Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.


A. Stanley Meiburg, 
Acting Regional Administrator, Region 4.

Part 52 of chapter I, title 40, Code of Federal Regulations, is amended as follows:

### EPA-APPROVED JEFFERSON COUNTY REGULATIONS FOR KENTUCKY

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Elsewhere in this Federal Register, we are proposing approval and soliciting written comment on this action; if adverse written comments are received, we will withdraw the direct final rule and address the comments received in a new final rule; otherwise no further rulemaking will occur on this approval action.

**DATES:** This rule is effective January 2, 2004, without further notice, unless we receive adverse comments by December 3, 2003. If EPA receives adverse comments, we will publish a timely withdrawal of the rule in the Federal Register and inform the public that this rule will not take effect.

**ADDRESSES:** Comments should be mailed or emailed to Wienke Tax, Office of Air Planning (AIR–2), U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105–3901, tax.wienke@epa.gov. Comments may also be submitted through the Federal Register Web site at http://www.regulations.gov. We prefer electronic comments.

You can inspect copies of EPA’s Federal Register document and Technical Support Document (TSD) at our Region IX office during normal business hours (see address above). Due to increased security, we suggest that you call at least 24 hours prior to visiting the Regional Office so that we can make arrangements to have someone meet you. The Federal Register notice and TSD are also available as electronic files on EPA’s Region 9 Web Page at http://www.epa.gov/region09/air.

You may inspect and copy the rulemaking docket for this notice at the following location during normal business hours.

Environmental Protection Agency, Region 9, Air Division, Air Planning Office (AIR–2), 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the State Implementation Plan (SIP) materials are also available.
for inspection at the address listed below:

Arizona Department of Environmental Quality, 1110 W. Washington Street, First Floor, Phoenix, AZ 85007, Phone: (602)771–4335.

FOR FURTHER INFORMATION CONTACT:
Wienke Tax, U.S. EPA Region 9, (520) 622–1622, tax.wienke@epa.gov, or http://www.epa.gov/region09/air.

SUPPLEMENTARY INFORMATION: Elsewhere in this Federal Register, we are proposing approval and soliciting written comment on this action. Throughout this document, the words “we,” “us,” or “our” mean U.S. EPA.

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I. Summary of Action

We are approving the maintenance plan for the Ajo SO₂ nonattainment area.¹ We are also approving the State of Arizona’s request to redesignate the Ajo area from nonattainment to attainment for the primary SO₂ NAAQS.

II. Introduction

A. What National Ambient Air Quality Standards Are Considered in Today’s Rulemaking?

Sulfur dioxide (SO₂) is the pollutant that is the subject of this action. The NAAQS are health-based and welfare-based standards for certain ambient air pollutants. SO₂ is among the ambient air pollutants for which we have established a health-based standard. SO₂ causes adverse health effects by reducing lung function, increasing respiratory illness, altering the lung’s defenses, and aggravating existing cardiovascular disease. Children, the elderly, and people with asthma are the most vulnerable. SO₂ has a variety of additional impacts, including acidic deposition, damage to crops and vegetation, and corrosion of natural and man-made materials.

There are both short- and long-term primary NAAQS for SO₂. The short-term (24-hour) standard of 0.14 parts per million (ppm) is not to be exceeded more than once per year. The long-term standard specifies an annual arithmetic mean not to exceed 0.030 ppm.² The primary standards were established in 1972. (See 40 CFR 50.4).

B. What Is a State Implementation Plan?

The CAA requires states to attain and maintain ambient air quality equal to or better than the NAAQS. The state’s commitments for attaining and maintaining the NAAQS are outlined in the State Implementation Plan (SIP) for that state. The SIP is a planning document that, when implemented, is designed to ensure the achievement of the NAAQS. Each state currently has a SIP in place, and the Act requires that SIP revisions be made periodically as necessary to provide continued compliance with the standards.

SIPs include, among other things, the following: (1) An inventory of emission sources; (2) statutes and regulations adopted by the state legislature and executive agencies; (3) air quality analyses that include demonstrations that adequate controls are in place to meet the NAAQS; and (4) contingency measures to be undertaken if an area fails to attain the standard or make reasonable progress toward attainment by the required date.

The state must make the SIP available for public review and comment through a public hearing, it must be adopted by the state, and submitted to us by the Governor or her/his designee. We take federal action on the SIP submittal, thus rendering the rules and regulations federally enforceable. The approved SIP serves as the state’s commitment to take actions that will reduce or eliminate air quality problems. Any subsequent revisions to the SIP must go through the formal SIP revision process specified in the Act.

C. What Is the Background for This Action?

1. When Was the Nonattainment Area Established?

Phelps Dodge Mining Company’s Ajo Incorporated (PDAI) operation was the largest point source in the Ajo nonattainment area. The PDAI copper smelter was situated at the eastern end of the Little Ajo Mountains.

On March 3, 1978, at 43 FR 8968, for lack of a state recommendation, we designated Pima County as a primary SO₂ nonattainment area based on monitored violations of the primary SO₂ NAAQS in the area between 1975 and 1977. At the request of the Arizona Department of Environmental Quality (ADEQ), the nonattainment area was subsequently reduced to five townships in and around Ajo on April 10, 1979 (44 FR 21261). As a result, townships T11S, R6W; T11S, R5W; T12S, R6W; T12s, R5W; and T13S, R6W make up the nonattainment area. Townships T11S, R7W; T12S, R7W; T13S, R7W; and T13S, R5W are classified as “cannot be classified” areas.

On the date of enactment of the 1990 CAA Amendments, SO₂ areas meeting the conditions of section 107(d) of the Act, including the pre-existing SO₂ nonattainment areas, were designated nonattainment for the SO₂ NAAQS by operation of law. Thus, the Ajo area remained nonattainment for the primary SO₂ NAAQS following enactment of the 1990 CAA Amendments on November 15, 1990.

2. How Has the SIP Addressed CAA Provisions?


¹For the definition of the Ajo nonattainment area, see 40 CFR 81.303. EPA designated the entire area of Pima County as nonattainment for SO₂ on March 3, 1978 for lack of a State recommendation. EPA approved the State’s request that the SO₂-affected portion of Pima County be limited to the townships surrounding Ajo on April 10, 1979 (44 FR 21261). Townships T11S,R6W; T11S, R5W; T12S, R6W; T12s, R5W; and T14S, R6W comprise the nonattainment area. Townships T11S, R7W; T12S, R7W; T13S, R5W; and T13S, R7W are designated as “cannot be classified.” Ajo is a town in Pima County in the southwestern portion of Arizona.

²The secondary SO₂ NAAQS (3-hour) of 0.50 ppm is to be exceeded more than once per year. Secondary NAAQS are promulgated to protect welfare. The Ajo area is not classified nonattainment for the secondary standard, and this action relates only to the primary NAAQS.
3. What Is the Current Status of the Area?

On April 4, 1985, the PDAI smelter was permanently deactivated. Dismantling of the Ajo facility began in 1995. By February of 1996, the facility was completely dismantled. On October 15, 1997, ADEQ confirmed that the facility was dismantled and no longer existed at the former site. The area remains sparsely settled, and there are only minor industrial or commercial activities in or near the nonattainment area that produce small quantities of SO\textsubscript{2} emissions. The only point source consists of several generators run by Phelps Dodge which have a potential to emit (PTE) of 49.2 tons per year (tpy) of SO\textsubscript{2}. The ADEQ submission also included emissions from a proposed Gila Bend regional landfill, which was expected to have a PTE of 24.1 tpy of SO\textsubscript{2} when built. Because of their potential emissions, ADEQ classified these two sources as point sources. The Phelps Dodge generators are used only as a backup energy source, have emitted less than 1 tpy of SO\textsubscript{2} for the past five years of operation, and are not expected to emit more than 1.2 tpy of SO\textsubscript{2} in 2015. The landfill has not been built, and we were informed by the State on August 8, 2003 that the permit for the landfill was terminated by the permittee on August 28, 2002.

Currently, there are no operating ambient SO\textsubscript{2} monitors in the Ajo area. However, we do not expect the cumulative impact of the sources in and around Ajo to cause a violation of the NAAQS because their emissions are so low. No significant new sources have located in the area, another reason why our action today is appropriate.

D. What Are the Applicable Clean Air Act (CAA) Provisions for SO\textsubscript{2} Nonattainment Area Plans?

The air quality planning requirements for SO\textsubscript{2} nonattainment areas are set out in subparts 1 and 5 of Part D of title I of the Act. We have issued guidance in a General Preamble describing our views on how we will review SIPs and SIP revisions submitted under title I of the Act, including those containing SO\textsubscript{2} nonattainment area and maintenance area SIP provisions. 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992). The General Preamble discusses our interpretation of the title I requirements, and lists SO\textsubscript{2} policy and guidance documents.

1. What Statutory Provisions Apply?

CAA Sections 191 and 192 address requirements for SO\textsubscript{2} nonattainment areas designated subsequent to enactment of the 1990 CAA Amendments and areas lacking fully approved SIPs immediately before enactment of the 1990 Clean Air Act Amendments. Ajo falls into neither of these categories and is therefore subject to the requirements of subpart 1 of Part D of title I of the CAA (Sections 171–179B). Section 172 of this subpart contains provisions for nonattainment plans in general; these provisions were not significantly changed by the 1990 CAA Amendments. Among other requirements, CAA Section 172 provides that SIPs must assure that reasonably available control measures (RACM) (including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of reasonably available control technology (RACT)) shall be implemented as expeditiously as practicable and shall provide for attainment.

E. What Are the Applicable Provisions for SO\textsubscript{2} Maintenance Plans and Redesignation Requests?

1. What Are the Statutory Provisions?

a. CAA Section 107(d)(3)(E).

The 1990 CAA Amendments revised section 107(d)(3)(E) to provide five specific requirements that an area must meet in order to be redesignated from nonattainment to attainment:

(1) the area must have attained the applicable NAAQS;
(2) the area has met all relevant requirements under section 110 and Part D of the Act;
(3) the area has a fully approved SIP under section 110(k) of the Act;
(4) the air quality improvement must be permanent and enforceable; and,
(5) the area must have a fully approved maintenance plan pursuant to section 175A of the Act.

b. CAA Section 175A.

CAA section 175A provides the general framework for maintenance plans. The maintenance plan must provide for maintenance of the NAAQS for at least 10 years after redesignation, including any additional control measures as may be necessary to ensure such maintenance. In addition, maintenance plans are to contain such contingency provisions as we deem necessary to assure the prompt correction of a violation of the NAAQS that occurs after redesignation. The contingency measures must include, at a minimum, a requirement that the state will implement all control measures contained in the nonattainment SIP prior to redesignation. Beyond these provisions, however, CAA section 175A does not define the content of a maintenance plan.

2. What General EPA Guidance Applies to Maintenance Plans?

Our primary general guidance on maintenance plans and redesignation requests is a September 4, 1992 memo from John Calcagni, entitled “Procedures for Processing Requests to Redesignate Areas to Attainment” (“Calcagni Memo”). Specific guidance on SO\textsubscript{2} redesignations also appears in a January 26, 1995 memo from Sally L. Shaver, entitled “Attainment Determination Policy for Sulfur Dioxide Nonattainment Areas” (“Shaver Memo”).

Guidance on SO\textsubscript{2} maintenance plan requirements for an area lacking monitored ambient data, if the area’s historic violations were caused by a major point source that is no longer in operation, is found in an October 18, 2000 memo from John S. Seitz, entitled “Redesignation of Sulfur Dioxide Nonattainment Areas in the Absence of Monitored Data” (“Seitz Memo”). The Seitz Memo exempts eligible areas from the maintenance plan requirements of continued monitoring.

3. What Are the Requirements for Redesignation of Single-Source SO\textsubscript{2} Nonattainment Areas in the Absence of Monitored Data?

Our historic redesignation policy for SO\textsubscript{2} has called for eight quarters of clean ambient air quality data as a necessary prerequisite to redesignation of any area to attainment. The Seitz memo provides guidance on SO\textsubscript{2} maintenance plan requirements for an area lacking monitored ambient data, if the area’s historic violations were caused by a major point source that is no longer in operation. In order to allow for these areas to qualify for redesignation to attainment, this policy requires that the maintenance plan address otherwise applicable provisions, and include:

(1) Emissions inventories representing actual emissions when violations occurred; current emissions; and emissions projected to the 10th year after redesignation;
(2) Dispersion modeling showing that no NAAQS violations will occur over the next 10 years and that the shut down source was the dominant cause of the high concentrations in the past;
(3) Evidence that if the shut down source resumes operation it would be considered a new source and be required to obtain a permit under the Prevention of Significant Deterioration provisions of the CAA; and
(4) A commitment to resume monitoring before any major SO\textsubscript{x} source commences operation.
III. Review of the Arizona State Submittals Addressing These Provisions

A. Is the Maintenance Plan Approvable?

1. Did the State Meet the CAA Procedural Provisions?

   On June 18, 2002, ADEQ submitted to EPA the “Ajo Sulfur Dioxide Nonattainment Area, State Implementation and Maintenance Plan” and a request to redesignate the area to attainment. The State verified that it had adhered to its SIP adoption procedures. On October 30, 2002, we found that the submittal met the completeness criteria in 40 CFR Part 51, Appendix V, which must be satisfied before EPA formal review.

2. Does the Area Qualify for Review Under the Seitz Memo?

   a. Were the Area’s Violations Caused by a Major Point Source of SO\textsubscript{2} Emissions that Is No Longer in Operation?

   As discussed above, the only major source of SO\textsubscript{2} emissions within the Ajo nonattainment area was the Phelps Dodge Mining Company’s Ajo Incorporated (PDAI) copper smelter, which ceased operation in 1985. The last recorded 24-hour or annual average exceedances of the primary NAAQS at PDAI occurred in 1984. During the monitoring network’s history, annual average SO\textsubscript{2} levels were generally one half of the current NAAQS standard (0.030 ppm). ADEQ removed the SO\textsubscript{2} monitor in 1985, the smelter operating permits expired, the smelting equipment was removed over a period of years, and the smelter was completely dismantled by February 1996. No new sources of SO\textsubscript{2} of the magnitude of PDAI have located in the area. Thus, Ajo meets this criterion for review under the Seitz Memo.

   b. Has the State Met the Requirements of the Seitz Memo?

   As discussed below, the State has addressed the requirements in the Seitz Memo for emissions inventories, modeling, permitting of major new sources, and agreement to commence monitoring if a new major source locates in the area. Therefore, the State has met the special criteria in the Seitz Memo for approval of maintenance plans and redesignation requests.

   (1) Emissions Inventory. The State provided the three emissions inventories specified in the Seitz Memo for the sources in, and within 50 kilometers of, the Ajo nonattainment area. For a representative year when the copper smelter was in operation (1981), direct SO\textsubscript{2} emissions from smelting operations were 39,596 tpy. The ADEQ submittal identifies only a single existing point source within the Ajo Area, the Phelps Dodge Generator Station, with 2000 SO\textsubscript{2} emissions of about 1 tpy, and 2015 projected emissions of 1.2 tpy. Phelps Dodge has only operated the generators as emergency/back up electric supply in recent years. The ADEQ submittal also identified the proposed Gila Bend Landfill, and projected its emissions at 29.7 tpy in 2015. We conclude that the inventories are complete, accurate, and consistent with applicable CAA provisions and the Seitz Memo.

   (2) Modeling. Past EPA policy memoranda on SO\textsubscript{2} redesignations all ask for dispersion modeling. The Seitz Memo asks for dispersion modeling of all point sources within 50 km of the nonattainment area boundary. Screening dispersion modeling was performed with SCREEN3 using conservative assumptions about source parameters and the meteorology. The modeling indicated that the existing and then-proposed (Gila Landfill) sources would likely have an impact of about 66 percent of any of the SO\textsubscript{2} standards.

   The Seitz Memo requires a modeling analysis that shows point sources were the dominant sources contributing to high SO\textsubscript{2} concentrations in the airshed. While MPR has been accepted by EPA for modeling of smelters, as a rollback method it assumes that the monitored SO\textsubscript{2} violations are completely due to the smelter being modeled. Thus, it cannot be relied upon for this analysis. Instead, screening modeling can be used to show that non-smelter sources have only an insignificant contribution. Since their emissions have changed relatively little since the time that emission controls were placed on the smelter, this same screening modeling shows that the non-smelter sources were insignificant in the past, and hence the smelter was the dominant source contributing to past high SO\textsubscript{2} concentrations. EPA therefore finds that the ambient SO\textsubscript{2} modeling requirement for redesignations and maintenance plans is met.

   (3) Permitting of New Sources. For the Ajo SO\textsubscript{2} nonattainment area, the nonattainment area new source review (NSR)permit program responsibilities are shared by ADEQ and Pima Department of Environmental Quality (PDEQ). ADEQ administers the preconstruction review and permitting provisions of Arizona Administrative Code, Title 18, Chapter 2, Articles 3 and 4. PDEQ administers the NSR program under Pima County Code, Title 17, Chapter 17.12 and Chapter 17.16. Article VIII. All new major sources and modifications to existing major sources are subject to the NSR requirements of these rules. We have not yet fully approved the ADEQ and PDEQ NSR rules.

   Section 172(c)(5) requires NSR permits for the construction and operation of new and modified major stationary sources anywhere in nonattainment areas. We have determined that areas being redesignated from nonattainment to attainment do not need to comply with the requirement that an NSR program be approved prior to redesignation provided that the area demonstrates maintenance of the standard without Part D nonattainment NSR in effect. The rationale for this decision is described in a memorandum from Mary Nichols dated October 14, 1994 (“Part D New Source Review (Part D NSR) Requirements for Areas Requesting Redesignation to Attainment”). We have determined that the maintenance demonstration for Ajo does not rely on nonattainment NSR. Prevention of Significant Deterioration (PSD) is the replacement for NSR in attainment areas, and part of the obligation under PSD is for a new source to review increment consumption and maintenance of the air quality standards. PSD also requires preconstruction monitoring. Therefore, the State need not have a fully approved nonattainment NSR program prior to approval of the redesignation request.

   ADEQ and PDEQ have PSD permitting programs (A.A.C. R18–2–406 and Pima County Code (PCC) 17.16.590) that were established to preserve the air quality in areas where ambient standards have been met. The State’s PSD program for all criteria pollutants except PM–10 was approved into the SIP effective May 3, 1983 (48 FR 19879). The federal PSD program for PM–10 was delegated to the State on March 12, 1999. Pima’s PSD program (for all criteria pollutants) was delegated effective April 14, 1994. The PSD program requires stationary sources to undergo preconstruction review before facilities are constructed, modified, or reconstructed and to apply Best Available Control Technology (BACT). These programs will apply to any major source wishing to locate in the Ajo area once the area is redesignated to attainment. The ADEQ and PDEQ commitments to treat any major source or modification as “new” under the PSD program satisfies the preconstruction permit provision of the
Seitz memo as one of the prerequisites to redesignation.

(4) Monitoring. ADEQ has confirmed that the State commits to resume monitoring before any major source of SO2 commences to operate. This addresses the monitoring provision of the Seitz Memo.

B. Has the State Met the Remaining Maintenance Plan Provisions?

As discussed above, CAA Section 175A sets forth the statutory requirements for maintenance plans, and the Calcagni and Shaver Memos cited above contain specific EPA guidance. The only maintenance plan element not covered by the Seitz Memo is the contingency provision. CAA Section 175A provides that maintenance plans “contain such contingency provisions as the Administrator deems necessary to assure that the State will promptly correct any violation of the standard which occurs after the redesignation of the area as an attainment area.”

The Ajo Maintenance Plan includes the State’s commitment to continue to implement and enforce measures necessary to maintain the SO2 NAAQS. ADEQ’s current operating permit program places limits on SO2 emissions from existing sources. Should an existing facility want to upgrade or increase SO2 emissions, the facility would be subject to the PSD program. Should a new facility be constructed in the Ajo area, the facility would also be subject to PSD as required in the Calcagni Memo.

If these measures prove insufficient to protect against exceedances of the NAAQS, the State has also committed to adopt, submit as a SIP revision, and implement expeditiously any and all measures needed to ensure maintenance of the NAAQS.

The Calcagni Memo emphasizes the importance of specific contingency measures, schedules for adoption, and action levels for the implementation of the contingency plan. Since there are no remaining sources of SO2 emissions of the magnitude of the Phelps Dodge smelter and there is no SO2 monitoring in the Ajo area, we agree with the State that this level of specificity is not appropriate, and we conclude that the State’s commitment satisfactorily addresses the CAA provisions. We believe that the State and County’s PSD permitting program is sufficient to track future air quality trends and to assure that the Ajo area will not violate the NAAQS. If either the State or the County identifies the potential for a NAAQS violation through the permitting process, they would ascertain what measures would be needed to avoid the violation.

C. Has the State Met the Redesignation Provisions of CAA Section 107(d)(3)(E)?

1. Has the Area Attained the 24-Hour and Annual SO2 NAAQS?

As discussed above, the normal prerequisite for redesignation is submittal of quality-assured ambient data with no violations of the SO2 NAAQS for the last eight consecutive quarters. However, the Seitz Memo recognizes that states should be provided an opportunity to request redesignation where there is no longer monitoring but where there is no reasonable basis for assuming that SO2 violations persist after closure of the sources that were the primary or sole cause of these violations. Ajo is such an area, and the State has submitted convincing evidence that no major stationary sources of SOx emissions remain in operation in or within 50 kilometers of the area that might cause a violation of the SO2 NAAQS. We do not believe that, even in the aggregate, the remaining minor sources which are present would cause a violation of the SO2 NAAQS.

2. Has the Area Met All Relevant Requirements Under Section 110 and Part D of the Act?

CAA Section 110(a)(2) contains the general requirements for SIPs (enforceable emission limits, ambient monitoring, permitting of new sources, adequate funding, etc.) and Part D contains the general provisions applicable to SIPs for nonattainment areas (emissions inventories, reasonably available control measures, demonstrations of attainment, etc.). Over the years, we have approved Arizona’s SIP as meeting the basic requirements of CAA Section 110(a)(2), and the CAA Part D requirements for Ajo addressed primarily by the regulations applicable to the Phelps Dodge facility during the period of its operation. The State has thus met the basic SIP requirements of the CAA.

3. Does the Area Have a Fully Approved SIP Under Section 110(k) of the Act?

We examined the applicable SIP, and also looked at the disapprovals listed in 40 CFR 52.125 and no disapprovals remain relevant to the applicable SIP. Arizona has a fully-approved SIP with respect to the Ajo area.

4. Has the State Shown That the Air Quality Improvement in the Area is Permanent and Enforceable?

Yes. The Maintenance Plan shows that the exclusive cause of past SO2 NAAQS violations (the Phelps Dodge copper smelter in Ajo) no longer exists. As a result, there is no reason to expect that SO2 ambient concentrations will exceed background levels.

5. Does the Area Have a Fully Approved Maintenance Plan Pursuant to Section 175A of the Act?

Yes. As discussed above, we are approving the Ajo Maintenance Plan in this action.

IV. Final Action

We are approving the Maintenance Plan for the Ajo area under CAA Sections 110 and 175A. We are also approving the State’s request to redesignate the Ajo area to attainment of the primary SO2 NAAQS.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this Federal Register publication, we are publishing a separate document that will serve as the proposal to approve the State plan and redesignate the area if relevant adverse comments are filed. This rule will be effective January 2, 2004 without further notice unless relevant adverse comments are received by December 3, 2003. If we receive such comments, this action will be withdrawn before the effective date. All public comments received will then be addressed in a subsequent final rule based on the proposed action. We will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective January 2, 2004.

V. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a “significant regulatory action” and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies 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.). Because this rule approves pre-existing requirements
under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does 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, as specified in Executive Order 13045 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA’s role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the state to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

The Congressional Review Act, 5 U.S.C. section 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 the Federal Register. A major rule cannot take effect until 60 days after it is published in the Federal Register. This action is not a “major rule” as defined by 5 U.S.C. section 804(2). Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 2, 2004. 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**

**40 CFR Part 81**

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur dioxide.

**ARIZONA—SO₂**

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<th>Designated area</th>
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

Possession, Use, and Transfer of Select Agents and Toxins

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Interim final rule and request for comments.

SUMMARY: We are amending an interim final rule published on December 13, 2002, that established requirements regarding possession and use in the United States, receipt from outside the United States, and transfer within the United States, of select agents and toxins. The requirements were established to implement provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The December 2002 interim final rule established a phase-in period for certain requirements to allow entities to comply without causing disruption or termination of research or educational projects. The phase-in for entities that on February 7, 2003, were already conducting activities regarding select agents and toxins, would be eligible for registration under 42 CFR 72.6, or were not already lawfully possessing select agents and toxins, required entities applying for registration with the select agent program, and individuals requiring access to select agents and toxins, to undergo a security risk assessment by the Attorney General before November 12, 2003. The regulations also provided that an entity that on February 7, 2003, was not already conducting activities under a certificate of registration issued under 42 CFR 72.6, or was not already lawfully possessing select agents and toxins, would be eligible for registration to possess, use, or transfer select agents and toxins as soon as the entity met all of the applicable requirements of Part 73, including the requirement for the Attorney General to conduct a security risk assessment.

In a document published in the Federal Register on December 13, 2002 (67 FR 76886), we promulgated an interim final rule to establish requirements regarding possession and use in the United States, receipt from outside the United States, and transfer within the United States, of certain biological agents and toxins (referred to below as select agents and toxins). This includes requirements concerning registration, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications. The December 2002 interim final rule is set forth at 42 CFR part 73.

In general, the entities regulated under the December 2002 interim final rule are academic institutions and biomedical centers; commercial or defense laboratories (including critical infrastructure) or distribution facilities; federal, state, and local laboratories, including clinical and diagnostic laboratories; and research facilities.

The Act also gives the United States Department of Agriculture (referred to below as USDA) the authority and responsibility for regulating activities regarding select agents and toxins to protect animal and plant health and animal and plant products. The Act gives the Secretary of HHS the authority and responsibility for regulating activities regarding select agents and toxins to protect the public health and safety. Some of the select agents and toxins regulated under the HHS December 2002 interim final rule are also regulated by USDA under 9 CFR part 121. The select agents and toxins subject to regulation by both agencies are identified as “overlap” select agents and toxins and those regulated solely by HHS are identified as HHS select agents and toxins. The Act provides for interagency coordination between the two departments regarding overlap select agents and toxins.

The December 2002 interim final rule established a phase-in period for certain requirements to allow entities to comply without causing disruption or termination of research or educational projects. The phase-in for entities that on February 7, 2003, were already conducting activities under a certificate of registration issued under 42 CFR 72.6, or were lawfully possessing select agents and toxins, required that entities applying for registration with the select agent program, and individuals requiring access to select agents and toxins, to undergo a security risk assessment by the Attorney General before November 12, 2003. The regulations also provided that an entity that on February 7, 2003, was not already conducting activities under a certificate of registration issued under 42 CFR 72.6, or was not already lawfully possessing select agents and toxins, would be eligible for registration to possess, use, or transfer select agents and toxins as soon as the entity met all of the applicable requirements of Part 73, including the requirement for the Attorney General to conduct a security risk assessment.

The Attorney General has assigned the responsibility to conduct the security risk assessments required by the Act to the Federal Bureau of Investigation (FBI). The Criminal Justice Information Services (CJIS) Division is the component of the FBI responsible for implementing this program. The CJIS Division continues to receive complete application packages, which consist of completed FBI fingerprint cards (FD-901) and usable fingerprint cards, and has finalized over 5,000 security risk...