 (1984);[46] and

(3) Because EPA has discretion to consider costs and similar factors where the health evidence is ambiguous, it must do so in light of Executive Order 12866, 58 FR 51735, Oct. 4, 1993, and two recent statutes, the Unfunded Mandate Reform Act of 1995, 2 U.S.C. secs. 1501–1571 (UMRA), and the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104–121, 110 Stat. 857 (SBREFA), which in part amended the Regulatory Flexibility Act, 5 U.S.C. secs. 601–808.

EPA believes all three assertions are clearly incorrect. Regarding the first point, it should be evident, both from previous NAAQS decisions and from the court opinions upholding them, that the scientific basis for NAAQS decisions has never pointed clearly and unambiguously to a single ''right answer.''[47] This is inherent in the statutory scheme for the establishment and revision of NAAQS, which in effect requires them to be based on the ''latest

[39] Section 109(d)(2)(C)(iv). Some commenters have argued that this provision requires EPA to consider such effects in setting NAAQS. From the language and structure of section 109(d), however, it is clear that CASAC's responsibility to advise on these factors is separate from its responsibility to review and recommend revision of air quality criteria and NAAQS, and that the advice pertains to the implementation of NAAQS rather than to setting them. The legislative history confirms this view, indicating that the advice was intended for the benefit of the States and Congress. See H.R. Rep. No. 95–294, at 183 (1977).

[40] The 1977 amendments also required EPA to prepare economic impact assessments for specified actions but limited the requirement to non-health-based standards, excluding decisions under sections 109 and 112. Section 317; H.R. Rep. No. 95–294, at 51–52 (1977). In this and other respects, Congress continued the approach it took in the l970 amendments, making careful choices as to when consideration of costs and similar factors would be required and giving paramount priority to protection of health. See 123 Cong. Rec. H8993 (daily ed. Aug. 4, 1977) (Clean Air Conference Report (1977); Statement of Intent; Clarification of Select Provisions), reprinted in 3 Senate Committee on Environment and Public Works, 95th Cong., A Legislative History of the Clean Air Act Amendments of 1977, at 319 (1978).

[41] In the interim, the National Commission on Air Quality had also submitted its report to Congress as required by a provision of the 1977 amendments. Among other things, the Commission recommended that the statutory approach of requiring NAAQS to be set at levels necessary to protect public health, without consideration of economic factors, be continued without change. National Commission on Air Quality, To Breathe Clean Air 55 (1981).]

[42] As the Administrator indicated in EPA's proposal to revise the PM standards:

''[T]hat review has revealed a highly limited data base—particularly where quantitative studies are concerned—and a wide range of views among qualified professionals about the exact pollution levels at which health effects are likely to occur. The setting of an 'adequate margin of safety' below these levels calls for a further judgment—in an area for which the scientific data base is even more sparse and uncertain***.''

''[L]ong and expert review of public health issues has to date revealed no scientific method of assessing exactly what level of standards public health requires. The scientific review indicates substantial uncertainties concerning the health risks associated with lower levels of particulate matter.''

49 FR 10408, 10409, Mar. 20, l984.

[43] Congress was clearly aware of the 1987 decision to revise the PM NAAQS, which among other things involved changing the indicator for particulate matter from ''total suspended particulate'' to PM_{10}, because it enacted special nonattainment provisions, as well as provisions for PSD increments, applicable to PM_{10}. Sections 188–190; section 166(f). It was clearly aware of the Vinyl Chloride decision because it amended section 112 in response to that decision, essentially creating a new scheme for setting emission standards for hazardous pollutants.

[44] H.R. Rep. No. 101–490, pt. 1, at 145 (1990). See also S. Rep. No. 101–228, at 5 (1989).

[45] Additional responses to points raised by this commenter and others are included, as appropriate, in the Response-to-Comments document.

[46] Several other commenters argue that the cited decisions are not dispositive because they held only that EPA is not required to consider costs and similar factors in setting NAAQS. As discussed below in connection with Chevron, however, the decisions clearly concluded that Congress intended to preclude consideration of such factors, and that EPA is not free to alter that congressional choice. Although these conclusions are technically dicta, nothing in the Court's opinions suggests that it would have interpreted section 109 differently had EPA claimed authority to consider costs and similar factors in NAAQS decisions. Indeed, the tone of the opinions argues to the contrary. See, e.g., PM_{10}, 902 F.2d at 973. Cf. *Ethyl Corp.* v. *EPA*, 51 F.3d 1053 (D.C. Cir. 1995).

[47] See, e.g., Lead Industries, 647 F.2d at 1146–47, 1153–56, 1160–61, 1167 n.106. In enacting the 1970 amendments, Congress was aware that there were gaps in the scientific information available then as a basis for establishing the original NAAQS. See, e.g., S. Rep. No. 91–1196, at 9–11 (1970). If anything, Congress had an even greater understanding of the point when it enacted that 1977 amendments without changing the substantive criteria for setting NAAQS. See H.R. Rep. No. 95–294, at 43–51, 181–82 (1977).

scientific knowledge'' on potential health and welfare effects of the pollutant in question. See sections 109(b), 108(a)(2). Although advances in science increase our understanding of such effects, they also raise new questions. For this reason, the key studies for any given decision on revision of a NAAQS are, almost by definition, ''at the very 'frontiers of scientific knowledge.' ''[48] That is, studies that call into question the adequacy of a standard are always those that go beyond previous studies—by reporting new kinds of effects, for example, or effects at lower concentrations than those at which effects have been reported previously.

As with pioneering work in other fields, such studies may have a variety of strengths and limitations.[49] As a result, the validity and implications of such studies may be both uncertain and highly controversial. Given the precautionary nature of section 109,[50] however, it is precisely these kinds of studies that the Administrator must grapple with when advances in science suggest that revision of a NAAQS is appropriate.

As a result, the EPA staff typically recommends for consideration, and the Administrator may propose for comment, a range of alternatives based on what the commenter would call ''ambiguous'' science. In this respect, the current reviews of the NAAQS for ozone and particulate matter are not unusual and do not differ, for example, from the review that led to adoption of the PM_{10} NAAQS in 1987.[51] Indeed, the NAAQS that were upheld in the Lead Industries, Ozone, and PM_{10} decisions were all based on highly controversial health evidence; the Lead Industries decision took note of congressional statements recognizing that there may be no thresholds for criteria pollutants; and the Ozone and PM_{10} decisions noted the Administrator's findings that clear thresholds could not be identified for ozone and particulate matter, respectively.[52] Thus, the present decisions on revision of the NAAQS for ozone and particulate matter cannot be distinguished from those past decisions in terms of the nature of the health evidence or pollutants involved.[53]

Regarding the second of the commenter's key assertions, EPA believes it is clear that the judicial decisions cited above were correctly decided and continue to be good law under Chevron. In Chevron, the Supreme Court essentially reaffirmed the principle that courts must defer to reasonable agency interpretations of the statutes they administer where Congress has delegated authority to them to elucidate particular statutory provisions. Where the intent of Congress on an issue is clear, however, it must be given effect by the agency and the courts. See 467 U.S. at 842–45. Thus, the first question on review of an agency's interpretation under Chevron is ''whether Congress has directly spoken to the precise question at issue.'' If the court determines that it has not, the remaining question for the court is ''whether the agency's answer is based on a permissible construction of the statute.'' 467 U.S. at 842–43 (footnote omitted). In determining whether Congress ''had an intention on the precise question at issue,'' a court employs ''traditional tools of statutory construction.'' *Id.* at 843 n.9.[54]

In essence, the commenter's argument here is that the Lead Industries decision did not address whether Congress had ''spoken directly'' to the precise issue posed by the commenter; that is, whether section 109 must be interpreted differently for NAAQS decisions involving non-threshold pollutants and ''ambiguous'' health evidence. The Lead Industries opinion, which pre-dated Chevron, did not pose the question in those terms. Its focus, however, was clearly on what Congress intended to be the basis for NAAQS decisions, in a context the Court understood to involve considerable uncertainty and debate about the health evidence, as well as the possibility that there was no threshold for health effects of the pollutant.[55] In short, the health evidence was hardly ''unambiguous,'' yet the Court interpreted section 109 as precluding consideration of costs and similar factors even in allowing a margin of safety. Nothing in the Lead Industries decision or in the subsequent cases suggests in any way that section 109 should be interpreted differently based on the nature of the pollutants or health evidence involved, and the Court's findings on congressional intent admit of no exceptions:

> [T]he statute and its legislative history make clear that economic considerations play no part in the promulgation of ambient air quality standards under section 109.

647 F.2d at 1148.

Alternatively, the commenter argues that the Lead Industries case decided the issue incorrectly in light of the principles announced subsequently in Chevron. In this context, the commenter essentially argues that the Lead Industries decision rested on two factors that are no longer probative: (1) That there was no indication that Congress meant to allow consideration of costs in NAAQS decisions, and (2) that Congress specifically provided for such consideration in other sections of the Act but not in section 109. On the first point, the commenter argues that EPA is free under Chevron to consider costs and similar factors (by reinterpreting section 109) unless there is evidence that Congress intended to restrict its discretion. As to the second point, the commenter argues that similar reasoning was rejected in Vinyl Chloride.

In Vinyl Chloride, however, an en banc decision that post-dated Chevron, the Court essentially underscored the point that such issues cannot be decided mechanically but must turn, instead, on more analytical attention to relevant indicia of congressional intent. See, e.g., 824 F.2d at 1157 n.4; *id.* at 1157–63. With reference to NAAQS decisions in particular, the Court concluded that there were concrete indications of congressional intent to preclude consideration of costs and similar factors; for example, the fact that section 108 ''enumerate[s] specific factors to consider and pointedly exclude[s] feasibility.'' 824 F.2d at 1159. In a later case, moreover, the same Court held that EPA could not consider certain factors, in decisions under section 211(f)(4) of the Act, for reasons exactly parallel to those that the commenter criticizes in Lead Industries. See *Ethyl Corp.* v. *EPA*, 51 F.3d 1053, 1057–63 (D.C. Cir. 1995).

[48] Lead Industries, 647 F.2d at 1147 (quoting *Ethyl Corp.* v. *EPA*, 541 F.2d 1, 24–27 (D.C. Cir.) (en banc), cert. denied, 426 U.S. 941 (1976)).

[49] They may have methodological flaws, for example, but nonetheless report effects that are of serious medical significance; or they may be of impeccable quality but involve effects of uncertain significance. Others may involve results that are striking but hard to explain in terms of previous knowledge, or results that seem plausible and important but are not yet replicated by other studies.]

[50] See, e.g., Lead Industries, 647 F.2d at 1155–56; H.R. Rep. No. 94–295, at 43–51 (1977).

[51] As previously discussed, the Administrator strongly emphasized the uncertainties involved in that review. As a result of the uncertainties, he proposed ''relatively broad'' ranges for comment, though he focused on lower levels within the ranges as providing greater margins of safety against the health risks involved. See 49 FR 10408, 10409, Mar. 20, l984.

[52] See, e.g., Lead Industries, 647 F.2d at 1152–53 & n. 43, 1159–60; Ozone, 665 F.2d at 1185, 1187; PM_{10}, 902 F.2d at 969–71, 972.

[53] Indeed, the present decisions on the NAAQS for PM and ozone are based on some of the best scientific information the Agency has ever been able to rely on in NAAQS decision-making. In particular, the science underlying these decisions is much more extensive and of much better quality than the science underlying the existing NAAQS for PM and ozone.

[54] In practice, analysis of this question is sometimes referred to as a ''Chevron step one'' analysis.

[55] See, e.g., 647 F.2d at 1148–51, 1152–53 & n.43, 1160–61.

Beyond this, the commenter's characterization of the Lead Industries decision ignores or discounts much of the key evidence cited by the Court, including the language, structure, and legislative history of the statutory scheme established in 1970, for its conclusion that Congress intended to preclude consideration of costs and similar factors in NAAQS decisions.[56] As indicated above, the Vinyl Chloride and PM_{10} cases, both of which post-dated Chevron, reached the same conclusion.

Moreover, this series of decisions went far beyond mere deference to an agency interpretation. As indicated in the Vinyl Chloride case, the Lead Industries court found ''clear evidence'' of congressional intent, which was to limit the factors EPA may consider under section 109. 824 F.2d 1159. Consistent with Chevron, these findings were based on traditional tools of statutory construction. See *id.* at 1157–59; Lead Industries, 647 F.2d at 1148–51. In terms of the analytical framework later established by Chevron, these were Chevron step one findings, meaning that the statute spoke directly to the issue and that the courts, as well as the agency, must give effect to Congress' intent as so ascertained. See 467 U.S. at 842–43.[57] Thus, absent a more recent legislative enactment overriding that intent, EPA has no discretion to alter its longstanding interpretation that consideration of costs and similar factors is precluded in NAAQS decisions under section 109.[58]

As to the commenter's third key assertion, Executive Order 12866 (58 FR 51735, October 4, 1993) UMRA sections 202 and 205, and the Regulatory Flexibility Act (RFA), as amended by SBREFA, do not conflict with this interpretation or require a different result. Basically, the commenter argues that the Executive Order, UMRA, and the RFA (as amended by SBREFA) require agencies to use cost (or similar factors) as a decisional criterion in making regulatory decisions, and that this modifies the Clean Air Act's directive that EPA is precluded from considering costs when setting a NAAQS. The commenter's argument is flawed on a number of grounds. First, UMRA and the RFA (as amended by SBREFA) do not conflict with section 109 because they do not apply to this decision, as discussed in Unit VIII of this preamble. Second, the Executive Order and both statutes are quite clear that they do not override the substantive provisions in an authorizing statute. Third, the commenter's premise that UMRA and the RFA (as amended by SBREFA) establish substantive decisional criteria that agencies are required to follow is wrong.

As a matter of law, the Executive Order cannot (and does not purport to) override the Clean Air Act. The Executive Order does not conflict with section 109 because the requirement that agencies ''select approaches that maximize net benefits'' does not apply if a ''statute requires another regulatory approach.'' EO 12866, sec. (1)(a), 58 FR 51735, Oct. 4, 1993. More generally, the Executive Order provides that agencies are to adhere to its regulatory principles only ''to the extent permitted by law.'' *Id.*, sec. (1)(b).

UMRA sections 202 and 205 do not apply to this decision, as discussed in Unit VII of this preamble. Even when they do apply to a regulatory action, they do not establish decisional criteria that an agency must follow, much less override decisional criteria established in the statute authorizing the regulatory action. UMRA does not require an agency to select any particular alternative. Rather, an agency can select an alternative that is not the least costly, most cost-effective or least burdensome if the agency explains why, sec. 205(b)(1). Such an explanation is not required if the least costly, most cost-effective or least burdensome alternative would have been ''inconsistent with law,'' sec. 205(b)(2), and the only alternatives that an agency should consider are ones that ''achieve[] the objectives of the rule,'' sec. 205(a). The UMRA Conference Report confirms that UMRA does not override the authorizing statute. ''This section [202] does not require the preparation of any estimate or analysis if the agency is prohibited by law from considering the estimate or analysis in adopting the rule.'' 141 Cong. Rec. H3063 (daily ed. March 13, 1995).

The RFA (as amended by SBREFA) also does not apply to this decision, as discussed in Unit VII of this preamble. As is the case with UMRA, even when the RFA (as amended by SBREFA) does apply to a regulatory action, it does not establish decisional criteria that an agency must follow, much less override the underlying substantive statute. When the RFA was adopted in 1980, Congress made clear that it did not alter the substantive standards contained in authorizing statutes: ''The requirements of section 603 and 604 of this title [to prepare initial and final regulatory flexibility analyses] do not alter in any manner standards otherwise applicable by law to agency action.'' Section 606 of the RFA. The legislative history further explains that section 606 ''succinctly states that this bill does not alter the substantive standard contained in underlying statutes which defines the agency's mandate.''[59] When Congress passed SBREFA in 1996 and amended parts of the RFA, it did not amend section 606.

Even when a regulatory decision is subject to sections 603 and 604 and an agency is therefore required to analyze alternatives that minimize significant economic impacts on small entities, the RFA (as amended by SBREFA) does not establish decisional criteria that an agency is required to follow. Both section 603 and 604 provide that the

[56] See 647 F.2d at 1148–51. By contrast, the commenter's argument that Congress actually intended EPA to consider such factors relies heavily on (1) statements made in subsequent legislative history, most of which were made in floor debate, that sought to justify controversial amendments to establish a different program than the NAAQS and did not involve any proposed changes in section 109 or related provisions; and (2) statements in early judicial decisions involving programs under other statutory provisions. In context, EPA believes these and other statements cited by the commenter are consistent with and do not alter the conclusion that Congress intended to preclude consideration of costs and similar factors under section 109.

[57] The commenter argues that the post-Chevron cases accepted the Lead Industries analysis uncritically rather than re-examining it under Chevron. Clearly, this elevates form over substance. It is true that neither case referred to Chevron in discussing the point at issue. In Vinyl Chloride, however, the Court retraced the steps in the Lead Industries analysis in some detail, characterized some of the key evidence reviewed in that analysis in terms going beyond mere rote repetition (e.g., ''a far clearer statement than anything in the present case that Congress considered the alternatives''), and used Chevron-like language in discussing the significance of that evidence; that is, that it demonstrated congressional intention on the point at issue. E.g., 824 F.2d at 1159. Given that the Vinyl Chloride case was decided 3 years after Chevron, that it was an en banc decision of the D.C. Circuit involving interpretation of statutory language very similar to that in Lead Industries, and that the Court cited Chevron twice in analyzing the language and history of section 112, it seems highly unlikely that the Court was unmindful of Chevron principles in concluding that Congress intended to preclude consideration of costs under section 109 but not under section 112.

In the PM_{10} decision, the Court confirmed the sharp distinction it had drawn, based on such evidence of congressional intent, between sections 109 and 112 in Vinyl Chloride. 902 F.2d at 972–73. Although discussion of the point was brief and did not mention Chevron, the industry petitioner raising the point had cited Chevron in arguing that the Lead Industries interpretation was not binding, and that EPA's decision on the PM_{10} standards should be reversed on the ground that it rested on a legal position that EPA unjustifiably believed was mandated by Congress. Reply Brief of the American Iron and Steel Institute at 11 & n.10, *Natural Resources Defense Council* v. *Administrator*, 902 F.2d 962 (D.C. Cir. 1990) (Nos. 87–1438 et al.). Thus, Chevron issues were properly before the Court and were brought squarely to its attention.

[58] See also 52 FR 24854, July 1, 1987.

[59] 126 Cong. Rec. 21452, 21455 (1980) (Description of Major Issues and Section-By-Section Analysis of Substitute for S. 299).

alternatives an agency should consider are to be ''consistent with the stated objectives of applicable statutes.'' Sec. 603 and 604(a)(5). Furthermore, although the RFA (as amended by SBREFA) requires agencies to consider alternatives that minimize impacts on small entities subject to the rules' requirements and to explain their choice of regulatory alternatives, it does not require agencies to select such alternatives. For these reasons, the RFA (as amended by SBREFA) does not conflict with or override the Clean Air Act's preclusion of considering costs and similar factors in setting NAAQS.

3. *Conclusion.* In summary, EPA believes that the judicial decisions cited above are both correct and dispositive on the question of considering costs in setting NAAQS, and that the Agency is not free to reinterpret the Act on that question.

B. Margin of Safety

Several commenters questioned the approach used by the Administrator in specifying O_3 standards that protect public health with an adequate margin of safety. Rather than the integrative approach applied by the Administrator, these commenters maintained that EPA must employ a two-step process. The line of argument was that the Administrator must first determine a ''safe level'' and then apply a margin of safety taking into account costs and societal impacts. It was argued that this was the only approach that would enable the Administrator to reach a reasoned decision on a standard level that protects public health against unacceptable risk of harm, such that any remaining risk was ''acceptable.'' In effect, these commenters argued that the Administrator must adopt the two-step methodology endorsed in Vinyl Chloride, 824 F.2d 1146, for setting hazardous air pollutant standards under section 112.

In recognition of the complexities facing the Administrator in determining a standard that protects public health with an adequate margin of safety, the courts have declined to impose any specific requirements on the Administrator's methodological approach. Thus, in Lead Industries the court held that the selection of any particular approach to providing an adequate margin of safety ''is a policy choice of the type Congress specifically left to the Administrator's judgment. This court must allow him the discretion to determine which approach will best fulfill the goals of the Act.'' 647 F.2d at 1161–62. As a result, the Administrator is not limited to any single approach to determining an adequate margin of safety and may, in the exercise of her judgment, choose an integrative approach, a two-step approach, or perhaps some other approach, depending on the particular circumstances confronting her in a given NAAQS review.

With respect to the approach advanced in comment, the PM_{10} case made clear that the two-step process endorsed in Vinyl Chloride was necessary because of the need under section 112 of the Act to ''sever determinations that must be based solely on health considerations from those that may include economic and technical considerations.'' 902 F.2d at 973. Because the Administrator may not consider cost and technological feasibility under section 109, however, the court concluded that ''the rationale for parsing the Administrator's determination into two steps is inapposite.'' *Id.*

Because such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, the types of health information available, and the kind and degree of uncertainties that must be addressed will vary from one pollutant to another, the most appropriate approach to establishing a NAAQS with an adequate margin of safety may be different for each standard under review. Thus, no generalized paradigm such as that imbedded in EPA's cancer risk policy can substitute for the Administrator's careful and reasoned assessment of all relevant health factors in reaching such a judgment. As noted above, both Congress and the courts have left to the Administrator's discretion the choice of analytical approaches and tools, including risk assessments, rather than prescribing a particular formula for reaching such determinations. Because of the inherent uncertainties that the Administrator must address in margin of safety determinations, they are largely judgmental in nature, particularly with respect to non-threshold pollutants, and may not be amenable to quantification in terms of what risk is ''acceptable'' or any other metric. In view of these considerations, the task of the Administrator is to select an approach that best takes into account the health effects and other information assessed in the air quality criteria for the pollutant in question and to apply appropriate and reasoned analysis to ensure that the scientific uncertainties are taken into account in an appropriate manner.

In this instance, the Administrator has clearly articulated the factors she has considered, the judgments she has had to make in the face of uncertain and incomplete information, and alternative views as to how such information should be interpreted, in reaching her decision on standard specifications that will protect public health with an adequate margin of safety. See Unit II of this preamble. Her conclusions on these matters are fully supported by the record.

C. Comment Period

A number of commenters maintained that EPA erred by not extending the comment period for the review of the O_3 standards by at least 60 days. The commenters further maintained there was no justification for keeping the O_3 standard review on the same schedule as the PM NAAQS, since the O_3 review is not subject to a court-ordered deadline as is PM.

The EPA believes that there are benefits to reviewing the O_3 and PM NAAQS on the same schedule, for the reasons set forth in the proposal, and that the period available for public comment was sufficient. All interested parties have had ample notice that EPA intended to complete this review of the O_3 standards on an expedited basis. The EPA first announced its intention in a March 9, 1993, **Federal Register** notice (58 FR 13008) when the Administrator announced her commitment to expedite the review in light of new scientific evidence of the effects of O_3 on human health. In a February 3, 1994, **Federal Register** notice (59 FR 5164), the Administrator announced a schedule for completion of the scientific assessment and review of the standards, including opportunities for public comment. This schedule called for proposal in mid-1996 and a final decision as to whether to revise the O_3 standard by mid–1997. On June 12, 1996, in an advance notice of proposed rulemaking (61 FR 29719), the Administrator announced her decision to delay the O_3 proposal schedule in order to place it on the same schedule as the PM standard review. In that notice, she explained her rationale for reviewing the O_3 and PM NAAQS on the same schedule and pointed to the benefits of developing integrated implementation strategies. She also provided advance notice of the kinds of revisions to the primary and secondary O_3 NAAQS that she was considering proposing. In effect, the delay of the O_3 proposal provided interested parties an additional 5 months to review EPA's assessments of the scientific and technical information, as well as staff and CASAC recommendations as to whether revisions were appropriate. With this background, EPA believes all interested parties had ample opportunity to develop specific

comments on the O_3 proposal during the 89 days allotted for public comment.[60]

Another commenter raised a more specific issue in requesting a 60–day extension of the public comment period. This commenter maintained that such an extension was necessary because EPA did not make publicly available certain O_3 exposure and health risk assessment reports and an explanatory memoranda in a timely manner. In response, EPA notes that the documents in question were entered into the docket on February 12, 1997, and placed on the OAQPS Technology Transfer Bulletin Board on February 13, 1997, so that they would have wide public circulation. Because this commenter's organization was aware that the reports were under preparation and had expressed interest in receiving them, copies were sent directly to the responsible staff person on February 12, 1997. Given that these reports build on analyses and methodologies that were available to the public during the scientific phase of the O_3 NAAQS review, well in advance of the proposal, and that the new analyses and explanatory memorandum were only 120 pages in length, EPA believes that this commenter had sufficient time to review the material and prepare comments before the close of the comment period on March 12, 1997.

D. 1990 Act Amendments

Contrary to the view expressed in some public comments, EPA maintains that the provisions of subpart 2 of Part D of Title I of the Clean Air Act, enacted in 1990, do not preclude EPA from revising the O_3 standard. The provisions of subpart 2 simply do not limit EPA's clear authority under section 109 to revise the standard.

The basic contention of the commenters is that because the provisions of subpart 2 are linked to the current 1–hour, 0.12 ppm O_3 standard, they prohibit EPA from revising the O_3 standard. These provisions, however, do not lead to such a conclusion. Moreover, the view expressed in these comments ignores provisions indicating that Congress believed that EPA could revise the O_3 NAAQS.

At the outset, it should be noted that Congress expressly authorized EPA to revise any ambient air quality standard in section 109. That section, which requires EPA to review and revise, as appropriate, each NAAQS every 5 years, contains no language expressly or implicitly prohibiting EPA from revising a NAAQS. If Congress had intended to preclude EPA from reviewing and revising a NAAQS, which is one of EPA's fundamental functions, Congress would have specifically done so. Clearly, Congress knew how to preclude EPA from exercising otherwise existing regulatory authority and did so in other instances. See section 202(b)(1)(C)(expressly precluding EPA from modifying certain motor vehicle standards prior to model year 2004); section 112(b)(2)(preventing EPA from adding to the list of hazardous air pollutants any air pollutants that are listed under section 108(a) unless they meet the specific exceptions of section 112(b)(2)); section 249(e)(3), (f) and section 250(b)(limiting EPA's authority regarding certain clean-fuel vehicle programs). No such language was included in either section 109 or elsewhere in the Act and no such implication may properly be based on the provisions of subpart 2 of Part D of Title I.

Second, other provisions of the Act expressly contemplate EPA's ability to revise any NAAQS, and provide no indication that such ability is limited to standards other than those whose implementation is the subject of subparts 2, 3 and 4 of Part D. For example, section 110(a)(2)(H)(i) provides that SIPs are to provide for revisions ''from time to time as may be necessary to take account of revisions of such national primary or secondary ambient air quality standard ***.'' Section 107(d)(1)(A) provides a process for designating areas as attainment, nonattainment, or unclassifiable ''after promulgation of a new or revised standard for any pollutant under section 109 ***.'' Section 172(e) addresses modifications of national primary ambient air quality standards. Finally, section 172(a)(1) expressly contemplates that EPA may revise a standard in effect at the time of enactment of the 1990 Clean Air Act Amendments. Section 172(a)(1)(A) provides EPA with authority to classify nonattainment areas on or after the designation of an area as nonattainment with respect to ''any revised standard, including a revision of any standard in effect on the date of the enactment of the Clean Air Act Amendments of 1990.'' Plainly, Congress had no intention of prohibiting EPA from revising any of the ambient standards in effect at the time of the enactment of the 1990 amendments.

Third, the provisions of subpart 2 of Part D do not support the contention that they somehow preclude EPA from exercising its authority to revise the NAAQS under section 109. The fact that Congress laid out an implementation program for the O_3 standard existing at the time of the 1990 amendments in no way suggests that Congress intended to preclude EPA from exercising the authority it provided EPA to revise the NAAQS when the health data on which EPA bases such decisions warranted a change in the standard. Contrary to this contention, section 181(a) does not preclude the designation of areas as nonattainment for O_3 that have design values less than 0.121 ppm. EPA has designated as nonattainment numerous areas whose design value was less than 0.121 ppm, but which violated the existing 1–hour, 0.12 ppm O_3 standard. These areas, referred to as ''nonclassifiable nonattainment areas,'' include ''submarginal'' areas (i.e., O_3 nonattainment areas with design values below 0.121 ppm), (See 57 FR 13498, 13524–27, April 16, 1992). These areas include areas that were designated nonattainment prior to the 1990 amendments and whose nonattainment designation Congress required to be continued after 1990. See section 107(d)(1)(C)(i). Clearly, Congress did not prohibit the designation of areas as nonattainment for O_3 with design values below 0.121 ppm; in fact, in some cases, Congress required it. Furthermore, the position advanced by the commenters would mean that, in effect, Congress in the 1990 amendments legislatively revised the then-existing 1–hour, 0.12 ppm O_3 standard to a 0.121 ppm standard. There is no indication that Congress intended to do that.

In addition, the fact that Congress directed EPA to use ''the interpretation methodology issued by the Administrator most recently'' before the date of the enactment of the Clean Air Act Amendments of 1990 in the context of subpart 2 does not add any support to the commenters' position; it merely shows that Congress intended the existing 1–hour, 0.12 ppm standard to be implemented in a specified way, not that Congress intended to preclude EPA from using its otherwise applicable authority to revise the standard.

The EPA also disagrees with the contention that sections 172(a)(1)(C) and (a)(2)(D), which provide that the general classification and attainment date provisions of section 172 do not apply to areas for which classifications or attainment dates ''are specifically provided under other provisions of this part,'' support the conclusion that Congress intended to prohibit EPA from revising the O_3 standard. These provisions simply mean that where Congress elsewhere provided for specific classifications and attainment dates, as in the case of subpart 2 regarding the 1–hour, 0.12 ppm standard, EPA is not to modify those

[60] This comment period reflects an extension of 22 days beyond the 67–day comment period originally announced in the proposal.

classifications or dates. The EPA is not purporting to do this. These provisions do not lead to the conclusion that because Congress established them for the O_3 standard in effect at the time of the 1990 amendments, Congress meant that EPA could not revise that standard in order to appropriately protect public health.

EPA does not accept the thesis that revising the O_3 standard forces EPA to violate other provisions of the Act and, therefore, is not an ''appropriate'' revision of the standard under section 109. Revising the O_3 standard in accordance with the language of section 109 does not result in EPA violating any provision of the Act. On the other hand, a determination by EPA that the O_3 standard should not be revised, even though EPA concludes that it needs to be revised to protect public health with an adequate margin of safety, would violate section 109.

Also, EPA does not believe that carrying out the provisions of section 109 to set a new O_3 standard to protect public health with an adequate margin of safety somehow ''risks undermining both perceptions and reality of the functioning of our democratic form of government.'' EPA is merely implementing the words of the Clean Air Act, a statute passed by the Congress and signed by the President. To refuse to revise the standard notwithstanding the need to protect public health as enunciated in section 109 would thwart the objectives of those who passed and signed the Clean Air Act on behalf of the American public.

Finally, for the reasons stated above, EPA's analysis of its ability to implement the revised O_3 standard under the provisions of subpart 1 of Part D of Title I does not support the view that Congress prohibited EPA from revising the standard. Congress clearly specified an approach to the implementation of the 1–hour, 0.12 ppm O_3 standard in the provisions of subpart 2 of Part D. EPA believes that the clear and express linkage of that approach to the 1–hour, 0.12 ppm standard indicates that it may implement a revised O_3 standard in accord with the general principles of subpart 1 of Part D, as informed by the no-backsliding principle embodied in section 172(e). That Congress directed specifically how EPA and the States should implement the 1–hour, 0.12 ppm O_3 standard does not carry with it the implication that Congress intended to prohibit EPA from exercising its otherwise clear and express authority to revise that standard in order to carry out one of its fundamental missions, the establishment of ambient air quality standards to protect public health with an ample margin of safety. If Congress had intended to prohibit EPA from exercising such a fundamental authority it would have clearly specified (as it did in other instances) that EPA could not do so.

The EPA also disagrees with the contention that a revised O_3 standard may not be implemented for so long as the current 1–hour, 0.12 ppm O_3 standard remains in effect. The fact that the provisions of subpart 2 of Part D are focused on the implementation of the current standard does not mean that, if a new or revised O_3 standard is promulgated pursuant to section 109, the new standard could not simultaneously be implemented under the provisions of section 110 and subpart 1 of Part D, which apply regardless of the criteria pollutant of concern. There is no language in sections 181 or 182 that precludes the implementation of a different standard under other authority; those provisions simply govern the implementation of the 1–hour, 0.12 ppm O_3 standard. EPA further notes that it has historically had more than one primary standard for criteria pollutants (e.g., annual and 24–hour PM_{10} and sulfur dioxide standards, and 8–hour and 1–hour CO standards) and believes that had Congress wanted to preclude EPA from implementing two primary O_3 standards simultaneously it would have expressly precluded EPA from doing so. Thus, EPA does not believe that it must repeal the 1–hour, 0.12 ppm O_3 standard before it can promulgate and implement a new primary O_3 standard.

V. Technical Changes to Part 50

In the proposal, the EPA proposed two alternative secondary standards: (1) A secondary standard set identical to the proposed 0.08 ppm, 8-hour primary standard; or (2) a seasonal secondary standard expressed in the SUM06 form. For the reasons discussed in Unit III, the EPA has decided to promulgate a secondary ambient air quality standard for O_3 that is identical to the primary ambient air quality standard. Accordingly, the language adopted in the final regulation (40 CFR 50.10) has been revised to reflect this change.

In the proposal, the regulatory text in § 50.9 inadvertently included language about what it means when the standard is not met, that should have been discussed in 40 CFR part 50, Appendix H. Therefore this sentence has been removed from § 50.10(b), and the discussion moved to the new Appendix I to 40 CFR part 50, which now provides additional clarification on calculations for sites with less than complete data, as discussed in Unit VI. of this preamble.

VI. Revisions to Appendices D, E, and H

The EPA is finalizing the changes to Appendices D and E to 40 CFR part 50, that were proposed and described in the proposal. No adverse comments were received on these changes.

Because the revocation of the existing 1–hour standard will become effective at a later date (as discussed above in Unit II.B.4.), EPA is retaining Appendix H in its current form. A new Appendix I explains the computations necessary for determining when the new 8–hour primary and secondary standards are met.

The new Appendix I addresses data completeness requirements, data reporting, handling, and rounding conventions, and example calculations. The discussion in this unit sometimes refers to the contents of the new Appendix I as revisions to Appendix H, so as to highlight how the new Appendix I differs from the current Appendix H. For example, the example calculations in Appendix I differ from those in Appendix H to reflect the final form of the new 8–hour primary standard.

In the proposal, two alternative secondary standards were proposed, and the proposed changes to Appendix H addressed both alternatives: A secondary standard set identical to the proposed 0.08 ppm, 8–hour primary standard; or a seasonal secondary standard expressed in the SUM06 form. For the reasons discussed above, the Administrator has decided to set the secondary standard identical to the primary standard as reflected in Appendix I.

Key elements of Appendix I, particularly as they differ from those of Appendix H, are outlined below.

A. Data Completeness

One key change to Appendix H, incorporated into Appendix I, for the new 0.08 ppm, 8–hour primary and secondary standards is that no numerical adjustment is made to the measured 8–hour concentrations to account for missing or incomplete data as was the case with the 1–hour standard. Instead, the EPA has decided to replace the methodology used to adjust the computation of estimated exceedances for missing data under the 1–hour standard with new data completeness requirements for the 8–hour standards.

The EPA proposed that, in order to determine that the 8–hour standards have been met at a monitoring site

during the current 3–year period, revisions to Appendix H would require 90 percent data completeness, on average, with no single year at the site having less than 75 percent data completeness. A site could be found not to have met the standards with less than complete data. Almost all commenters supported deleting the estimated exceedances missing data adjustment procedure of the current 1–hour standard and replacing it with minimum data completeness requirements. Several commenters felt that the proposed data completeness requirement might be too stringent and would be difficult to attain. Other commenters recommended that some consideration be made for hours lost due to instrument calibration. A few commenters thought that EPA should establish higher minimum data completeness requirements.

Based on its analysis of available air quality data, the EPA believes that, with the changes to the proposal described below, the data completeness requirement in Appendix I is reasonable given that 90 percent of all monitoring sites that currently operate on a continuous basis meet this objective. The EPA believes that a missing hour during the day resulting from instrument calibration should not negatively impact the ability of a monitoring site to meet the data completeness requirements because data completeness is based on the number of days with valid daily maximum 8–hour concentrations, not on the number of non-missing hours.

In the proposal, the EPA sought comment on whether meteorological data could provide an objective basis for determining, on a day for which there is missing data, that the meteorological conditions were not conducive to high O_3 concentrations, and therefore, that the day could be assumed to have an 8–hour daily maximum O_3 concentration less than 0.08 ppm. Under the 0.12 ppm 1–hour standard, a missing day is assumed less than the level of the standard only if the two adjacent days are non-missing, and the daily maximum 1–hour concentration on each of those days is less than or equal to 0.09 ppm. In the proposal, the EPA specifically requested comment on the appropriateness of using data on meteorological conditions, as well as on other information that would permit better definition of those necessary conditions likely to result in peak 8–hour O_3 concentrations in the ranges of concern. Most commenters expressing an opinion supported the use of meteorological data, as well as ambient data from nearby monitoring sites to establish that missing hours could be assumed less than the level of the standard. Days assumed less than the level of the standard would be counted as non-missing when computing whether the data completeness requirements have been met at the site. Taking these comments into account, EPA has revised the proposed revisions to Appendix H, as reflected in Appendix I, to count missing days assumed less than the standard when computing whether the data completeness requirement has been met. EPA will develop guidance on methodologies necessary for using meteorological data and ambient measurements to make such determinations.

Several commenters expressed concerns about the possibility that stratospheric O_3 intrusion from aloft or forest fires may lead to exceedances of the level of the standard, particularly within the context of peak O_3 concentrations that have been observed at background sites. Commenters expressed concern that such events could lead to violations of the 8–hour standard and, therefore, they questioned the attainability of the proposed standard. Consistent with a forthcoming update to EPA's policy on natural events for the new 8–hour standard, EPA has revised Appendix H to specifically address this concern by stating that whether to use data affected by stratospheric O_3 intrusion or other natural events when determining if the standards have been met is subject to the approval of the appropriate Regional Administrator.

B. Data Handling and Rounding Conventions

For the reasons cited above, and taking into account the advice of CASAC, the Administrator has set the level of the new 8–hour primary and secondary standards at 0.08 ppm. As EPA explained in the proposal, the level of the 8–hour standard is expressed to the second decimal place, 0.08 ppm, with the support of CASAC and in part to reflect uncertainties in the health effects evidence upon which the proposed standard is based. More specifically, these uncertainties include the measurement uncertainty and representativeness inherent in the reported ambient O_3 concentrations used in field and epidemiological studies and the uncertainty in the exposure estimates upon which quantitative risk assessments have been based. In the proposal, EPA stated its belief that expressing the proposed standard to the second decimal place is also consistent with the quality assurance guidelines that indicate the precision[61] for such O_3 measurements shall be within ± 15 percent.

To determine whether the standard is met, EPA proposed that the calculated value of the third-highest maximum 8–hour average concentrations, averaged over 3 years, is compared to the level of the standard. It is the level of the standard, 0.08 ppm, expressed to two decimal places that determines the number of significant digits to be used when comparing air quality measurements to the standard. The EPA proposed that, for hourly data, 8–hour average O_3 concentrations computed from such hourly data, and the 3–year averages of the third highest maximum 8–hour average concentrations, that the third decimal place is carried forward as the rounding digit, and the insignificant digits are truncated. To compare the calculated 3–year average O_3 concentration to the level of the standard, the third decimal place of the calculated value is rounded. The current rounding convention is to round up digits equal to or greater than 5.

In the proposal, EPA recognized that the level of public health protection afforded by the use of the current rounding convention could be increased by replacing the current rounding convention with a convention that defined the smallest increment above the level of the standard to be 0.001 ppm for the purposes of determining whether the standard has been met. The EPA solicited comment on the use of such an alternative rounding convention, with regard to potential increased public health protection, as well as to potential effects on the probability of attainment misclassifications and on the stability of the standard.

Of the many States that commented specifically on the rounding convention, most State agencies cited concerns by their monitoring staffs about the precision and accuracy of measured O_3 concentrations in ambient environments and recommended maintaining the current rounding convention. A tribal association also supported the current rounding convention. Other State agencies felt that newer instruments were capable of supporting a rounding convention set at 0.001 ppm. Of those environmental and health associations that commented, all supported replacing the current rounding convention with

[61] The term precision is used to denote both the reproducibility of a measurement under a constant set of conditions, as well as other components of measurement uncertainty such as instrument drift and relative bias.

the alternative 0.001 ppm convention.[62] All industry and trade associations that commented on rounding recommended that EPA retain the current rounding convention.

After taking these comments into account, EPA has decided that the current rounding approach is appropriate for comparing monitoring data to the level of the standard expressed to two decimal places. The current rounding procedure has the effect of reducing the probability of misclassifying an attainment area as nonattainment and of producing a more stable attainment test. The EPA believes that measures that promote a stable control program will lead to greater long-term health protection and risk reduction. For the reasons stated above, and taking into account the uncertainty in the exposure estimates upon which quantitative risk assessments have been based, measurement uncertainty, data representativeness, and the desirability of these resulting effects, EPA is retaining the current rounding convention and finalizing the data handling and rounding conventions, in Appendix I, as proposed.

VII. Regulatory and Environmental Impact Analyses

As discussed in Unit IV of this preamble, the Clean Air Act and judicial decisions make clear that the economic and technological feasibility of attaining ambient standards are not to be considered in setting NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although, as described below, a Regulatory Impact Analysis (RIA) has been prepared, neither the RIA nor the associated contractor reports have been considered in issuing this final rule.

A. Executive Order 12866

Under Executive Order 12866, 58 FR 51735 (October 4, 1993), the Agency must determine whether a regulatory action is ''significant'' and, therefore, subject to Office of Management and Budget (OMB) review and other requirements of the Executive Order. The order defines ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency.

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

In view of its important policy implications, this action has been judged to be a ''significant regulatory action'' within the meaning of the Executive Order. As a result, under section 6 of the Executive Order, EPA has prepared an RIA, entitled ''Regulatory Impact Analysis for Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule (July 1997).'' This RIA assesses the costs, economic impacts, and benefits associated with potential State implementation strategies for attaining the PM and O_3 NAAQS and the proposed Regional Haze Rule. Changes made in response to OMB suggestions or recommendations will be documented in the public docket and made available for public inspection at EPA's Air and Radiation Docket Information Center (Docket No. A-95-58). The RIA will be publicly available in hard copy by contacting the U.S. Environmental Protection Agency Library at the address under ''Availability of Related Information'' and in electronic form as discussed above in ''Electronic Availability.''

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., provides that, whenever an agency is required to publish a general notice of rulemaking for a proposed rule, the agency must prepare an initial regulatory flexibility analysis for the proposed rule unless the head of the agency certifies that the rule ''will not, if promulgated, have a significant economic impact on a substantial number of small entities'' (section 605(b)). The EPA certified each of the proposed NAAQS rules based on its conclusion that the rule would not establish requirements applicable to small entities and therefore would not have a significant economic impact on small entities within the meaning of the RFA. See 61 FR 65638, 65668 (PM proposal); 61 FR 65716, 65746 (ozone proposal), both published on December 13, 1996. Accordingly, the Agency did not prepare an initial regulatory flexibility analysis for the proposed rule, but it did conduct a more general analysis of the potential impact on small entities of possible State strategies for implementing any new or revised NAAQS.

At the heart of EPA's certification of the proposed NAAQS rule was the Agency's interpretation of the word ''impact'' as used in the RFA. Is the ''impact'' to be analyzed under the RFA a rule's impact on the small entities that will be subject to the rule's requirements, or the rule's impact on small entities in general, whether or not they will be subject to the rule? In the case of NAAQS rules, the question arises because of the congressionally-designed mixture of Federal and State responsibilities in setting and implementing the NAAQS.

As EPA explained in the proposal, NAAQS rules establish air quality standards that States are primarily responsible for meeting. Under section 110 and part D of Title I of the CAA, every State develops a State Implementation Plan (SIP) containing the control measures that will achieve a newly promulgated NAAQS. States have broad discretion in the choice of control measures. As the U.S. Supreme Court noted in *Train* v. *NRDC*:

> [P]rimary [NAAQS] deal with the quality of outdoor air and are fixed on a nationwide basis at a level which the agency determines will protect the public health. It is the attainment and maintenance of these standards which section 110(a)(2)(A) requires that State plans provide. In complying with this requirement, a State's plan must include ''emission limitations'' which are regulations of the composition of substances emitted into the ambient air from such sources as power plants, service stations and the like. They are the specific rules to which operators of pollution sources are subject and which, if enforced, should result in ambient air which meets the national standards.
>
> The Agency is plainly charged by the Act with the responsibility for setting the national ambient air standards. Just as plainly, it is relegated to a secondary role in the process of determining and enforcing the specific, source-by-source emission limitations which are necessary if the national standards are to be met. Under 110(a)(2), the Agency *is required* to approve a State plan which provides for the timely attainment and maintenance of the ambient air standards, and which also satisfies that section's other general requirements. The Act gives the agency no authority to question the wisdom of a State's choices of emission limitations if they are part of a plan which satisfies the standards of 110(a)(2) and the Agency may devise and promulgate a plan of

[62] One individual commenter provided an analysis of current monitoring technology and suggested that the precision and accuracy data supported setting the standard to three decimal places and rounding the annual average third-highest 8–hour average concentration up at 0.001 ppm. EPA believes that the precision and accuracy data cited by the commenter does not capture all of the uncertainty inherent in ambient air quality measurements.

its own only if the state fails to submit an implementation plan which satisfies those standards. Section 110(c).

421 U.S. 60, at 78–79 (1975) (emphasis in original). In short, NAAQS rules themselves do not establish any control requirements applicable to small entities. State rules implementing the NAAQS may establish such requirements and the extent to which they do depends primarily on each State's strategy for meeting the NAAQS.[63]

To determine the proper interpretation of ''impact'' under the RFA, EPA considered the RFA's stated purpose, its requirements for regulatory flexibility analyses, its legislative history, the amendments made by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)(Pub. L. 104–121), and caselaw. The EPA concluded that all of these traditional tools of statutory construction point in one direction—that an agency is required to assess the impact of a rule on the small entities that will be subject to the rule's requirements, because the purpose of a regulatory flexibility analysis is to consider ways of easing or even waiving a rule's requirements as they will apply to small entities, consistent with the statute authorizing the rule. That purpose cannot be served in the case of the rules like the NAAQS that do not have requirements that apply to small entities.

More specifically, EPA noted that its interpretation of ''impact'' flows from the express purpose of the RFA itself. As the RFA's ''Findings and Purposes'' section (Pub. L. 96–354, section 2) makes clear, Congress enacted the RFA in 1980 out of concern that agencies were writing one-size-fits-all regulations that in fact did not fit the size and resources of small entities. Congress noted that it is generally easier for big businesses to comply with regulations, and that small businesses are therefore at a competitive disadvantage in complying with uniform rules. Congress also noted that small entities' relative contribution to the problem a rule is supposed to solve may not warrant applying the same requirements to large and small entities alike. In the RFA itself, Congress therefore stated:

It is the purpose of this Act to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.

[Pub. L. 96–354, section 2(b).]

The EPA further noted that the RFA sections governing initial and final regulatory flexibility analyses reflect this statement of purpose. RFA sections 603 and 604 require that initial and final regulatory flexibility analyses identify the types and estimate the numbers of small entities ''to which the proposed rule will apply'' (sections 603(b)(3) and 604(a)(3)). Similarly, they require a description of the ''projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement'' (sections 603(b)(4) and 604(a)(4)). At the core of the analyses is the requirement that agencies identify and consider ''significant regulatory alternatives'' that would ''accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities'' (section 603(c) and 604(a)(5)). Among the types of alternatives agencies are to consider are the establishment of different ''compliance or reporting requirements or timetables'' for small entities and the exemption of small entities ''from coverage of the rule, or any part'' of the rule (section 603(c)(1) and (4)). The RFA thus makes clear that regulatory flexibility analyses are to focus on how to minimize rule requirements on small entities.

As EPA further explained, since regulatory flexibility analyses are not required for a rule that will not have a ''significant economic impact on a substantial number of small entities,'' it makes sense to interpret ''impact'' in light of the requirements for such analyses. Regulatory flexibility analyses, as described above, are to consider how a rule will apply to small entities and how its requirements may be minimized with respect to small entities. In this context, ''impact'' is appropriately interpreted to mean the impact of a rule on the small entities subject to the rule's requirements.

The Agency cited two Federal court cases in support of its interpretation. In *Mid-Tex Elec. Co-op* v. *FERC*, 773 F.2d 327, 342 (D.C. Cir. 1985), petitioners claimed that the RFA required an agency to analyze the effects of a rule on small entities that were not regulated by the rule but might be indirectly impacted by it. Petitioners noted that the Small Business Administration (SBA) also interpreted the RFA to require analysis of a rule's impact on small entities not regulated by the rule, and argued that the court should defer to the SBA's position in light of its compliance monitoring role under the RFA. After reviewing the RFA's ''Findings and Purposes'' section, its legislative history, and its requirements for regulatory flexibility analyses, the Mid-Tex court rejected petitioners' interpretation. As the court explained:

The problem Congress stated it discerned was the high cost to small entities of compliance with uniform regulations, and the remedy Congress fashioned—careful consideration of those costs in regulatory flexibility analyses—is accordingly limited to small entities subject to the proposed regulation. *** [W]e conclude that an agency may properly certify that no regulatory flexibility analysis is necessary when it determines that the rule will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule.

Id. at 342. Notably, Congress let this interpretation stand when it recently amended the RFA in enacting the SBREFA.

The EPA also cited a recent case affirming the Mid-Tex court's interpretation. In *United Distribution Companies* v. *FERC*, 88 F.3d 1105, 1170 (D.C. Cir. 1996), the court noted that the Mid-Tex court:

*** conducted an extensive analysis of the RFA provisions governing when a regulatory flexibility analysis is required and concluded that no analysis is necessary when an agency determines ''that the rule will not have a significant economic impact on a substantial number of small entities *that are subject to the requirements of the rule*''.

Id., citing and quoting Mid-Tex (emphasis added by United Distribution court).

The Agency went on to explain that given the Federal/State partnership for attaining healthy air, the proposed NAAQS, if adopted, would not establish any requirements applicable to small entities. Instead, any new or revised standard would establish levels of air quality that States would be primarily responsible for achieving by adopting plans containing specific control measures for that purpose. The proposed NAAQS rule was thus not susceptible to regulatory flexibility analysis as prescribed by the amended RFA. Since it would establish no requirements applicable to small entities, it afforded no opportunity for EPA to fashion for small entities less burdensome compliance or reporting requirements or timetables, or

[63] It is worth noting that Federal rules that apply nationally also play a role in reducing emissions governed by NAAQS. For instance, EPA rules under Title II of the CAA require reductions in ozone-forming emissions from on and off-road vehicles and the fuels that power them. When EPA issues such rules, it conducts the analysis required under the RFA. For example, EPA performed regulatory flexibility analyses for the reformulated gasoline rule issued under section 211(k) of the CAA. See 59 FR 7716, February 16, 1994.

exemptions from all or part of the rule. For these reasons, EPA certified that the proposed rule ''will not, if promulgated, have a significant economic impact on a substantial number of small entities,'' within the meaning of the RFA. Because EPA was not required to prepare an initial regulatory flexibility analysis for the rule, it was also not required to convene a Small Business Advocacy Review Panel for the rule under RFA section 609(b) as added by SBREFA.

Notwithstanding its certification of the proposed rule, EPA recognized that the proposed NAAQS, if adopted, would begin a process of State implementation that could eventually lead to small entities having to comply with new or different control measures, depending on the implementation plans developed by the States. EPA also recognized that the CAA does not allow EPA to dictate or second-guess how States should exercise their discretion in regulating to attain any new or revised NAAQS. Under those circumstances, EPA concluded that the best way to take account of small entity concerns regarding any new or revised NAAQS was to work with small entity representatives and States to provide information and guidance on how States could address small entity concerns when they write their implementation plans.

In line with this approach, as part of the RIA it prepared for the proposed NAAQS, EPA analyzed how hypothetical State plans for implementing the proposed rule might affect small entities. The analysis was necessarily speculative and limited, since it depended on projections about what States might do several years in the future and did not take into account any new strategies that might be developed and recommended by the FACA subcommittee formed to help devise potential strategies for implementing a new or revised NAAQS (see discussion of RIA and FACA process in the previous Unit of this notice). Nevertheless, the analysis provided as much information on potential small entity impacts as was reasonably available at the time of the proposed rule.

The Agency also took steps to ensure that small entities' voices were heard in the NAAQS rulemaking itself. With Jere Glover, Chief Counsel for Advocacy of the SBA, EPA convened outreach meetings modeled on the SBREFA panel process to solicit and convey small entities' concerns with the proposed NAAQS. Two meetings were held as part of that process, on January 7 and February 28, 1997, with a total attendance of 41 representatives of small businesses, small governments and small nonprofit organizations. Both meetings were attended by representatives of SBA and the Office of Management and Budget, as well as of EPA. The key concerns raised by small entities at those meetings related to the scientific foundation of the proposed NAAQS and the potential cost of implementing it, the same concerns raised by other industry commenters on the proposed rule. The Agency produced a report on the meetings to ensure that small entity concerns were part of the rulemaking record when EPA made its final decision on the proposal.

In light of States' pivotal role in NAAQS implementation, EPA also undertook a number of additional activities to assist and encourage the States to be sensitive to small entity impacts as they implement any new or revised NAAQS. With the SBA, EPA began an interagency panel process to collect advice and recommendations from small entity representatives on how States could lessen any impacts on small entities. The EPA plans to issue materials in two phases to help States develop their implementation plans. In view of States' discretion in implementing the NAAQS, these materials will mostly take the form of guidance, which is not subject to the RFA's requirement for initial regulatory flexibility analysis. (Under RFA section 603, that requirement applies only to binding rules that are required to undergo notice-and-comment rulemaking procedures.) But regardless of the form such materials take, EPA is employing panel procedures to ensure that small entities have an opportunity to raise any concerns prior to the materials being issued in draft form.

To supplement the input the Agency receives from the ongoing CAAAC process (described earlier in this Unit of this preamble), EPA also added more small entity representatives to the subcommittee on implementation of any new or revised NAAQS. These representatives have formed a small entity caucus to develop and bring to the subcommittee a focused approach to small entity issues. These new subcommittee members are also part of the group in the aforementioned panel process. By means of these various processes, EPA hopes to promote the consideration of small entity concerns and advice throughout the NAAQS implementation process.

In response to the proposed rule, a number of commenters questioned EPA's decision to certify that the proposed NAAQS will not have a significant impact on a substantial number of small entities. Some commenters disagreed with EPA's view that the proposed NAAQS would not establish regulatory requirements applicable to small entities. These commenters argued that a number of control requirements applicable to small entities would automatically result from promulgation of the proposed NAAQS, such as new reasonable further progress, SIP and Federal Implementation Plan (FIP) requirements. Other commenters stated that it is possible for EPA to assess the impacts of the NAAQS revision on small entities and that, to a limited extent, EPA has already done so. Further, a number of commenters argued that EPA has a legal obligation under the RFA, as amended by SBREFA, to choose a NAAQS alternative that minimizes the impact on small entities. Some commenters questioned EPA's interpretations of the Mid-Tex and United Distribution cases. In addition, other commenters stated that EPA's position regarding the NAAQS and the RFA is inconsistent with its past practice and the legislative history of the RFA. Finally, a few commenters noted that the panel process EPA conducted for the proposed NAAQS did not satisfy the requirements of SBREFA.

EPA disagrees that promulgation of the NAAQS will automatically result in control requirements applicable to small entities that EPA can and must analyze under the RFA. As noted previously, a NAAQS rule only establishes a standard of air quality that other CAA provisions call on States (or in case of State inaction, the Federal government) to achieve by adopting implementation plans containing specific control measures for that purpose. Following promulgation of a new or revised NAAQS, section 110 of the CAA requires States and EPA to engage in a designation process to determine what areas within each State's borders are attaining or not attaining the NAAQS. Under section 110 and parts C and D of Title I of the CAA, States then conduct a planning process to develop and adopt their SIPs. Depending on an area's designation for the particular NAAQS, these and other Title I provisions require a State's SIP to contain certain control programs in addition to the control measures that the State decides are also needed to attain and maintain the NAAQS.

The fact that the CAA requires SIPs to contain certain control programs under certain circumstances does not mean that EPA either can or must conduct a regulatory flexibility analysis of a rule establishing a NAAQS. Just from the standpoint of feasibility, EPA cannot know which areas will be subject to what mandatory SIP programs until

after the designation process is completed. Beyond that, any mandatory SIP programs are still implemented by the States, and States have considerable discretion in how they implement them. For instance, the reasonable further progress requirement under section 172 leaves States broad discretion to determine the rate of progress and the control measures to achieve that progress.[64] As a result, EPA cannot be certain where and how any mandatory programs will be implemented with respect to small (or large) entities. Much less can EPA know about how States will exercise their discretion to develop additional controls needed to attain and maintain the NAAQS.

Even if EPA could know exactly how any mandatory SIP programs would apply to small entities, the purpose of the RFA is not served by attempting a regulatory flexibility analysis of State implementation of those programs. As explained previously, the RFA and the caselaw interpreting it clearly establish that the purpose of the RFA is to promote Federal agency efforts to tailor a rule's requirements to the scale of the small entities that will be subject to it. That purpose cannot be served in the case of a NAAQS rule since the rule does not establish requirements applicable to small entities. In promulgating a NAAQS, the only choice before EPA concerns the level of the standard, not its implementation. While mandatory SIP programs may ultimately follow from promulgation of the NAAQS, there is nothing EPA can do in setting the NAAQS to tailor those programs as they apply to small entities. Whether and how the programs will apply in particular nonattainment areas is beyond the scope of the NAAQS rulemaking and, indeed, beyond EPA's reach in any rulemaking to the extent the applicability and terms of the programs are prescribed by statute.[65] Moreover, any mandatory SIP programs are supplemented by discretionary State controls that EPA has no power to tailor under the RFA or the CAA (see *Train* v. *NRDC*, quoted previously).

The commenters' suggestions for minimizing the potential impact of the NAAQS rule on small entities run afoul of both the RFA and the CAA. Some suggested that EPA set a less stringent standard (or no standard at all in the case of $PM_{2.5}$) to reduce the chance that small entities would become subject to new or tighter SIP requirements. Others suggested that EPA require States to exempt small entities from new or tighter SIP requirements. However, as explained in a previous Unit of this notice addressing the Agency's authority to consider factors other than public health in setting primary NAAQS, the RFA neither requires nor authorizes EPA to set a less stringent NAAQS than the applicable CAA provisions allow in order to reduce potential small entity impacts. Indeed, the RFA provides that any means of providing regulatory flexibility to small entities be consistent with the statute authorizing the rule. Moreover, even if EPA set a less stringent standard, States could still exercise their discretion to obtain any needed emission reductions from small entities. As the Supreme Court in *Train* v. *NRDC* made clear, EPA has no authority to forbid States from obtaining reductions from any particular category of stationary sources, including small entities. See also, *Virginia* v. *EPA*, No. 108 F.3d 1397, 1408 (D.C. Cir. 1997), quoting *Union Electric* v. *EPA*, 427 U.S. 246, 269 (1976) (''section 110 left to the states the power to determine which sources would be burdened by regulations and to what extent'').

EPA's approval of SIPs for the new or revised NAAQS also will not establish new requirements, but will instead simply approve requirements that a State is already imposing. And again, EPA does not have authority to disapprove a State's plan except to the extent that the plan fails to demonstrate attainment and maintenance of the NAAQS as required by Title I of the CAA. In cases where EPA promulgates a FIP, EPA might establish control requirements applicable to small entities, and in such a circumstance, EPA would conduct the analyses required by the RFA.

Some commenters argued that under the RFA as amended by SBREFA, EPA now has an obligation to choose the alternative that minimizes the impact on small entities when setting the NAAQS. As indicated above, EPA disagrees with the commenters' argument for the reasons stated in the Unit of this notice discussing the Agency's authority to consider costs and other factors not related to public health in setting and revising primary NAAQS. In a nutshell, both the text and legislative history of the RFA make clear that the RFA does not override the substantive provisions of the statute authorizing the rule, but only requires agencies to identify and consider ways of minimizing the economic impact on small entities subject to the rule in a manner consistent with the authorizing statute.

Some commenters disagreed with EPA's interpretation of the Mid-Tex and United Distribution cases. In particular, these commenters noted that in those cases the relevant regulatory agency, FERC, wholly lacked jurisdiction to regulate the small entities at issue. According to these commenters, EPA does have the ability and jurisdiction to regulate small entities in the case of the NAAQS, and therefore EPA's reliance on Mid-Tex and United Distribution is misplaced.

The commenters' attempt to distinguish the FERC cases from the NAAQS rulemaking wholly overlooks the courts' reasoning, which in fact fully supports EPA's certification of the proposed NAAQS. As described above, the Mid-Tex court exhaustively reviewed the relevant sections of the RFA and its legislative history. Its analysis revealed that Congress passed the RFA out of concern with one-size-fits-all regulations and fashioned a remedy limited to regulations that apply to small entities. This principle is fully applicable to the NAAQS, which creates no rule requirements that apply to small entities.

The fact that FERC had no regulatory authority over the small entities indirectly affected by its rules played no essential role in the court's rationale. FERC could (and apparently did in the Mid-Tex rulemaking) estimate the potential indirect impact of its rules on small entities. Presumably, FERC could have also mitigated any indirect impact by changing some aspect of the rule (or else the small entities would have had no incentive to sue the agency). The court nevertheless found it unnecessary for FERC to do either, based on its reading of the RFA as limited to analysis of a rule's impact on the small entities subject to the rule's requirements. In reaching its decision, the court noted that requiring agencies to ''consider every indirect effect that any regulation might have on small businesses *** is a very broad and ambitious agenda, *** that Congress is unlikely to have embarked on *** without airing the matter.'' Mid-Tex, 773 F.d. at 343.

The commenters also overstate EPA's regulatory authority over small entities

[64] Contrary to what some commenters assumed, the SIP requirements of subpart 2 of part D of Title I will not apply to SIPs to implement the revised ozone NAAQS. Those requirements were enacted by Congress in 1990 to address nonattainment of a 0.12 ppm 1-hour ozone NAAQS. To the extent those requirements remain in effect, they apply only to SIPs for areas still in nonattainment with that standard; they do not apply to SIPs for areas in nonattainment only with respect to the ozone NAAQS adopted today. Further, to the extent SIPs for areas in nonattainment with the previous ozone standard remain subject to subpart 2 requirements, there will be no incremental change in the impact on sources regulated by the States' SIPs pursuant to the requirements as a result of today's promulgation.

[65] If and when the Agency issues any rules addressing State implementation of any statutorily required actions, EPA would analyze and address the impact of those rules on small entities as appropriate under the RFA.

with respect to the regulation of criteria pollutants. Various CAA provisions authorize EPA to regulate various types of sources at the Federal level to accomplish specified goals. However, EPA's authority to more generally regulate sources, including small entities, in the manner of SIPs is limited to instances of State default of SIP responsibilities. When that occurs, EPA may issue a FIP containing specific control measures, and to the extent a proposed FIP would establish control measures applicable to small entities, EPA would analyze the small entity impact of those measures as required by the RFA. In 1994, for example, EPA prepared an initial regulatory flexibility analysis when it proposed a FIP for Los Angeles. See 59 FR 23264, May 5, 1994.

As noted above, Congress let the Mid-Tex interpretation stand when it recently amended the RFA in enacting SBREFA. If it had disagreed with the court's decision, it would have revised the relevant statutory provisions or otherwise indicated its disagreement when it enacted SBREFA. Instead, Congress actually reinforced the Mid-Tex court's interpretation of the RFA in enacting section 212(a) of SBREFA. That section requires that an agency issue a ''small entity compliance guide'' for ''each rule *** for which an agency is required to prepare a final regulatory flexibility analysis under section 604'' of the RFA. The guide is ''to assist small entities in complying with the rule'' by ''explain[ing] the actions a small entity is required to take to comply'' with the rule (SBREFA section 212(a)). Obviously, it makes no sense to prepare a small entity compliance guide for a rule that does not apply to small entities. SBREFA thus stands as further confirmation that Congress intended regulatory flexibility analyses to address only rules that establish requirements small entities must meet. Since SBREFA's passage, the United Distribution court has affirmed the Mid-Tex court's interpretation.

Some commenters noted that EPA's informal panel process did not comply with the requirements of SBREFA. The EPA did not convene a SBREFA panel because such a panel is not required for rules like the NAAQS that do not apply to small entities. Under the RFA as amended by SBREFA, since the Agency certified the proposal, it was not required to convene a panel for it. Nevertheless, EPA conducted the voluntary panel process described above, as well as other voluntary small business outreach efforts. The process could not comply with the analytical requirements of the RFA for the reasons given above. However, it could and did ensure that EPA heard directly from small entities about the NAAQS proposals.

A few commenters stated that EPA's view of the NAAQS and the RFA is inconsistent with EPA's past positions regarding the RFA and NAAQS revisions. Some commenters also cited the Regulatory Impact Analysis for the proposed NAAQS and noted that this analysis demonstrates EPA's ability to estimate the impact of the NAAQS on small entities, thereby undercutting EPA's argument that it is not able to perform a regulatory flexibility analysis when setting the NAAQS.

Past **Federal Register** notices make clear that the nature of the NAAQS makes a regulatory flexibility analysis inapplicable to NAAQS rulemakings. For instance, in 1984, EPA stated that a ''NAAQS for NOx by itself has no direct impact on small entities. However, it forces each State to design and implement control strategies for areas not in attainment.'' 49 FR 6866, 6876, February 23, 1984; see also, 50 FR 37484, 37499, September 13, 1985; 50 FR 25532, 25542, June 19, 1985 (NAAQS for NO_2 do not impact small entities directly). EPA stated again in 1987 that the NAAQS ''themselves do not contain emission limits or other pollution controls. Rather, such controls are contained in State implementation plans.'' 52 FR 24634, 24654, July 1, 1987.

EPA has typically performed an analysis to assess, to the extent practicable, the potential impact of retaining or revising the NAAQS on small entities, depending on possible State strategies for implementing the NAAQS. These analyses have provided as much insight into the potential small entity impacts of implementing revised NAAQS as could be provided at the NAAQS rulemaking stage. In some instances, these preliminary ''analyses'' were described as ''regulatory flexibility analys[es]'' or as analyses ''pursuant to this [Regulatory Flexibility] Act.'' See, e.g., 52 FR 24634, 24654, July 1, 1987; 50 FR 37484, 37499, September 13, 1985.

However, these analyses were based on hypothetical State control strategies, and EPA made the point on various occasions that any conclusions to be drawn from such analyses were ''speculative,'' given that the NAAQS themselves do not impose requirements on small entities. Although these past analyses reflected the Agency's best efforts to evaluate potential impacts, they were not regulatory flexibility analyses containing the necessary elements required by the RFA. These analyses, for example, did not describe the ''reporting, recordkeeping and other compliance requirements'' of the proposed NAAQS rules that would apply to small entities, since the NAAQS rules did not apply to small entities. Nor did they determine how the proposed NAAQS rules could be eased or waived for small entities. Such an analysis is not possible in the case of the NAAQS. To the extent EPA labeled these analyses regulatory flexibility analyses in the past, that label was inappropriate. EPA's current practice is to describe such an analysis more accurately as a ''general analysis of the potential cost impacts on small entities.'' See, e.g., 61 FR 65638, 65669, 65747, December 13, 1996 (current O_3 and PM NAAQS proposals).[66] EPA's analytical approach to small entity impacts of the NAAQS has thus remained consistent over time.

One commenter noted that the legislative history of the RFA suggests that the RFA was intended to apply to the NAAQS. As noted previously, EPA's reading of both the RFA and SBREFA, based on the language of the statute as amended and its legislative histories and applicable caselaw, is that the RFA requirements at issue do not apply to the NAAQS. The legislative history cited by the commenter does not change this conclusion.

In fact, the statement by Senator Culver on which the commenter relies does not indicate that the NAAQS should be subject to regulatory flexibility analyses. Rather, Senator Culver uses the NAAQS as an example of the type of standard that agencies would not change as a result of the Regulatory Flexibility Act. According to Senator Culver, Section 606 ''succinctly states that this bill does not alter the substantive standard contained in underlying statutes which defines the agency's mandate.'' 126 Cong. Rec. S 21455 (Aug. 6, 1980) daily ed. After citing CAA section 109, Senator Culver goes on to describe EPA's bubble policy

[66] As commenters pointed out, the RIA for the proposed PM NAAQS does state that ''[t]he screening analysis *** provides enough information for an initial regulatory flexibility analysis (RFA) if such an analysis were to be done.'' That statement was mistaken and was not made in the RIA for the proposed ozone NAAQS. While both RIAs attempted to gauge the potential impact on small entities of State implementation of the proposed NAAQS, neither could or did identify any specific control or information requirements contained in the NAAQS rule that would apply to small entities. Indeed, both RIAs made clear that the impact being analyzed was that of potential State measures to attain the NAAQS, and that such an analysis was inherently speculative and uncertain. Thus, the RIAs actually confirm EPA's statement in the preambles for the proposed NAAQS that conducting a complete regulatory flexibility analysis is not feasible for rules setting or revising a NAAQS.

(which addresses the limits on emissions from a particular facility) as the type of flexible regulation that agencies should consider, once EPA has set a NAAQS. ''The important point for purposes of this discussion is that the 'bubble concept', a type of flexible regulation, in no manner altered the basic statutory substantive standard of the EPA *** . No regulatory flexibility analysis alters the substantive standard otherwise applicable by law to agency action.'' Id. Thus, contrary to the suggestion of the commenter, Senator Culver's statement actually confirms that the time to consider regulatory flexibility is when regulations applicable to sources are being established, not when a NAAQS itself is being set.

Under section 604 of the RFA, whenever an agency promulgates a final rule under section 553 of the Administrative Procedure Act, after being required by that section or any other law to publish a general notice of proposed rulemaking (NPRM), the agency is required to prepare a final regulatory flexibility analysis. RFA section 605(b) provides, however, that section 603 (re initial regulatory flexibility analyses) and section 604 do not apply if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities and publishes such certification at the time of publication of the NPRM or at the time of the final rule.

As noted above, EPA certified today's rule at the time of the NPRM. After considering the public comments on the certification, EPA continues to believe that today's rule will not have a significant economic impact on a substantial number of small entities for the reasons explained above and that it therefore appropriately certified the rule. Further, as required by the CAA, EPA is promulgating today's rule under CAA section 307(d). For all the foregoing reasons, EPA has not prepared a final regulatory flexibility analysis for the rule. The Agency has nonetheless analyzed in the final RIA for the rule the potential impact on small entities of hypothetical State plans for implementing the NAAQS. The Agency also plans to issue guidance to the States on reducing the potential impact on small entities of implementing the NAAQS.

C. Impact on Reporting Requirements

There are no reporting requirements directly associated with the finalization of ambient air quality standards under section 109 of the Act (42 U.S.C. 7409). There are, however, reporting requirements associated with related sections of the Act, particularly sections 107, 110, 160, and 317 (42 U.S.C. 7407, 7410, 7460, and 7617).

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. This requirement does not apply if EPA is prohibited by law from considering section 202 estimates and analyses in adopting the rule in question. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. These requirements do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements. Section 204 of UMRA requires each agency to develop ''an effective process to permit elected officers of State, local and tribal governments *** to provide meaningful and timely input'' in the development of regulatory proposals containing a significant Federal intergovernmental mandate.[67]

The EPA has determined that the provisions of sections 202 and 205 of the UMRA do not apply to this decision. ''Unless otherwise prohibited by law,'' EPA is to prepare a written statement under Section 202 of UMRA that is to contain assessments and estimates of the costs and benefits of a rule containing a Federal mandate. Congress clarified that ''unless otherwise prohibited by law'' referred to whether an agency was prohibited from considering the information in the rulemaking process, not to whether an agency was prohibited from collecting the information. The Conference Report on UMRA states, ''This section [202] does not require the preparation of any estimate or analysis if the agency is prohibited by law from considering the estimate or analysis in adopting the rule.'' 141 Cong. Rec. H3063 (daily ed. March 13, 1995). Because the Clean Air Act prohibits EPA, when setting the NAAQS, from considering the types of estimates and assessments described in section 202, UMRA does not require EPA to prepare a written statement under section 202.[68] The requirements in section 205 do not apply because those requirements only apply to rules ''for which a written statement is required under section 202 ***.''

The EPA has determined that the provisions of section 203 of UMRA do not apply to this decision. Section 203 only requires the development of a small government agency plan for requirements with which small governments might have to comply. Since setting the NAAQS does not establish requirements with which small governments might have to comply, section 203 does not apply. The

[67] As noted in Unit VII.B. of this preamble, a NAAQS rule only establishes a standard of air quality that other provisions of the Act call on States (or in the case of State inaction, the Federal government) to achieve by adopting implementation plans containing specific control measures for the purpose. Thus, it is questionable whether the NAAQS itself imposes an enforceable duty and thus whether it is a significant Federal mandate within the meaning of UMRA. EPA need not and does not reach this issue today. For the reasons given in this unit, even if the NAAQS were determined to be a significant Federal mandate, EPA does not have any obligations under sections 202 and 205 of UMRA, and EPA has met any obligations it would have under section 204 of UMRA.

[68] In addition to the estimates and assessments described in section 202 of UMRA, written statements are also to include an identification of the Federal law under which the rule is promulgated (section 202(a)(1) of UMRA) and a description of outreach efforts under section 204 of UMRA (section 202(a)(5) of UMRA). Although these requirements do not apply here because a written statement is not required under section 202 of UMRA, this preamble identifies the Federal law under which this rule is being promulgated and a written statement describing EPA's outreach efforts with State, local, and tribal governments will be placed in the docket.

EPA acknowledges, however, that any corresponding revisions to associated State implementation plan requirements and air quality surveillance requirements, 40 CFR part 51 and 40 CFR part 58, respectively, might result in such effects. Accordingly, EPA will address unfunded mandates as appropriate when it proposes any revisions to 40 CFR parts 51 and 58.

With regard to the outreach described in UMRA section 204, EPA did follow a process for providing elected officials with an opportunity for meaningful and timely input into the proposed NAAQS revisions, although EPA did not describe this process in the proposal. The EPA conducted a series of pre-proposal outreach meetings with State and local officials and their representatives that permitted these officials to provide meaningful and timely input on issues related to the NAAQS and the monitoring issues associated with them. Beginning in January, 1996, EPA briefed State and local air pollution control officials at national meetings with State and Territorial Air Pollution Program Administrators (STAPPA)/Association of Local Air Pollution Control Officials (ALAPCO) in Washington DC, North Carolina, Chicago and Nevada. The EPA also held briefings for the Washington DC representatives of several State and local organizations, including National Conference of State Legislators, U.S. Conference of Mayors, National Governors Association, and National League of Cities, and STAPPA/ALAPCO. EPA also held separate briefings and discussions with State and local officials at meetings set up by the National Governors Association, the U.S. Conference of Mayors and the Council of State Governments. The EPA also conducted in-depth briefings at each EPA regional office and regional staff also had several meetings and discussions with their State counterparts about the standards. The efforts described above, which provided elected officials with opportunity for meaningful and timely input into the proposed NAAQS revisions, met any requirements imposed by section 204. The docket will contain a written statement describing these outreach efforts, including a summary of the comments and concerns presented by State, local, and tribal governments and a summary of EPA's evaluation of those comments and concerns.

Several commenters disagreed with EPA that UMRA sections 202, 203 and 205 do not apply to this decision. These commenters argued that EPA is not prohibited from considering costs in setting NAAQS under the Clean Air Act and applicable judicial decisions. Some commenters also expressed the view that there is no conflict between UMRA and the Clean Air Act with regard to the NAAQS. These commenters argued that UMRA and the NAAQS can be ''harmonized'' by reading UMRA as an information gathering statute and that EPA should therefore perform the analyses required by UMRA, regardless of whether costs may be considered. Finally, at least one commenter argued that in past NAAQS reviews, EPA did not dispute its UMRA obligations.

As discussed more fully in Unit IV of this preamble, EPA is prohibited from considering cost in setting the NAAQS. Given that fact (as noted in Unit IV preamble), sections 202 and 205 do not apply.[69] As the Conference Report clarifies, UMRA itself states that the section 202 estimates and analyses are not required in cases such as the NAAQS, where an agency is prohibited by law from considering section 202 estimates and analyses. Reading UMRA in the manner suggested by the commenters would effectively read this provision out of UMRA; UMRA contains an exception for rules like the NAAQS, it must be given effect.

With regard to EPA's position regarding UMRA in previous NAAQS review exercises, EPA simply made plain in those situations that because it did not plan on revising the NAAQS, it determined, without further review, that UMRA sections 202, 203 and 205 did not apply. EPA thus stated that:

> Because the Administrator has decided not to revise the existing primary NAAQS for SO_2, this action will not impose any new expenditures on governments or on the private sector, or establish any new regulatory requirements affecting small governments. Accordingly, EPA has determined that the provisions of section 202, 203 and 205 do not apply to this final decision.

61 FR 25566, 25577, May 22, 1996; See also 61 FR 52852, 52856, October 8, 1996 (Same statement for NO_2 NAAQS). As this statement makes clear, EPA only determined that UMRA sections 202, 203 and 205 did not apply to the NAAQS when EPA fails to revise the standard. Having made that determination, EPA had no reason to catalogue additional bases for finding UMRA inapplicable. Nothing in that statement was intended to preclude EPA, or precludes EPA, from concluding for other reasons (such as those discussed above) that UMRA also does not apply when EPA in fact revises an applicable NAAQS.

E. Environmental Justice

Executive Order 12848 requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. These requirements have been addressed to the extent practicable in the RIA cited above.

F. Submission to Congress and the Comptroller General

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in today's **Federal Register**. This rule is a ''major rule'' for purposes of SBREFA.

VIII. Response to Petition for Administrator Browner's Recusal

On March 13, 1997, the Washington Legal Foundation (WLF), filed a petition with EPA asking that I, Carol Browner, disqualify myself in rulemaking regarding the NAAQS for PM and O_3. The petition claims that my public statements indicate a ''clear and convincing showing'' that I had ''already decided to revise the NAAQS for PM and ozone'' and that I therefore ''could not give meaningful consideration'' to comments adverse to the proposed rule. On May 12, 1997, EPA's General Counsel, Jonathan Z. Cannon, sent a letter to WLF regarding the petition. This letter and the WLF petition were then placed in the dockets for the proposed O_3 and PM standards pending ''consideration and final response in connection with the Agency's final actions.''

Contrary to WLF's assertions, I have maintained an open mind throughout these proceedings, and have based today's decisions on the rulemaking

[69] One commenter argued that in reviewing the SO_2 NAAQS, EPA determined that it need not revise the SO_2 NAAQS, but could instead pursue an alternative regulatory program under other authority. This commenter argued that EPA has similar flexibility in reviewing the PM and Ozone NAAQS, and thus UMRA requires EPA to identify the least burdensome alternative (such as retaining the current NAAQS) as part of that process. As discussed more fully above at Unit IV of this preamble, EPA does not agree that it has flexibility to choose such an alternative; nor does EPA agree with the commenter's characterization of the action it took in deciding not to revise the SO_2 NAAQS. In fact, in deciding not to revise the SO_2 NAAQS, EPA determined, for reasons independent of section 303 of the Clean Air Act that a NAAQS revision was not warranted. See 61 FR 25566, 25575, May 22, 1996.

record—including consideration of comments opposed to the proposal. The law does not require the Administrator of EPA to disqualify herself merely for expressing views on a proposed regulation; in fact, it is part of my responsibility to engage in the public debate on the proposals. Moreover, the assertions in WLF's petition do not accurately represent my views. The petition takes quotes out of context and repeatedly misinterprets my statements. For example, WLF quotes a statement that I made at the Children's Environmental Health Network Research Conference as an indication that I had ''prejudged the issue.'' However, my statement that ''I will not be swayed'' did not refer to adopting the NAAQS as proposed. Instead, as is clear from reviewing the entire speech, I was addressing my broader concern about children's health and the range of EPA standards affecting children's health. I also appeared at several congressional hearings and testified before members of Congress, some of whom were strongly opposed to the proposals. At those hearings, I explained the basis for the proposals and put forward the reasons why I concluded the proposals were appropriate, given the information before me at the time. At the same time, I made clear that I took very seriously my obligation to keep an open mind, and to consider fully and fairly all significant comments that the Agency received. For these reasons and others, as set forth in Mr. Cannon's May 12, 1997 response to WLF, which I adopt in full, I have decided not to recuse myself from any aspect of considering revisions to the NAAQS for O_3 and PM. Accordingly, I am hereby denying WLF's petition.

IX. References

(1) American Thoracic Society. (1985) Guidelines as to what constitutes an adverse respiratory health effect, with special reference to epidemiologic studies of air pollution. *American Review of Respiratory Disease.*. 131: 666–668.

(2) Freas (1996) Ambient air quality relationships among alternative ozone air quality standards. Internal memorandum from Warren P. Freas to file, U.S. EPA, EMAD/OAQPS/OAR, RTP, NC, dated October 30, 1996. Docket No. A–95–58 Item II–B–6.

(3) Freas (1997) Ambient air quality relationships for counties meeting alternative air quality standards. Internal memorandum from Warren P. Freas to file, U.S. EPA, EMAD/OAQPS/OAR, RTP, NC, dated July 1, 1997. Docket No. A–95–58 Item xxx.

(4) Heck, Walter W. And Ellis B. Cowling. January, 1997. EM Journal. ''The Need for a Long Term Cumulative Secondary Ozone Standard - An Ecological Perspective.'' Air and Waste Management Association, Pittsburgh, PA.; pp. 23–33.

(5) Johnson, T; Capel, J.; Mozier, J.; McCoy, M. (1996a) Estimation of ozone exposures experienced by outdoor children in nine urban areas using a probabilistic version of NEM. Prepared by IT/Air Quality Services for U.S. EPA, OAQPS; Research Triangle Park, NC, August.

(6) Johnson, T.; Capel, J.; McCoy, M.; Mozier, J. (1996b) Estimation of ozone exposures experienced by outdoor workers in nine urban areas using a probabilistic version of NEM. Prepared by IT/Air Quality Services for U.S. EPA, OAQPS; Research Triangle Park, NC, August.

(7) McClellan, R. O., (1989) Letter from Chairman of Clean Air Scientific Advisory Committee to the EPA Administrator, dated May 1, 1989. EPA–SAB-CASAC-LTR–89–019.

(8) Richmond (1997) Supplemental ozone exposure and health risk analyses. Internal memorandum from Harvey M. Richmond to Karen M. Martin, U.S. EPA, AQSSD/OAQPS/OAR, RTP, NC, dated February 11, 1997. Docket No. A–95–58 Item IV–A–1.

(9) Seitz (1996) Revocation date for the existing 1–hour ozone standards. Internal memorandum from John S. Seitz to Mary D. Nichols, U.S. EPA, OAQPS/OAR, RTP, NC, dated November 20, 1996. Docket No. A–95–59 Item II–B–3.

(10) Thurston, G.D.; Ito, K.; Kinney, P.L.; Lippmann, M. (1992) A multi-year study of air pollution and respiratory hospital admissions in three New York State metropolitan areas: results for 1988 and 1989 summers. *Journal of Exposure Analysis and Environmental Epidemiology.* 2:429–450.

(11) U.S. Department of Health and Human Services (1996) Vital and health statistics: current estimates from the national health interview survey, 1994. Hyattsville, MD: Public Health Service, National Center for Health Statistics; DHHS publication no. (PHS) 96–278.

(12) U.S. Environmental Protection Agency (1996a) Air quality criteria for Ozone and related photochemical oxidants. Research Triangle Park, NC: Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office; EPA report nos. EPA/600/AP–93/004a–c.

(13) U.S. Environmental Protection Agency (1996b) Review of the national ambient air quality standards for ozone: assessment of scientific and technical information. OAQPS staff paper. Research Triangle Park, NC: Office of Air Quality Planning and Standards; EPA report no. EPA–452/R–96–007. Available from: NTIS, Springfield, VA; PB96–203435.

(14) Whitfield, R.G.; Biller, W.F.; Jusko, M.J.; Keisler, J.M. (1996) A probabilistic assessment of health risks associated with short-term exposure to tropospheric ozone. Report prepared for U.S. EPA, OAQPS. Argonne National Laboratory; Argonne, IL, June. (For copies, contact Harvey M. Richmond, U.S. Environmental Protection Agency, OAQPS, MD–15, Research Triangle Park, N.C. 27711, (919) 541–5271.)

(15) Wolff, G. T., (1995a) Letter from Chairman of Clean Air Scientific Advisory Committee to the EPA Administrator, dated November 28, 1995. EPA–SAB–CASAC–LTR–96–001.

(16) Wolff, G. T., (1995b) Letter from Chairman of Clean Air Scientific Advisory Committee to the EPA Administrator, dated November 30, 1995. EPA–SAB–CASAC–LTR–96–002.

(17) Wolff, G. T., (1996) Letter from Chairman of Clean Air Scientific Advisory Committee to the EPA Administrator, dated April 4, 1996. EPA–SAB–CASAC–LTR–96–006.

List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated: July 16, 1997.

Carol M. Browner,

Administrator.

Therefore, for the reasons set forth in the preamble, title 40, chapter I, part 50 of the Code of Federal Regulations is amended as follows:

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

1. The authority citation for part 50 continues to read as follows:

Authority: Secs. 109 and 301(a), Clean Air Act, as amended (42 U.S.C. 7409, 7601(a)).

2. Section 50.9 is revised to read as follows:

§ 50.9 National 1–hour primary and secondary ambient air quality standards for ozone.

(a) The level of the national 1-hour primary and secondary ambient air quality standards for ozone measured by a reference method based on Appendix D to this part and designated in accordance with part 53 of this chapter, is 0.12 parts per million (235 $\mu g/m^3$). The standard is attained when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 parts per million (235 $\mu g/m^3$) is equal to or less than 1, as determined by Appendix H to this part.

(b) The 1–hour standards set forth in this section will no longer apply to an area once EPA determines that the area has air quality meeting the 1–hour standard. Area designations are codified in 40 CFR part 81.

3. Section 50.10 is added to read as follows:

§ 50.10 National 8–hour primary and secondary ambient air quality standards for ozone.

(a) The level of the national 8–hour primary and secondary ambient air quality standards for ozone, measured

by a reference method based on Appendix D to this part and designated in accordance with part 53 of this chapter, is 0.08 parts per million (ppm), daily maximum 8–hour average.

(b) The 8–hour primary and secondary ozone ambient air quality standards are met at an ambient air quality monitoring site when the average of the annual fourth-highest daily maximum 8–hour average ozone concentration is less than or equal to 0.08 ppm, as determined in accordance with Appendix I to this part.

4. Appendix D is amended by revising references 8 and 9 and by removing all of the text and figures immediately following ''Figure 2, Schematic Diagram of a Typical UV Photometric Calibration System (Option 1), through the end of Appendix D.

Appendix D to Part 50—Measurement Principle and Calibration Procedure for the Measurement of Ozone in the Atmosphere

* * * * *

6. *References.*

* * * * *

8. Transfer Standards for Calibration of Ambient Air Monitoring Analyzers for Ozone, EPA publication number EPA–600/4–79–056, EPA, National Exposure Research Laboratory, Department E, (MD–77B), Research Triangle Park, NC 27711.

9. Technical Assistance Document for the Calibration of Ambient Ozone Monitors, EPA publication number EPA–600/4–79–057, EPA, National Exposure Research Laboratory, Department E, (MD–77B), Research Triangle Park, NC 27711.

* * * * *

Appendix E [Removed and Reserved]

5. Appendix E is removed and reserved.

6. Appendix H is amended by revising the appendix heading to read ''Appendix H To Part 50—Interpretation of The 1-Hour Primary and Secondary National Ambient Air Quality Standards for Ozone''.

7. Appendix I is added to read as follows:

Appendix I to Part 50—Interpretation of the 8–Hour Primary and Secondary National Ambient Air Quality Standards for Ozone

1. *General.*

This appendix explains the data handling conventions and computations necessary for determining whether the national 8–hour primary and secondary ambient air quality standards for ozone specified in § 50.10 are met at an ambient ozone air quality monitoring site. Ozone is measured in the ambient air by a reference method based on Appendix D of this part. Data reporting, data handling, and computation procedures to be used in making comparisons between reported ozone concentrations and the level of the ozone standard are specified in the following sections. Whether to exclude, retain, or make adjustments to the data affected by stratospheric ozone intrusion or other natural events is subject to the approval of the appropriate Regional Administrator.

2. *Primary and Secondary Ambient Air Quality Standards for Ozone.*

2.1 *Data Reporting and Handling Conventions.*

2.1.1 *Computing 8–hour averages.* Hourly average concentrations shall be reported in parts per million (ppm) to the third decimal place, with additional digits to the right being truncated. Running 8–hour averages shall be computed from the hourly ozone concentration data for each hour of the year and the result shall be stored in the first, or start, hour of the 8–hour period. An 8–hour average shall be considered valid if at least 75% of the hourly averages for the 8–hour period are available. In the event that only 6 (or 7) hourly averages are available, the 8–hour average shall be computed on the basis of the hours available using 6 (or 7) as the divisor. (8–hour periods with three or more missing hours shall not be ignored if, after substituting one-half the minimum detectable limit for the missing hourly concentrations, the 8–hour average concentration is greater than the level of the standard.) The computed 8–hour average ozone concentrations shall be reported to three decimal places (the insignificant digits to the right of the third decimal place are truncated, consistent with the data handling procedures for the reported data.)

2.1.2 *Daily maximum 8–hour average concentrations.* (a) There are 24 possible running 8–hour average ozone concentrations for each calendar day during the ozone monitoring season. (Ozone monitoring seasons vary by geographic location as designated in part 58, Appendix D to this chapter.) The daily maximum 8–hour concentration for a given calendar day is the highest of the 24 possible 8–hour average concentrations computed for that day. This process is repeated, yielding a daily maximum 8–hour average ozone concentration for each calendar day with ambient ozone monitoring data. Because the 8–hour averages are recorded in the start hour, the daily maximum 8–hour concentrations from two consecutive days may have some hourly concentrations in common. Generally, overlapping daily maximum 8–hour averages are not likely, except in those non–urban monitoring locations with less pronounced diurnal variation in hourly concentrations.

(b) An ozone monitoring day shall be counted as a valid day if valid 8–hour averages are available for at least 75% of possible hours in the day (i.e., at least 18 of the 24 averages). In the event that less than 75% of the 8–hour averages are available, a day shall also be counted as a valid day if the daily maximum 8–hour average concentration for that day is greater than the level of the ambient standard.

2.2 *Primary and Secondary Standard-related Summary Statistic.* The standard-related summary statistic is the annual fourth-highest daily maximum 8–hour ozone concentration, expressed in parts per million, averaged over three years. The 3–year average shall be computed using the three most recent, consecutive calendar years of monitoring data meeting the data completeness requirements described in this appendix. The computed 3–year average of the annual fourth-highest daily maximum 8–hour average ozone concentrations shall be expressed to three decimal places (the remaining digits to the right are truncated.)

2.3 *Comparisons with the Primary and Secondary Ozone Standards.* (a) The primary and secondary ozone ambient air quality standards are met at an ambient air quality monitoring site when the 3–year average of the annual fourth-highest daily maximum 8–hour average ozone concentration is less than or equal to 0.08 ppm. The number of significant figures in the level of the standard dictates the rounding convention for comparing the computed 3–year average annual fourth-highest daily maximum 8–hour average ozone concentration with the level of the standard. The third decimal place of the computed value is rounded, with values equal to or greater than 5 rounding up. Thus, a computed 3–year average ozone concentration of 0.085 ppm is the smallest value that is greater than 0.08 ppm.

(b) This comparison shall be based on three consecutive, complete calendar years of air quality monitoring data. This requirement is met for the three year period at a monitoring site if daily maximum 8–hour average concentrations are available for at least 90%, on average, of the days during the designated ozone monitoring season, with a minimum data completeness in any one year of at least 75% of the designated sampling days. When computing whether the minimum data completeness requirements have been met, meteorological or ambient data may be sufficient to demonstrate that meteorological conditions on missing days were not conducive to concentrations above the level of the standard. Missing days assumed less than the level of the standard are counted for the purpose of meeting the data completeness requirement, subject to the approval of the appropriate Regional Administrator.

(c) Years with concentrations greater than the level of the standard shall not be ignored on the ground that they have less than complete data. Thus, in computing the 3–year average fourth maximum concentration, calendar years with less than 75% data completeness shall be included in the computation if the average annual fourth maximum 8–hour concentration is greater than the level of the standard.

(d) Comparisons with the primary and secondary ozone standards are demonstrated by examples 1 and 2 in paragraphs (d)(1) and (d) (2) respectively as follows:

(1) As shown in example 1, the primary and secondary standards are met at this monitoring site because the 3–year average of the annual fourth-highest daily maximum 8–hour average ozone concentrations (i.e., 0.084 ppm) is less than or equal to 0.08 ppm. The data completeness requirement is also met because the average percent of days with valid ambient monitoring data is greater than

90%, and no single year has less than 75% data completeness.

EXAMPLE 1. AMBIENT MONITORING SITE ATTAINING THE PRIMARY AND SECONDARY OZONE STANDARDS

Year	Percent Valid Days	1st Highest Daily Max 8–hour Conc. (ppm)	2nd Highest Daily Max 8–hour Conc. (ppm)	3rd Highest Daily Max 8–hour Conc. (ppm)	4th Highest Daily Max 8–hour Conc. (ppm)	5th Highest Daily Max 8–hour Conc. (ppm)
1993	100%	0.092	0.091	0.090	0.088	0.085
1994	96%	0.090	0.089	0.086	0.084	0.080
1995	98%	0.087	0.085	0.083	0.080	0.075
Average	98%				0.084	

(2) As shown in example 2, the primary and secondary standards are not met at this monitoring site because the 3–year average of the fourth-highest daily maximum 8–hour average ozone concentrations (i.e., 0.093 ppm) is greater than 0.08 ppm. Note that the ozone concentration data for 1994 is used in these computations, even though the data capture is less than 75%, because the average fourth-highest daily maximum 8–hour average concentration is greater than 0.08 ppm.

EXAMPLE 2. AMBIENT MONITORING SITE FAILING TO MEET THE PRIMARY AND SECONDARY OZONE STANDARDS

Year	Percent Valid Days	1st Highest Daily Max 8–hour Conc. (ppm)	2nd Highest Daily Max 8–hour Conc. (ppm)	3rd Highest Daily Max 8–hour Conc. (ppm)	4th Highest Daily Max 8–hour Conc. (ppm)	5th Highest Daily Max 8–hour Conc. (ppm)
1993	96%	0.105	0.103	0.103	0.102	0.102
1994	74%	0.090	0.085	0.082	0.080	0.078
1995	98%	0.103	0.101	0.101	0.097	0.095
Average	89%				0.093	

3. *Design Values for Primary and Secondary Ambient Air Quality Standards for Ozone.*

The air quality design value at a monitoring site is defined as that concentration that when reduced to the level of the standard ensures that the site meets the standard. For a concentration-based standard, the air quality design value is simply the standard-related test statistic. Thus, for the primary and secondary ozone standards, the 3–year average annual fourth-highest daily maximum 8–hour average ozone concentration is also the air quality design value for the site.

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