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WHAT: Free public briefings (approximately 3 hours) to present: 1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
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WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

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WHEN: June 15; at 9:00 a.m.
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Agencies have begun including a Regulation Identifier Number in the headings of their Federal Register documents. RINs also appear in entries listed in the Unified Agenda of Federal Regulations, which is published in the Federal Register in April and October of each year. Assigning RINs makes it easier for the public and agency managers to track the entries at the various stages of their development.
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By the President of the United States of America

A Proclamation

The lure of the open water attracts increasing numbers of Americans to the scenic waterways of our country each year. Recreational boating has become one of this Nation's most popular leisure-time activities. It is estimated that more than 70 million Americans will take to the water this year to enjoy fishing, hunting, waterskiing, cruising, sailing, and other activities involving the use of a boat.

Unfortunately, an improperly handled boat can be a dangerous or even deadly instrument. More than one thousand persons die each year on our country's lakes, rivers, streams, oceans, and bays. National Safe Boating Week is proclaimed, therefore, as an appeal to all Americans to respect the marine environment and to operate watercraft in a safe and prudent manner.

Boating remains one of the least regulated transportation activities, making it imperative that all pilots be familiar with safe operating procedures as well as the rules and courtesies of the waterways. Because safe boating is not a simple proposition and because there is much information every operator needs to know before going out on the water, the theme of the 1989 National Safe Boating Week is "Know Before You Go." All boaters, especially those who operate small vessels for fishing, hunting, and other sports, need to know the craft they are using and the environment in which they will be operating. Most important, all boaters should know their own personal limitations and responsibilities so they do not lead themselves and others into situations beyond their skill or physical endurance.

The majority of boating accidents are the result of pilot error; ignorance and intoxication are major threats to safety. Boaters should be aware that operating a vessel while under the influence of alcohol or drugs is not only dangerous and irresponsible, but also a Federal offense punishable by substantial civil and criminal penalties. Those using watercraft must be well-informed, sober, and prepared to deal with hazardous situations.

Safe boating is the responsibility of everyone who uses America's waterways. Let us all join with the Coast Guard Auxiliary, the U.S. Power Squadrons, the American Red Cross Water Safety Program, and the other member organizations of the National Safe Boating Council in making National Safe Boating Week the start of a major campaign to educate boaters to "know before they go."

In recognition of the need for boating safety, the Congress, by a joint resolution approved June 4, 1958 (36 U.S.C. 161), as amended, authorized and requested the President to proclaim annually the week commencing on the first Sunday in June as National Safe Boating Week.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim the week beginning June 4, 1989, as National Safe Boating Week. I also invite the Governors of the States, Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, and American Samoa and the Mayor of the District of Columbia to provide for the observance of this week.
IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fourth day of May, in the year of our Lord nineteen hundred and eighty-nine, and of the Independence of the United States of America the two hundred and thirteenth.
Rules and Regulations

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.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

SMALL BUSINESS ADMINISTRATION

13 CFR Part 120
[Rev. 8; Amdt. 3]

Business Loans, Fees

AGENCY: Small Business Administration.

ACTION: Final rule.

SUMMARY: This final rule changes the present regulation with respect to which fees a participating lender and others may charge an applicant borrower for services. Major changes: a lender may charge a borrower reasonable packaging fees, and are based on time and hourly charges. A lender is required to disclose to SBA any fees of which it has knowledge.

This is the standard an SBA local office will use in evaluating the reasonableness of fees. While SBA will not generally review lease payments made by its borrowers, neither does it review prices paid to vendors for supplies. But, the Agency does recognize the importance of ensuring that SBA borrowers are not being charged excessive fees. Thus, the SBA will review the complaint of any borrower who alleges it was charged excessive fees. In any event, the Agency reserves the right to review fees at any time. If the Agency determines that a lender did charge a borrower an excessive fee, SBA can request that the lender refund what has been deemed to be excessive. If a lender refuses to refund the fees, the Agency can suspend or revoke lenders' privilege to participate with SBA in accordance with 13 CFR 120.305.

Under this final rule, the borrower cannot be charged a processing or commitment fee, or bonus, brokerage fees, commissions or points. It may be charged fees for legal and other services so long as they are based upon requested services actually rendered and are based on time and hourly charges. A lender is forbidden from sharing the premium which it may receive when it sells the SBA guaranteed portion of a loan. A lender may charge the borrower reasonable fees for packaging or other services not otherwise prohibited. Reasonable is defined as what is customary for lenders in the geographic area where the loan is being made. That is the standard an SBA local office will use in evaluating the reasonableness of fees, whether it is called upon by the borrower or whether it reviews fees on its own in any particular case. The regulation requires that each lender must advise the applicant in writing that such applicant is not required to obtain or pay for services that are unwanted. This is intended to eliminate the possibility of duplication of services and fees. While SBA will not generally review any fees charged in the absence of complaint by an applicant, the Agency reserves the right to do so at any time. A lender is required to disclose to SBA any fees of which it has knowledge.

For further information contact:

Charles R. Hertzberg, Deputy Associate Administrator for Financial Assistance, 1441 L Street NW., Washington, DC 20416, telephone (202) 653-6574.

SBA received 27 comments in favor of the proposal and one comment from a member of Congress against the proposal. One of the commenters suggested that SBA put in the rule the existing policy which forbids a lender from sharing, with a loan packager or referring lender, the premium it may receive on the sale of the guaranteed portion in the secondary market. This policy has been existent for several years but has not been reflected in the Agency's regulation. The Agency has adopted this suggestion. Another commenter suggested that SBA limit the amount of the packaging fee to no more than $2,000. The Agency's experience has been that when a cap is used it invariably becomes the floor. The Agency believes that its personnel are able to ascertain what is not reasonable in the various geographic parts of the country and can so advise the lenders. Accordingly, the Agency did not adopt this suggestion.

Another commenter suggested that SBA use a time frame in the regulation during which a borrower could complain about the fee. SBA did not adopt this suggestion since it did not want to penalize any borrower who feels it has been charged excessive fees by placing an arbitrary time limit. Two commenters suggested that the Agency continue to prohibit the payment of commitment and processing fees, and bonuses, brokerage fees and commissions. SBA did not intend to eliminate this prohibition in the proposed regulation, but that was not clear. Accordingly, the Agency has expressly retained this prohibition in this final rule. Another commenter suggested that the Agency permit a lender to charge a flat processing fee with an additional fee based on a percentage of the total loan amount. SBA did not adopt this since the Agency seeks only to permit fees which are charged for provable services rendered. Another commenter suggested that the Agency not permit the payment of referral fees. SBA is not taking any action on referral fees at this time, but it plans to propose a regulation on this point at an early date.

The Congressman's objections were based on recommendations made in H. Rep. 915, 97th Cong., 2d Sess. (1982) concerning fees charged borrowers for work on SBA guaranteed loans. Because of resource constraints, the Agency can no longer monitor each and every fee payable by borrowers. The Agency does not review lease payments made by its borrowers, neither does it review prices paid to vendors for supplies. But, the Agency does recognize the importance of ensuring that SBA borrowers are not being charged excessive fees. Thus, the SBA will review the complaint of any borrower who alleges it was charged excessive fees. In any event, the Agency reserves the right to review fees at any time. If the Agency determines that a lender did charge a borrower an excessive fee, SBA can request that the lender refund what has been deemed to be excessive. If a lender refuses to refund the fees, the Agency can suspend or revoke lenders' privilege to participate with SBA in accordance with 13 CFR 120.305.

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knowledge and must agree to refund any fee which SBA determines to be excessive. If a lender fails to disclose to SBA any fee of which it has knowledge, SBA may consider that to be a failure to disclose material facts within the meaning of § 120.202-5 of its regulations. If a lender refuses to refund excessive fees, SBA may suspend or revoke lender participation status pursuant to § 120.305 of its regulations. The Agency continues to forbid the charging of points or add-on interest.

For purposes of the Regulatory Flexibility Act (5 U.S.C. 605(b)), this final rule will have a significant economic impact on a substantial number of small entities. In fiscal 1988, SBA approved 14,988 guaranteed loans for an aggregate amount of $2.42 billion. The Agency does not collect or maintain statistics on the fees participating lenders charge borrowers, but it may be presumed that each borrower paid some fees with respect to each loan, payable to the borrower’s own attorney or accountant (which is not covered by this regulation), and some payable to the lender or to the professional persons engaged by the lender with borrower’s concurrence. Based upon the largest conceivable estimate for fiscal 1988, the fees would not have exceeded $24 million. This final rule does not contemplate any reporting or recordkeeping requirements. There are no Federal rules which duplicate, overlap or conflict with this final rule. There are no significant alternatives which would accomplish stated objectives and would minimize any significant impact of the final rule on small entities.

SBA certifies that this final rule does not constitute a major rule for the purpose of Executive Order 12291, since, as above stated, the rule is not likely to result in an annual effect on the economy of $100 million or more. As stated above, this final rule does not impose any additional reporting or recordkeeping requirements pursuant to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

This final rule would not have federalism implications warranting the preparation of a Federal Assessment in accordance with Executive Order 12291.

List of Subjects in 13 CFR Part 120

Loan programs/business, Small business

Accordingly, pursuant to the authority contained in section 5(b)(6) of the Small Business Act (15 U.S.C. 631(b)(6)), SBA amends Part 120, Chapter I, Title 13, Code of Federal Regulations, as follows:

PART 120—BUSINESS LOAN POLICY

1. The authority citation for Part 120 continues to read as follows:

Authority: 15 U.S.C. 634(b)(6) and 636 (a) and (b).

2. Section 120.104-2 is amended by revising paragraph (e) to read as follows:

§ 120.104-2 Service and commitment fees.

(e) Fees for other services. (1) A Lender or Associate shall not charge an applicant any processing or commitment fee, or any bonus, brokerage fee or commission (including points) for the purpose of, or in connection with, obtaining financial assistance through SBA. A Lender shall not share the premium which it may receive from the sale of an SBA guaranteed loan in the secondary market with either a loan package or to the Lender or with another lender which refers the loan applicant to the Lender.

(2) A Lender or Associate may charge an applicant reasonable fees for packaging and/or other services not otherwise prohibited. Reasonable is defined as customary for Financial Institutions in the geographic area where the loan is being made. The Lender shall advise the applicant in writing that the applicant is not required to obtain or pay for services that are unwanted. The applicant must take responsibility for the decision as to whether fees are reasonable. As a general rule, SBA will not review any fees in the absence of a complaint by the applicant, although it reserves the right to do so at any time.

(3) A Lender shall disclose to SBA any fees of which it has knowledge and shall agree to refund to the applicant any fee which SBA determines to be excessive. Failure of a Lender to disclose to the SBA any fee of which it has knowledge may be considered by SBA to be a failure to disclose material facts within the meaning of § 120.202-5 of this Title. Failure of a Lender to refund excessive fees to the applicant may result in an action by SBA to suspend or revoke Lender participation status in accordance with § 120.305 of this Title. Lender fees for legal services may be charged to an applicant provided they are based upon requested services actually rendered, and are based on time and hourly charges. Expenses for necessary out-of-pocket costs, such as filing or recordation to perfect security interests, may be passed on to the applicant.

(4) A Lender shall not require that borrower pay points, and add-on interest may not be used.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 89-11-M—81—AD; Amdt. 39—6229]

Airworthiness Directives; Aerospatiale Model ATR42 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Aerospatiale Model ATR42 series airplanes, which requires inspection and modification, if necessary, of the aileron control tab hinge pins. This amendment is prompted by reports of aileron binding due to migration of the aileron tab inboard hinge pin, which contacts adjacent structure. This condition, if not corrected, could lead to excessive aileron forces and loss of controllability of the airplane.

EFFECTIVE DATE: June 12, 1989.

ADDRESSES: The applicable service information may be obtained from Aerospatiale, 31060 Toulouse, Cedex 9, France. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. Robert C. McCracken, Standardization Branch, ANM-113; telephone (206) 431-1967. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68906, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: The Direction Generale de L'Aviation Civile (DGAC), which is the airworthiness authority of France, in accordance with existing provisions of a bilateral airworthiness agreement, has notified the FAA of an unsafe condition which
may exist on certain Aerospatiale Model ATR42 series airplanes. There has been a recent report of an aileron binding due to migration of the aileron control tab hinge pin, which contacts adjacent structure. Further inspection of the hinge pin revealed the pin became displaced due to a damaged lock plate. This condition, if not corrected, could lead to excessive aileron forces and loss of controllability of the airplane.

Aerospatiale has issued Service Bulletin ATR42-57-0019, Revision 1, dated June 7, 1988 (applicable to Serial Numbers 003 thru 068), which describes procedures for removal of the lock plate and modification of the aileron control tab hinge pins; and Service Bulletin ATR42-57-0028, Revision 1, dated April 20, 1989 (applicable to Serial Numbers 003 through 135), which describes procedures for inspection, and modification, if necessary, of aileron control tab hinge pins. DGAC France has classified these service bulletins as mandatory, and has issued French Airworthiness Directive T-89-077-021B to address this subject.

This airplane model is manufactured in France and type certificated in the United States under the provisions of Section 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement. Since this condition is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD requires modification of the aileron control tab hinge pins, in accordance with the service bulletins previously described. Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable, and good cause exists for making this amendment effective in less than 30 days.

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 12291, 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 and is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291, with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it, when filed, may be obtained from the Rules Docket.

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 as follows:

PART 39—[AMENDED]

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


§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Aerospatiale: Applies to all Model ATR42 series airplanes, certificated in any category. Compliance is required within 7 days after the effective date of this AD, unless previously accomplished.

To prevent displacement of the aileron control tab inboard hinge pin, accomplish the following:

A. For airplanes, Serial Numbers 003 through 068, modify the aileron control tab hinge pins, in accordance with Service Bulletin ATR42-57-0019, Revision 1, dated June 7, 1988.

B. For airplanes, Serial Numbers 003 through 135, perform an inspection of the aileron control tab hinge pins in accordance with the service bulletin.

C. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

Note: The request should be forwarded through the FAA Principal Maintenance Inspector (PMI), who will either concur or comment and then send it to the Manager, Standardization Branch, ANM-113.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service information from the manufacturer may obtain copies upon request to Aerospatiale, 216 Route de Bayonne, 31060 Toulouse, Cedex 03, France. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective June 12, 1989.

Issued in Seattle, Washington, on May 18, 1989.

Darrell M. Pederson,
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 89-12754 Filed 5-26-89; 8:45 am]
BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 89-NM-17-AD; Amdt. 39-6227]

Airworthiness Directives; Learjet Model 24, 25, 28, 29, 35, 36, and 55 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Learjet series airplanes, which requires an inspection of the manufacture date stamp on the risers of all drag chutes, and replacement of certain unairworthy risers, if necessary. This amendment is prompted by reports of faulty thread stitching used in risers manufactured in May 1987 and later. Drag chute risers that are not properly stitched could cause the chute to break away prematurely if deployed during landing.


ADDRESSES: The applicable service information may be obtained from Learjet Corporation, P.O. Box 7707, Wichita, Kansas 67277. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or the FAA, Central Region, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas.

FOR FURTHER INFORMATION CONTACT: Mr. Larry Abbott, Wichita Aircraft Certification Office, FAA, Central Region, 1801 Airport Road, Room 100.
Mid-Continent Airport, Wichita, Kansas 67209; telephone (316) 946-4400.  

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations to include an airworthiness directive, applicable to certain Learjet series airplanes, which requires an inspection of the manufacture date stamp on the risers of all drag chutes, and replacement of certain unairworthy risers, if necessary, was published in the Federal Register on March 28, 1989 (54 FR 12642).

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received in response to the proposal.

After careful review of the available data, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

It is estimated that 1,473 Learjet series airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 manhour per airplane to accomplish the required actions, and that the average labor cost will be $40 per manhour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $58,920.

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 "major rule" 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 final evaluation has been prepared for this action and is contained in the regulatory docket. A copy of it may be obtained from the Rules Docket.

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 as follows:

PART 39—[AMENDED]

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


§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Learjet (Formerly GATES LEARJET):

Applies to the following Learjet series airplanes and serial numbers, certified in any category:

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<th>Model number/series</th>
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Compliance is required as indicated, unless previously accomplished.

To prevent failure of drag chute upon deployment, accomplish the following:

A. Within the next 10 hours time-in-service or 2 calendar weeks after the effective date of this AD, whichever occurs first, determine the manufacture date that is stamped on the drag chute riser, in accordance with the applicable service bulletin.

B. Prior to return to service after deployment, accomplish the following:

1. If the drag chute riser is dated prior to May 1987, reidentify the riser and reinstall the drag chute and canopy, in accordance with the Accomplishment Instructions of the applicable service bulletin.

2. If the drag chute riser is dated May 1987 or later, accomplish either subparagraph a. or b., below:

a. Replace the suspect riser with a new riser.

b. Remove the riser and install a placard stating "DRAG CHUTE INOPERATIVE" on the drag chute deploy handle and drag chute mechanism, in accordance with the Accomplishment Instructions of the applicable Learjet service bulletin listed above. This placard may be removed once the drag chute riser is replaced, in accordance with paragraph A.2.a., above.

B. Prior to return to service after reidentification or replacement of the drag chute riser, as required by paragraph A. of this AD, perform a drag chute control system adjustment and drag chute functional test, in accordance with paragraph 2.C.(2)(f) of the Accomplishment Instructions of the applicable Learjet Service Bulletin specified in paragraph A. of this AD (reference Learjet Maintenance Manual, Chapter 25-62-01).

C. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Wichita Aircraft Certification Office, FAA, Central Region.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service information from the manufacturer may obtain copies upon request to Learjet Corporation, P.O. Box 7707, Wichita, Kansas 67277. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or at the FAA, Central Region, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas.


Leroy A. Keith,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 89-12775 Filed 5-26-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 89-NM-74-AD; Amdt. 39-6228]

Airworthiness Directives; British Aerospace Model BAE 125-800A Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to British Aerospace Model Bae 125-800A series airplanes, which requires inspection of the airflow angle sensor vanes to determine the presence of a balance weight feature, repetitive inspections of vanes having the feature, and replacement of the vanes, if necessary. This amendment is prompted by a report that a balance weight insert...
became detached from an angle sensor vane and was ingested into the engine. This condition, if not corrected, could result in damage to the engine fan blades.

**EFFECTIVE DATE:** June 12, 1989.

**ADDRESSES:** The applicable service information may be obtained from British Aerospace, PLC. Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. This information may be examined at the FAA, Transport Airplane Directorate, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 2010 East Marginal Way South, Seattle, Washington.

**FOR FURTHER INFORMATION CONTACT:** Mr. William Schroeder, Standardization Branch, ANM-113; telephone (206) 431-1505. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

**SUPPLEMENTARY INFORMATION:** The United Kingdom Civil Aviation Authority (CAA), in accordance with existing provisions of a bilateral airworthiness agreement, has notified the FAA of an unsafe condition which may exist on certain British Aerospace Model BAe 125–800A series airplanes. There has been a report of damage to an airplane’s engine due to a balance weight insert detaching from an angle sensor vane and being ingested into the engine. Only a limited number of angle sensor vanes were manufactured with this balance weight insert. This condition, if not corrected, could result in damage to the engine fan blades.

British Aerospace has issued BAe 125 Service Bulletin 27–149, dated March 17, 1989, which describes procedures for inspection of the airflow angle sensor vane to determine if the balance weight feature is present, repetitive inspections of the vane balance weight for security prior to each flight, and replacement of the vane, if necessary. The service bulletin also allows for discontinuing the repetitive inspections prior to each flight when improved airflow angle sensor vanes not having the balance weight insert are installed. The United Kingdom CAA has classified this service bulletin as mandatory.

This airplane model is manufactured in the United Kingdom and type certified in the United States under the provisions of Section 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement.

Since this condition is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD requires inspection of the airflow angle sensor vanes to determine the presence of a balance weight insert, and replacement, if necessary, in accordance with the service bulletin previously described. This is considered to be interim action. The FAA intends to revise this rulemaking action to require, on all affected airplanes, the installation of the improved airflow angle sensor vanes not having the balance weight insert.

However, the proposed compliance time for such installation is sufficiently long so that public notice and comment will not be impracticable.

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

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 and is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required).

**PART 39—[AMENDED]**

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

   **Authority:** 49 U.S.C. 1354(a), 1423 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

   § 39.13 [Amended]

2. By adding the following new airworthiness directive:

   **British Aerospace:** Applies to all Model BAe 125–800A series airplanes, up to and including serial number 258147, certificated in any category. Compliance is required as indicated, unless previously accomplished.

To prevent damage to the engine fan blades, accomplish the following:

A. Within 14 days after the effective date of this AD, inspect the left and right airflow angle sensor vanes for the trailing edge balance weight installation feature, in accordance with British Aerospace Service Bulletin 27–149, dated March 17, 1989.

   1. If the inspection reveals an airflow angle sensor vane that has the balance weight feature installed, use the BAe 125–800A Service Bulletin 27–149 to determine the presence of a balance weight feature. If the balance weight feature is present, the balance weight must be removed and replaced with a new balance weight.

   2. By adding the following new airworthiness directive:

   **British Aerospace:** Applies to all Model BAe 125–800A series airplanes, up to and including serial number 258147, certificated in any category. Compliance is required as indicated, unless previously accomplished.

   To prevent damage to the engine fan blades, accomplish the following:

A. Within 14 days after the effective date of this AD, inspect the left and right airflow angle sensor vanes for the trailing edge balance weight installation feature, in accordance with British Aerospace Service Bulletin 27–149, dated March 17, 1989.

   1. If the inspection reveals an airflow angle sensor vane that has the balance weight feature installed, use the BAe 125–800A Service Bulletin 27–149 to determine the presence of a balance weight feature. If the balance weight feature is present, the balance weight must be removed and replaced with a new balance weight.

   2. If the inspection reveals an airflow angle sensor vane that has the balance weight feature installed, visually inspect the balance weight for security of its attachment in the trailing edge of the airflow angle sensor vane, in accordance with the service bulletin.

   a. If the balance weight is loose, damaged, or missing, replace it with a new airflow angle sensor vane prior to further flight, in accordance with the service bulletin.

   b. If the balance weight is secure and is not damaged, reinspect the balance weight for security, prior to each flight, until it is replaced with a new airflow angle sensor vane that does not have the trailing edge balance weight installation feature.

   c. If the balance weight is loose, damaged, or missing, replace it with a new airflow angle sensor vane prior to further flight, in accordance with the service bulletin.

3. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service information from the manufacturer may obtain copies upon request to British Aerospace, PLC. Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. This information may be examined at the FAA, Transport Airplane Directorate, Northwest Mountain Region, 17900 Pacific Highway...
Airworthiness Directives; British Aerospace Model BAC 1-11 200 and 400 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to British Aerospace Model BAC 1-11 200 and 400 series airplanes, which requires repetitive visual inspections of the fuselage station 178 frame splice joint, skin, stringers, and connecting structure in the crown area for cracks, and repair of all cracks prior to further flight. This amendment is prompted by reports of fatigue cracks found in the fuselage crown area of the frame joint at Station 178. This condition, if not corrected, could compromise the structural capability of the fuselage.


ADDRESSES: The applicable service information may be obtained from British Aerospace, Inc., Service Bulletin Librarian, P.O. Box 17414, Dulles International Airport, Washington, DC 20141. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or at the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. William Schroeder, Standardization Branch, ANM-113; telephone (206) 431-1561. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68996, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations, to include a new airworthiness directive, applicable to British Aerospace Model BAC 1-11 200 and 400 series airplanes, which requires repetitive visual inspections of the fuselage station 178 frame splice joint, skin, stringers, and connecting structure in the crown area for cracks, and repair of all cracks prior to further flight, was published in the Federal Register on March 1, 1989 (54 FR 6549).

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the single comment received. The commenter supported the proposal.

After careful review of the available data, including the comment above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

It is estimated that 70 airplanes of the U.S. registry will be affected by this AD, that it will take approximately 1 manhour per airplane to accomplish the required actions, and that the average labor cost will be $40 per manhour. Based on these figures, the total cost impact of this AD to U.S. operators is estimated to be $2,800.

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 "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11094; February 28, 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 final evaluation has been prepared for this regulation and has been placed in the docket. A copy of it may be obtained from the Rules Docket.

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 of Part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

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


§ 39.13 [Amended]
2. Section 30.13 is amended by adding the following new airworthiness directive:

British Aerospace: Applies to all Model BAC 1-11 200 and 400 series airplanes, certificated in any category. Compliance is required as indicated, unless previously accomplished.

To prevent structural failure of the fuselage accomplish the following:
A. Prior to the accumulation of 30,000 landings or within 1,600 landings after the effective date of this AD, whichever occurs later, and thereafter at intervals not to exceed 1,600 landings, perform visual inspections of the fuselage frame splice joint, skin, stringers, and connecting structure at fuselage station 178 between stringers 2 left and 2 right, in accordance with British Aerospace Alert Service Bulletin 53-A-PM5964, Issue 2, dated June 1, 1988. Any cracks found must be repaired prior to further flight, in accordance with the service bulletin.
B. If cracks are found during inspections required by paragraph A., perform additional inspections in accordance with paragraph 2.2. of the Accomplishment Instructions, of British Aerospace Alert Service Bulletin 53-A-PM5964, Issue 2, dated June 1, 1988, and repair all cracks, prior to further flight, in accordance with the service bulletin.
C. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment and then send it to the Manager, Standardization Branch, ANM-113.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to British Aerospace, Inc., Service Bulletin Librarian, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. These documents may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or at the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective July 3, 1989.
Airworthiness Directives; General Electric Company (GE) CF6-80C2A/- 80C2B Series Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action publishes in the Federal Register and makes effective as to all persons an amendment adopting a new airworthiness directive (AD) which was previously made effective as to all known U.S. owners and operators of certain CF6-80C2 series turbofan engines by individual telegrams. The AD supersedes the requirements of AD 88-24-14, Amendment 39-6033 (FR 45894; November 15, 1988), by establishing a reduced cyclic life for fuel manifolds installed on GE CF6-80C2 engines, and removing the requirement for a one time inspection. The AD is needed to prevent fuel leakage and the possible loss of engine power or an engine fire resulting from cyclic fatigue cracking of the fuel manifold.

DATES: Effective May 31, 1989, as to all persons except those to whom it was made immediately effective by Telegraphic Airworthiness Directive (TAD) No. T89-03-52, issued February 1, 1989, which contained this amendment. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of May 31, 1989.

Compliance: As indicated in the body of this AD.

ADDRESSES: The applicable service bulletin [SB] may be obtained from General Electric Aircraft Engines, CF6 Distribution Clerk, Room 132, 111 Merchant Street, Cincinnati, Ohio 45246, or may be examined at the Regional Rules Docket, Room 311, Office of the Assistant Chief Counsel, Federal Aviation Administration, New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803.


SUPPLEMENTARY INFORMATION: On February 1, 1989, TAD T89-03-52, which superseded the requirements of AD 88-24-14, was issued and made effective immediately as to all known U.S. owners and operators of certain GE CF6-80C2 series turbofan engines. Since publication of AD 88-24-14, a fuel manifold in revenue service developed a leak within the service life established by AD 88-24-14. Investigation results indicated that the leak was from a crack which initiated as a result of low cycle fatigue (LCF) of the fuel manifold tube. The Federal Aviation Administration (FAA) has determined that this condition is likely to exist or develop on other engines of the same type design. Therefore, this AD supersedes the requirements of Airworthiness Directive (AD) 88-24-14, Amendment 39-6033 (FR 45894; November 15, 1988), and establishes a reduced cyclic life limit for the affected fuel manifolds, and provides a schedule for removal from service of CF6-80C2 fuel manifolds, to prevent fuel leaks resulting from LCF cracking.

This AD also removes the requirement for a one time inspection which was imposed by AD 88-24-14. The original intent of this inspection was to aid in the definition and control of potentially unsafe conditions. Based on the results of inspections, revised fuel manifold manufacturing processes, revised fuel manifold installation procedures, and reduced fuel manifold cyclic life established by this AD, the FAA has concluded that continued inspections are not required to maintain a satisfactory level of safety. Therefore, this AD removes the requirement for the one time inspection of the fuel manifold and the fuel manifold supports which was established by AD 88-24-14.

Since it was found that immediate corrective action was required, notice and public procedure thereon were impracticable and contrary to the public interest, and good cause existed to make the AD effective immediately by individual telegrams, issued February 1, 1989, to all known U.S. owners and operators of certain GE CF6-80C2 series turbofan engines. In the conditions still exist, and the AD is hereby published in the Federal Register as an amendment to § 39.13 of Part 39 of the Federal Aviation Regulations (FAR) to make it effective as to all persons.

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 12291, 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 is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Executive Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required). A copy of it, if filed, may be obtained by contacting the Rules Docket at the location provided under the caption "ADDRESSES".

List of Subjects in 14 CFR Part 39

Engines, Air transportation, Aircraft, Aviation safety, and Incorporation by reference.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration (FAA) amends Part 39 of the Federal Aviation Regulations (FAR) as follows:

PART 39—[AMENDED]

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


§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive (AD) which supersedes AD 88-24-14, Amendment 39-6033 as follows:


Compliance is required as indicated, unless already accomplished.

To prevent fuel leakage and the possible loss of engine power or an engine fire resulting from cyclic fatigue cracking of the fuel manifold, accomplish the following:

(a) Remove from service and replace with serviceable parts. CF6-80C2 fuel manifold
The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore,—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71
Aviation Safety, VOR Federal Airways.

Adoption of the Amendment
Accordingly, pursuant to the authority delegated to me, Part 71 of the Federal Aviation Regulations (14 Part 17) is amended, as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

§ 71.123 [Amended]
2. Section 71.123 is amended as follows:

V-143 [Amended]
By removing the words "Form INT Charlotte, NC, 043° and Greensboro, NC, 223° radial;" and substituting the words "From INT Charlotte, NC, 034° and Greensboro, NC, 238° radial;"

V-454 [Amended]
By removing the words "From INT Charlotte 043° and Liberty, NC, 250° radial;" and substituting the words "From INT Charlotte 034° and Liberty, NC, 253° radial;"

Issued in Washington, DC, on May 19, 1989.

Harold W. Becker,
Manager, Airspace Rules and Aeronautical Information Division.
[F.R. Doc. 89-13274 Filed 5-28-89; 8:45 am]
PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR Part 510 continues to read as follows:

Authority: Secs. 512, 701(a) (21 U.S.C. 360b, 371(a)); 21 CFR 5.10 and 5.83.

2. Section 510.600 is amended in paragraph (c)(1) by removing the entry "Pharmaceutical Basics, Inc.," and by alphabetically adding the new entry "Pegasus Laboratories, Inc.," and in paragraph (c)(2) by removing the entry "000832" and by numerically adding the entry "055246" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

<table>
<thead>
<tr>
<th>Firm name and address</th>
<th>Drug labeler code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514</td>
<td>055246</td>
</tr>
</tbody>
</table>

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

3. The authority citation for 21 CFR Part 520 continues to read as follows:


§ 520.1720a [Amended]

4. Section 520.1720a Phenylbutazone tablets and boluses is amended in paragraph (b)(4) by removing "000832" and adding in its place "055246".

Robert C. Livingston,
Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 89–12721 Filed 5–26–89; 8:45 am]
BILLING CODE 4160–01–M
Office of the Assistant Secretary for Public and Indian Housing

24 CFR Part 965

[Docket No. R-89-1396; FR-2482]

RIN 2577-AA67

Change in Consolidated Supply Program

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Final rule.

SUMMARY: This rule makes final a previously published proposed rule to simplify and strengthen the Consolidated Supply Program (CSP) by eliminating the purchase agreement portion of the program. This rule will promote competition for small purchases (under $25,000) among supply contractors and will reduce HUD's involvement in Public Housing Agency (PHA) and Indian Housing Authority (IHA) purchasing decisions. The rule retains, without change, HUD's competitive contracts for large commodities (refrigerators, ranges, etc.) commonly needed by PHAs/IHAs.

EFFECTIVE DATE: July 13, 1989.

FOR FURTHER INFORMATION CONTACT: Michael E. Diggs, Chief, Consolidated Supply and Procurement Branch, Public and Indian Housing, Department of Housing and Urban Development, Room 4134, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 472-4703. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The information collection requirements contained in this rule have been submitted to the Office of Management and Budget (OMB) for review under the Paperwork Reduction Act of 1980 and have been assigned OMB control number 2577-0091. Public reporting burden for each of these collections of information is estimated to include the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The information on the estimated public burden and its distribution by type of respondent, number of respondents, and average time to respond is available in this rule and contains the following information:

I. Background

HUD's regulations at 24 CFR Part 965, Subpart G govern the operation of the Consolidated Supply Program (CSP) consistent with the low-income character of projects as required under sections 6(a) and (9) of the United States Housing Act of 1937. The Department published a proposed rule on July 6, 1988 (53 FR 25346) to eliminate the purchase agreement portion of the Consolidated Supply Program (CSP), under which Public Housing Agencies (PHAs) and Indian Housing authorities (IHAs) purchase routine supply items with a value not in excess of the current Open-Market Purchase Limitation of $25,000. HUD received ten public comments in response to the proposed rule. Two of the comments confused the types of contracts available under the Consolidated Supply Program, and indicated that the commenters interpreted HUD's proposed rule change as more sweeping than it in fact was intended to be.

The two types of purchasing procedures available under the CSP consist of "Consolidated Supply Contracts" and "Purchase Agreements." Consolidated Supply Contracts are awarded on the basis of competitive bids submitted by suppliers to HUD in response to formal Invitations for Bids (IFBs). The general availability of each IFB is announced in the Commerce Business Daily (CBD). The Invitations for Bids are also directly mailed to interested suppliers. Contracts are awarded to the responsible bidders whose products meet HUD's specifications, and whose prices are at or below the average of all acceptable bid prices received for a particular item. There is no dollar limit on the amount of an individual PHA/IHA procurement action under a Consolidated Supply Contract. These contracts cover such items as refrigerators, ranges, doors, windows, bathroom and kitchen rehabilitations, floors, etc.

Purchase Agreements are negotiated agreements that are awarded on the basis of proposals submitted by contractors to HUD in response to a Request for Proposals. The general availability of each Request for Proposal is announced in the Commerce Business Daily.

The Purchase Agreement portion of the program differs from the CSP contracts in two important respects: HUD's solicitation of offers is not based on a technical specification, but rather on a description of a class of routine supplies (e.g., janitorial chemicals, wall protecting chemicals, graffiti removers, etc.); and, there is no price competition. Responding vendors provide copies of their published price lists and indicate any discount they will offer to PHAs and IHAs. HUD reviews this information and provides each vendor with a Purchase Agreement. These vendors may then market to the PHAs/IHAs by direct contact, or by mailing them their price lists or catalog.

The Purchase Agreement (PA) portion of the CSP was based on the theory that it would provide discounts for common, routine supplies not otherwise available to PHAs and IHAs. Because PAs are not awarded on the basis of price competition or HUD-sanctioned specifications, individual PHA/IHA purchases are limited to $25,000, or any lesser amount required by State law. As a further safeguard, HUD's CSP Handbook (7460.9) cautions PHAs/IHAs to ensure that the offered supplies meet their needs and recommends that they obtain competitive quotes for purchases above $1,000.

Some public commenters opposed the proposed rule because they believed the elimination of the Purchase Agreement program would limit the quantity buying power of small PHAs/IHAs (less than 500 units). It is apparent that many of these commenters confused the Purchase Agreement aspect of the Consolidated Supply Program with the Consolidated Supply Contract.

The elimination of the Purchase Agreement program will not limit the quantity buying power of small PHAs/IHAs. Purchase Agreements are not awarded on the basis of price competition or HUD-sanctioned specifications. Their elimination will not impair the ability of PHAs/IHAs to procure any replacement part or service available in the United States. Also, the existing group of vendors will continue to solicit a PHAs/IHA's business. By encouraging the participation of existing vendors and other vendors currently without purchase agreements, greater competition and lower prices may be available.

HUD emphasizes that the procurement of major supply items will remain in the Consolidated Supply Program, and that there will be continued availability of contracts and catalogs for refrigerators, ranges, windows, doors, etc. This rule will eliminate fourteen general maintenance products and services for which HUD currently does not enter into competitive agreements.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

Seventh Street, SW., Room 10276, Washington, DC 20410; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.
One commenter opposed the proposed rule, claiming that many small PHAs/IHAs do not have access to retail and wholesale outlets that have the extensive inventory needed to meet the needs of the PHAs’s and IHAs. Also, those small PHAs/IHAs do not have the expert knowledge to understand and implement HUD procurement policies. HUD recently issued regulations [24 CFR Part 85] which simplified PHA procurement requirements. The types of supplies currently covered by purchase agreements would be obtained by PHAs using small purchase procedures. These procedures are defined in 24 CFR 85.36(d)(1) as “... simple and informal procurement methods for securing services, supplies or other property that do not cost more than $25,000 in the aggregate.” Competition for such purchases is considered adequate if price or rate quotations are obtained from three sources. Normally, such quotes can be handled by telephone without the use of formal written solicitations. Additionally, HUD is in the process of training its Regional and Field Office staffs about procurement regulations. This information will be available to PHAs/IHAs.

HUD believes that PHAs/IHAs are able to administer their own small purchase programs without the involvement of the Federal government. Small PHAs/IHAs can call or visit hardware or plumbing supply houses in larger metropolitan areas. (Note: There are no plumbing supply houses currently included in the PA program.) Existing PA vendors are still available for price quotations and competition will be introduced when the PHAs/IHAs solicit other quotations using simplified small purchase procedures.

The Department, therefore, affirms its previous decision to remove the purchase agreement portion of the Consolidated Supply Program.

II. Other Matters

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations in 24 CFR Part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332. The Finding of No Significant Impact is available for public inspection during regular business hours in the Office of the General Counsel, Rules Docket Clerk, Room 10278, 451 Seventh Street, SW., Washington, DC 20410.

This rule would not constitute a "major rule" as that term is defined in section 1(b) of Executive Order 12291, issued by the President on February 17, 1981. Analysis of the proposed rule indicates that it would not (1) have an annual effect on the economy of $100 million or more; (2) cause a major increase in cost or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Under 5 U.S.C. 605(b), the Regulatory Flexibility Act, the Undersigned certifies that this rule does not have substantial direct effects on States or their political subdivisions or on the relationship or distribution of power among the various levels of government. The rule, which removes HUD’s involvement in the purchasing of supplies to develop, maintain, or repair buildings owned or leased by PHAs and IHAs, will have little, if any, impact on family formation, maintenance or general well-being.

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12611, Federalism, has determined that the final rule does not involve the preemption of State law by Federal statute or regulation, and does not have substantial direct effects on States or their political subdivisions or on the relationship or distribution of power among the various levels of government. The rule, which reduces HUD’s involvement in the purchasing of supplies to develop, maintain, or repair buildings owned or leased by PHAs and IHAs, will not have a significant impact on the States.

This rule was listed as item 1034 in the Department’s Semiannual Agenda of Regulations published on April 24, 1989 (54 FR 10768, 10744) under Executive Order 12291 and the Flexibility Act.

The information collection requirements contained in this final rule have been submitted to the OMB for review under section 3504(h) of the Paperwork Reduction Act of 1980. Section 965.605(a) of this final rule has been determined by the Department to contain a collection of information requirements. Information on these requirements is provided as follows:

<table>
<thead>
<tr>
<th>Description of information collection</th>
<th>Section of 24 CFR affected</th>
<th>No. of respondents</th>
<th>No. of responses per respondent</th>
<th>Total annual responses</th>
<th>Hours per response</th>
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<tr>
<td>Report on purchases (annual reporting)</td>
<td>965.605(a)</td>
<td>400</td>
<td>2.0</td>
<td>800</td>
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<td>1600</td>
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<tr>
<td>Report on purchases (annual recordkeeping)</td>
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<td>1600</td>
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<td>Total annual burden</td>
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</tbody>
</table>
List of Subjects in 24 CFR Part 965

Energy conservation; Loan programs; housing and community development; Public housing; Utilities.

Accordingly, the Department amends 24 CFR Part 965, Subpart G, as follows:

PART 965—PHA-OWNED OR LEASED PROJECTS—MAINTENANCE AND OPERATION

Subpart G—Consolidated Supply Program

1. The authority citation for Part 965 is revised to read as follows:

Authority: Secs. 2, 3, 6, 9, United States Housing Act of 1937 (42 U.S.C. 1437, 1437a, 1437d, 1437g); sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 5353(d)); Subpart H is also issued under the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. 4821-4846).

§ 965.602 Definitions

2. In § 965.602, paragraph (f) is removed and paragraph (g) and (h) are redesignated as paragraph (f) and (g), respectively.

§ 965.604 [Removed and Reserved]

3. Section 965.604 is removed and reserved.

§ 965.605 Reports.

4. Section 965.605(a) is revised to read as follows:

(a) Report on purchases. Within 90 days after the expiration of a CSC, the Contractor shall submit a report to the CSC Contracting Officer including the contract number and the total dollar volume of PHA/IHA purchases under the contract during the preceding fiscal year.


Thomas Sherman, Acting General, Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 89-12666 Filed 5-26-89; 8:45 am]

BILLING CODE 4210-33-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL—3567-6]

Prevention of Significant Deterioration, Delegation of Authority to the State of Nevada

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Final Rulemaking.

SUMMARY: The Regional Administrator for EPA Region 9, San Francisco, has amended the agreement delegating full authority to the State of Nevada to implement and enforce the Federal Prevention of Significant Deterioration (PSD) Program.

DATES: The effective date of the initial delegation was May 20, 1983. The effective date of the revised delegation is October 10, 1988.

ADDRESS: Nevada Department of Conservation and Natural Resources, 201 South Full Street, Carson City, Nevada 89710.

FOR FURTHER INFORMATION CONTACT: Robert Baker, New Source Section (A-3-1), Air Operations Branch, Air and Toxics Division, U.S. Environmental Protection Agency, 215 Fremont Street, San Francisco, California 94105, Telephone (415) 974-8209.

SUPPLEMENTARY INFORMATION: The Environmental Protection Agency has delegated under the provision which are found in 40 CFR 52.21(u), to the State of Nevada: (A) Authority over all sources in that State subject to review for the prevention of significant deterioration of air quality, pursuant to Part C, 160-169 of Title 1 of the Clean Air Act as amended August 7, 1977 and the requirements promulgated in the July 1, 1979 edition of 40 CFR 52.21 as amended August 7, 1980 under authority of sections 101, 110 and 160-169 of the Clean Air Act; and (B) authority to review, administer, and enforce throughout the State the PSD requirements imposed by the Clean Air Act sections 101, 110 and 160-169, and 40 CFR 52.21 as amended August 7, 1980.

Information on this delegation together with a copy of the delegation is provided below:

On August 12, 1982, the Director of the Nevada Department of Conservation and Natural Resources requested delegation of authority for PSD. Full delegation was granted on May 20, 1983. The delegation was amended on October 5, 1988, and the amended delegation became effective on October 10, 1988. The following letter and attached agreement represent the terms and conditions of the amended delegation.

Roland D. Westergard, Director.

Dear Mr. Westergard: I have enclosed a revised version of the EPA-Nevada DCNR-DEP Prevention of Significant Deterioration (PSD) delegation agreement which I have signed. As provided in the agreement, we will administer and enforce all provisions of the PSD delegation as contained in this revision effective today.

We look forward to a continuing close relationship with EPA in the control of air pollution.

Sincerely,

Daniel W. McGovern, Regional Administrator.

Enclosure.


Dear Mr. McGovern: Enclosed is the revised 9/15/88 version of the EPA-Nevada DCNR-DEP Prevention of Significant Deterioration (PSD) delegation agreement which I have signed. As provided in the agreement, we will administer and enforce all provisions of the PSD delegation as contained in this revision effective today.

We look forward to a continuing close relationship with EPA in the control of air pollution.

Sincerely,

Roland D. Westergard, Director.

Enclosure.

Amended Agreement for Delegation of Authority for the Regulations for Prevention of Significant Deterioration of Air Quality (40 CFR 52.21) Between USEPA and NDCNR-DEP

The undersigned, on behalf of the Nevada Department of Conservation and Natural Resources, Division of Environmental Protection (NDCNR-DEP) and the United States Environmental Protection Agency (USEPA), hereby agree to the delegation of authority for the administrative, technical and enforcement elements of the source review provisions of 40 CFR 52.21, Prevention of Significant Deterioration (PSD), as they may be amended and in accordance with the permit review requirements in 40 CFR Part 124, Subparts A and C, from the USEPA to the NDCNR-DEP, subject to the terms and conditions below. This delegation is enacted pursuant to 40 CFR 52.21 (u), Delegation of Authority.

1. General Delegation Conditions

A. Authority is delegated for all sources under the jurisdiction of NDCNR-DEP that are subject to review for PSD. This includes all source categories listed in 40 CFR 52.21 for each pollutant regulated by the Clean Air Act.

B. This delegation may be amended at any time by the formal written agreement of both the NDCNR-DEP and the USEPA, including amendments to add, change, or remove conditions or terms of this Agreement.
C. If the Regional Administrator determines that the State is not implementing or enforcing the PSD program in accordance with the terms and conditions of this delegation, the requirements of 40 CFR 52.21, 40 CFR Part 124, or the Clean Air Act, this delegation, after consultation with the NDCNR-DEP, may be revoked in whole or in part. Any such revocation shall be effective as of the date specified in a Notice of Revocation to the State. Nothing in this paragraph shall preclude USEPA from exercising its enforcement authority, as provided in paragraph V.B. below.

D. The permit appeal provisions of 40 CFR 124.19 shall apply to all appeals to the Administrator or permits issued by the NDCNR-DEP under this delegation. For purposes of implementing the federal permit appeal provisions under this delegation, if there is a public comment requesting a change in a draft preliminary determination or draft permit conditions, the final permit issued by NDCNR-DEP is required to contain statements which indicate that for Federal PSD purposes and in accordance with 40 CFR 124.15 and 124.19, (1) the effective date of the permit is 30 days after the final decision to issue, modify, revoke and reissue the permit; and (2) if an appeal is made to the Administrator, the effective date of the permit is suspended until such time as the appeal is resolved. The NDCNR-DEP shall inform USEPA (Region IX) in accordance with conditions of this delegation when there is public comment requesting a change in the preliminary determination or in a draft permit condition. Failure by NDCNR-DEP to comply with the terms of this paragraph shall render the subject permit invalid for Federal PSD purposes.

E. By this agreement, the NDCNR-DEP assumes authority for enforcement and permit modifications/amendment for EPA issued NSR/PSD permits.

F. This delegation of authority becomes effective upon the date that both parties have signed this Agreement.

II. Communications Between USEPA and NDCNR-DEP

The NDCNR-DEP and USEPA will use the following communication procedures:

A. The NDCNR-DEP will report to the USEPA on a quarterly basis the compliance status of the sources that have received a PSD permit from either the NDCNR-DEP or USEPA. The Compliance Data System (CDS) will be used for this purpose. Compliance determinations will be made with respect to the conditions established in the PSD permits.

B. The NDCNR-DEP will forward to USEPA, at the beginning of the public comment period, a summary of (1) the findings related to each PSD application and, (2) the justification for the NDCNR-DEP's preliminary determination. Should there be any comments or concerns about this pending PSD permit, USEPA will consider these comments and concerns to the NDCNR-DEP as soon as possible prior to the close of the public comment period.

C. The NDCNR-DEP will forward to USEPA copies of the final action on the PSD permit applications at the time of issuance, as well as copies of substantive public comments.

D. The NDCNR-DEP will send USEPA copies of preliminary determinations on PSD permit modifications and amendments. USEPA will provide comments to the NDCNR-DEP prior to the close of the public comment period.

E. The NDCNR-DEP will send to EPA a copy of all applicability determinations and justifications made that would involve PSD exemptions due to offsetting or netting (40 CFR 52.21(b)(3) and 52.21(b)(21)).

III. Revisions to Title 40 CFR 52.21

A. This delegation covers any revisions that are promulgated for 40 CFR 52.21 and 40 CFR Part 124. The terms “40 CFR 52.21” and “40 CFR Part 124” as used in the delegation request and throughout this Agreement, include such regulations as are in effect on the date this Agreement is executed and any revisions that are promulgated after that date.

B. The revisions that have been promulgated for 40 CFR 52.21 since the effective date (May 27, 1983) of the previous delegation agreement include the following:

1. Slack Height Regulations: 40 CFR 51.100(hh), 51.100(kk), 51.116(b).

2. Revised Modeling Guidelines: 40 CFR 52.21(1).

3. PM-10 Regulations: 40 CFR 52.21(2).

4. According to USEPA guidance published on June 26, 1987, all delegated agencies are required to look at certain control options when making BACT determinations for municipal waste combustors. Specifically, these agencies should consider a dry scrubber for sulfur dioxide control, a baghouse or electrostatic precipitator for particulate control, and efficient combustion techniques for carbon monoxide control in their BACT determinations for this type of source.

5. Additional BACT guidance issued on December 1, 1987, by USEPA, states that the Regional Office is to encourage the application of “top-down” BACT determinations in the Region. This means that USEPA will consider as deficient any BACT determination that does not begin with the most stringent control options available for that source category.

6. Upon notification from EPA, NDCNR-DEP will implement such new regulations or directives pending revision of this agreement.
IV. Permits

A. In any matter involving interpretation of sections 190-199 of the Clean Air Act, or 40 CFR 52.21, and of 40 CFR Part 124 where guidance on the implementation, review, administration, or enforcement of these Sections has not been sent to the NDCNR-DEP, USEPA will be contacted and requested to provide the appropriate guidance.

B. The NDCNR-DEP will at no time grant any waiver to the PSD permit requirements.

C. Permits issued under this delegation shall contain language stating that the Federal PSD requirements have been satisfied.

D. Authorities to Construct must include appropriate provisions, as specified in Attachment A, to ensure permit enforceability. Permit conditions shall, at a minimum, contain reporting requirements on initiation of construction, startup, and source testing (where applicable). Upset/breakdown and malfunction conditions shall be included in all permits.

V. Permit Enforcement

A. The primary responsibility for enforcement of the PSD regulations in the State of Nevada (except for Clark and Washoe Counties) will rest with the NDCNR-DEP. However, the State has enforcement authority over sources in Clark and Washoe which generate electricity using steam produced by the burning of fossil fuel. The NDCNR-DEP will enforce the provisions that pertain to the PSD program, except in those cases where the rules or policy of the NDCNR-DEP are more stringent. In such cases, the NDCNR-DEP may elect to implement the more stringent requirements.

B. Taking into consideration the terms of the USEPA-NDCNR-DEP Enforcement Agreement, nothing in this delegation agreement shall prohibit EPA from enforcing the PSD provisions of the Clean Air Act, the PSD regulations or any PSD permit issued by the NDCNR-DEP pursuant to this agreement.

C. In the event that the NDCNR-DEP is unwilling or unable to enforce a provision of this delegation with respect to a source subject to the PSD regulations, the NDCNR-DEP will immediately notify the Regional Administrator. Failure to notify the Regional Administrator does not preclude USEPA from exercising its enforcement authority.

Date: 10-10-88.
Roland D. Westergard,
Department of Conservation & Natural Resources-Division of Environmental Protection.

Date: 10-8-88.
Daniel W. McGovern,
U.S. Environmental Protection Agency.

Attachment A

1. Identification of all points of emission (both stack and fugitive).
2. Specification of a numerical emission limitation for each point of emission in terms of mass rate or concentration limitations. If emission testing based on a numerical emission limitation is feasible, the permit may instead prescribe a design, operational, or equipment standard. Any permit issued without numerical emission limitations must contain conditions which assure that the design characteristics or equipment will be properly maintained or that the operational conditions will be properly performed so as to continuously achieve the assumed degree of control.
3. Limitation of factors which were the basis for air quality impact analyses must be specified (e.g. hours of operation, stack height, materials processed which affect emissions).
4. Methods and frequency of determining continued compliance for each point of emission must be referenced (if part of the SIP or subject to NSPS or NESHAPS) or explicitly identified if a reference method is not used.
5. Record keeping requirements which enable the agency to ascertain continued compliance especially where factors such as hours of operation, throughput of materials, sulfur content of fuels, fuel usage, type or quantity of materials processed are conditions of the permit.
6. A condition that the permit will expire if the construction is not commenced within a certain specified time frame.
7. The condition that the source is responsible for providing sampling and testing facilities at its own expense.
8. Reporting requirements which enable the agency to monitor the progress of source construction and compliance including the date by which construction is completed, and if different from the completion of construction date, the date by which full compliance is to be achieved.
9. Permits issued under this delegation should contain language stating that the Federal PSD requirements have been satisfied.
10. As a courtesy to sources exempted from PSD review due to federally enforceable operational or process restrictions, or the use of controls more stringent than required by applicable SIP limits, the source should be advised that any relaxation of those limits may subject the entire source to full PSD review as if construction had not yet begun. Suggested language is as follows:

This source is exempt from PSD review because of (e.g. "a requirement that operation is limited to eight hours per day"). Any relaxation in this limit that increases your potential to emit above the applicable PSD threshold will require a full PSD review of the entire source.

The Regional Administrator finds good cause for foregoing prior public notice and for making this rulemaking effective immediately in that it is an administrative change and not one of substantive content. No additional substantive burdens are imposed on the parties affected. This delegation became effective on August 15, 1989; therefore, it serves no purpose to delay this technical revision, adding the State's address to the Code of Federal Regulations.

A copy of the request for delegation of authority is available for public inspection at the U.S. Environmental Protection Agency, Region 9 Office, Air and Toxics Division, Air Operations Branch, 215 Fremont Street, San Francisco, California 94105.

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Sulfur oxides, Nitrogen dioxide, Lead, Particulate matter, Carbon monoxide, Hydrocarbons, Intergovernmental relations.

Authority: 42 U.S.C. 7401-7501.
Date: May 16, 1989.
Daniel W. McGovern,
Regional Administrator.

[FR Doc. 89-12673 Filed 5-26-89; 8:45 am]
BILLING CODE 6560-50-M

40 CFR Part 52

[A-1-FRL-3576]

Approval and Promulgation of Air Quality Implementation Plans; Connecticut; Reasonably Available Control Technology for Two Pratt & Whitney Facilities.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving State Implementation Plan (SIP) revisions submitted by the State of Connecticut.
These revisions establish and require the use of reasonably available control technology (RACT) to control volatile organic compound (VOC) emissions from two Pratt & Whitney Division of United Technologies Corporation facilities in East Hartford and North Haven, Connecticut. The intended effect of this action is to approve two source-specific RACT determinations made by the State in accordance with commitments made in its 1982 Ozone Attainment Plan which was approved by EPA on March 21, 1984 (49 FR 10542). This action is being taken in accordance with section 110 of the Clean Air Act.

**Effective Date:** This action will become effective July 31, 1989 unless notice is received on or before June 29, 1989 that adverse or critical comments will be submitted. If the effective date is delayed, timely notice will be published in the Federal Register.

**Addresses:** Comments may be mailed to Louis F. Cito, Director, Air Management Division, U.S. Environmental Protection Agency, Region I, JFK Federal Building, Room 2133, Boston, MA 02203. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Management Division, U.S. Environmental Protection Agency, Region I, JFK Federal Building, Room 2133, Boston, MA 02203; and the Air Compliance Unit, Department of Environmental Protection, State Office Building, 165 Capitol Avenue, Hartford, CT 06106.

**For Further Information Contact:** David B. Conroy, (617) 565-3252; FTS 835-3252.

**Supplementary Information:** On April 7, 1989, the State of Connecticut submitted formal revisions to its state implementation plan (SIP). The revisions consist of State Order No. 8014 issued by the Connecticut Department of Environmental Protection (DEP) to Pratt & Whitney Division of United Technologies Corporation in East Hartford, Connecticut, and State Order No. 8027 issued to Pratt & Whitney Division of United Technologies Corporation in North Haven, Connecticut. These State Orders were issued to these facilities to control volatile organic compound (VOC) emissions from these facilities’ VOC-emitting processes. The revisions of State Order No. 8014 and 8027 constitute reasonably available control technology (RACT) for these facilities as required by subsection 22a-174-20(ee). "Reasonably Available Control Technology for Large Sources," of Connecticut’s Regulations for the Abatement of Air Pollution. Under subsection 22a-174-20(ee), the Connecticut DEP determines and imposes RACT on all stationary sources with the potential to emit one hundred tons per year or more of VOC that are not already subject to RACT under Connecticut’s regulations developed pursuant to the control techniques guidelines (CTG) documents. EPA approved this regulation on March 21, 1984 (49 FR 10542) as part of Connecticut’s 1982 Ozone Attainment Plan. That approval was granted with the agreement that all source-specific RACT determinations made by the DEP would be submitted to EPA as source-specific SIP revisions.

**Summary of RACT Determination**

Pratt & Whitney in East Hartford operates 33 open-top vapor degreasers that were in use prior to July 1, 1980. Pratt & Whitney in North Haven operates 29 open-top vapor degreasers that were in use prior to July 1, 1980. The control of solvent metal cleaning operations in Connecticut is covered under subsection 22a-174-20[l], "Metal cleaning," of Connecticut’s regulations. Final approval of this regulation was granted by EPA on February 1, 1984 (49 FR 39988). Under subparagraph 22a-174-20[l][2)(ii) of Connecticut’s solvent metal cleaning regulation, however, open top vapor degreasers and convectored degreasers that were in operation prior to July 1, 1980 are exempt from the control and operating requirements prescribed in subsection 22a-174-20[l]. Therefore, all of the open-top vapor degreasers at both Pratt & Whitney facilities were in operation prior to July 1, 1980. These open-top vapor degreasers are now being required to meet RACT pursuant to subsection 22a-174-20(ee).

Pratt & Whitney in East Hartford has converted 29 of its 33 existing (pre-July 1, 1980) open-top vapor degreasers from perchloroethylene, a VOC, to 1,1,1 trichloroethane which is one of the organic compounds which EPA has designated as having negligible photochemical reactivity. It is not considered a VOC under the definition of VOC in Connecticut’s SIP. As such, State Order No. 8014 is not requiring any control requirements on these 31 open-top vapor degreasers. State Order No. 8027 does, however, contain requirements for the 28 open-top vapor degreasers in case Pratt & Whitney ever converts any of them back to using a VOC. State Order No. 8014 requires Pratt & Whitney to meet the control requirements of subsection 22a-174-20(l) of Connecticut’s regulations and some additional requirements in paragraph 7 of the State Order for any vapor degreaser that it converts back to a VOC on the day it starts production using the VOC.

Similarly, Pratt & Whitney in North Haven has converted 19 of its 29 existing open-top vapor degreasers from perchloroethylene to 1,1,1 trichloroethane. As such, State Order No. 8027 is also not requiring any control requirements on these 19 open-top vapor degreasers. State Order No. 8027 does, however, also contain requirements for the 19 open-top vapor degreasers in case Pratt & Whitney ever converts any of them back to using a VOC. State Order No. 8027 requires Pratt & Whitney to meet the control requirements of subsection 22a-174-20[l] of Connecticut’s regulations and some additional requirements in paragraph 7 of the State Order for any vapor degreaser that it converts back to a VOC on the day it starts production using the VOC.

The remaining open-top vapor degreasers at the Pratt and Whitney facilities (4 at the East Hartford facility and 10 at the North Haven facility) continue to use VOC solvents. As RACT for these units, the State Orders are requiring these units to meet the requirements in subsection 22a-174-20[l] of Connecticut’s regulations which requires these units to meet the state implementation plan (SIP) revisions. (Connecticut’s solvent metal cleaning regulation) as well as other additional requirements contained in the State Order which increase the stringency of the control requirements imposed on these degreasing units.

In addition to each facility’s degreasing operations, each facility has hand dipping operations which use VOC to clean metal or fiberglass parts outside the confines of any degreaser. As RACT for these operations, the State Orders are requiring that all dispensing containers be equipped with a cover and be closed when not in use, all dirty rags and all rags that have previously been used be stored in covered containers, and no rags be visibly dripping during use.

In addition, each facility operates solvent recovery stills. As RACT for these operations, the State Orders are requiring that Pratt and Whitney cease operation of any solvent recovery still whenever the condenser coil outlet water temperature exceeds 100°F. This is the temperature above which the solvent recovery still is achieving less than the minimum required ninety-five percent solvent recovery rate. The condenser coil outlet water temperature
on each solvent recovery is required to be monitored with an alarm which will be triggered should the condenser coil outlet water temperature exceed 100 °F. Furthermore, Pratt and Whitney is required to store all waste VOC, before being recovered in the solvent recovery stills or before being sent out as a waste product, in closed containers which prevent the evaporation of VOC to the atmosphere.

Additionally, each State Order requires Pratt & Whitney to maintain a recordkeeping system of all adds to each vapor degreaser using VOC at each facility. Further, Pratt & Whitney is required to maintain a recordkeeping system of all waste VOC that is generated from these vapor degreasers. With this information, Pratt & Whitney is required to calculate VOC emissions from its degreasing operations from each facility on a quarterly basis. Pratt & Whitney's East Hartford and North Haven facilities.

EPA has reviewed State Order No. 8014 and State Order No. 8027 and has determined that the level of control required by these Orders represents RACT for Pratt & Whitney's East Hartford and North Haven facilities.

EPA is approving these SIP revisions without prior proposal because the Agency views these as noncontroversial amendments and anticipates no adverse comments. This action will be effective 60 days from the date of this Federal Register notice unless, within 30 days of its publication, notice is received that adverse or critical comments will be submitted. If such notice is received, this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. If no such comments are received, the public is advised that this action will be effective on July 31, 1989.

Final Action

EPA is approving Connecticut State Order No. 8014 and State Order No. 8027 as revisions to the Connecticut SIP. The provisions of State Order No. 8014 and State Order No. 8027 define and impose RACT on Pratt & Whitney's facilities in East Hartford and North Haven, respectively, as required by subsection 22a-174-20[ee] of Connecticut's regulations.

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291.

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 July 31, 1989. 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

Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements.

Note: Incorporation by reference of the State Implementation Plan for the State of Connecticut was approved by the Director of the Federal Register on July 1, 1982.

Date: May 15, 1989.

Michael R. Doland, Regional Administrator, Region I.

Subpart H, Part 52 of Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—(AMENDED)

Subpart H—Connecticut

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

Authority: 42 U.S.C. 7401-7662.

2. Section 52.370 is amended by adding paragraph (c)(50) to read as follows:

§ 52.370 Identification of plan.

* * *

(c) * * *

(50) Revisions to the State Implementation Plan submitted by the Connecticut Department of Environmental Protection (DEP) on April 7, 1989.

(i) Incorporation by reference (A) Letter from the Connecticut DEP dated April 7, 1989 submitting a revision to the Connecticut State Implementation Plan.

(B) State Order No. 8014 and attached Compliance Timetable for Pratt & Whitney Division of United Technologies Corporation in East Hartford, Connecticut. State Order No. 8014 was effective on March 22, 1989.

(C) State Order No. 8027 and attached Compliance Timetable for Pratt & Whitney Division of United Technologies Corporation in North Haven, Connecticut. State Order No. 8027 was effective on March 31, 1989.

(ii) Additional materials

(A) Technical Support Document prepared by the Connecticut DEP providing a complete description of the reasonably available control technology determination imposed on Pratt and Whitney's East Hartford facility.

(B) Technical Support Document prepared by the Connecticut DEP providing a complete description of the reasonably available control technology determination imposed on Pratt and Whitney's North Haven facility.

[FR Doc. 89-12672 Filed 5-26-89; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 52

[FRL-3558-4]

Approval and Promulgation of State Implementation Plans; Colorado

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This notice approves a revision to the Colorado Springs Carbon Monoxide (CO) State Implementation Plan (SIP) for Colorado Springs submitted on June 15, 1988, by the Governor of Colorado. The revision includes the Clean Air Campaign (CAC), a voluntary no-drive program, into the SIP, which EPA is approving as helpful for attainment. The revision contains a new attainment demonstration, but it was developed prior to the May 26, 1988, CO SIP Call for Colorado Springs. This action does not address the issues raised in that SIP Call. Likewise, EPA is not acting on the attainment demonstration.

DATES: This action will be effective on July 31, 1989 unless notice is received by June 29, 1989 that someone wishes to submit adverse or critical comments. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Copies of the revision are available for public inspection between 8:00 a.m. and 4:00 p.m., Monday through Friday at the following offices:

Environmental Protection Agency, Region VIII, Air Programs Branch, 18th Street, Suite 500, Denver, Colorado 80202-2405, and Environmental Protection Agency, Public Information Reference Unit, Waterside Mall, 401 M Street, SW, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Dale M. Wells, Air Programs Branch, Environmental Protection Agency, One Denver Place, Suite 500, 999 18th Street, Suite 500, Denver, Colorado 80202-2405, (303) 294-1773, (PTS) 564-1773.

SUPPLEMENTARY INFORMATION: On June 15, 1988, the Governor of Colorado submitted a CO SIP revision for Colorado Springs. The SIP included the CAC measure, as well as an attainment demonstration. The submittal did not
If such notice is received, this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. If no such comments are received, the public is advised that this action will be effective July 31, 1989.

Final Action

EPA hereby approves a revision to the Colorado CO SIP for Colorado Springs to include the Clean Air Campaign as part of the SIP. This action, however, does not include approval of the attainment demonstration, nor does it give emission credit reduction of the CAC measure. The State must submit a SIP revision to comply with the May 26, 1988, SIP Call.

EPA finds that good cause exists for making the action taken in this notice immediately effective because the implementation plan revisions are already in effect under State law or regulation. EPA's approval poses no additional regulatory burden.

Under 5 U.S.C. 605(b), I certify that this SIP revision will not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709.)

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 July 31, 1989. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

The Office of Management and Budget has exempted this rule from the regulatory review process because the rule involves a waiver of a State or local requirement.

List of Subjects in 40 CFR Part 52

Air pollution control, Particulate matter, Sulfur oxides, Incorporation by reference.

Note: Incorporation by reference of the State Implementation Plan for the State of Colorado was approved by the Director of the Federal Register on July 1, 1982.


William K. Reilly,
Administrator

Part 52 Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

Subpart G—Colorado

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

Authority: 42 U.S.C. 7401-7642.

§ 52.320 [Amended]
2. Section 52.320 is amended by adding paragraph (c)(43) to read as follows:

(c) Identification of plant.

(43) On June 15, 1988, the Governor submitted revisions to the CO SIP for Colorado Springs. The revisions contain a new measure, the Clean Air Campaign. EPA considers all other aspects of the submittal to be surplus.

(i) Incorporation by reference


Summary: This Notice announces the Administrator's approval of a revision to the Maryland State Implementation Plan that amends Code of Maryland Air Regulation (COMAR) 10.18.21.10 (Graphic Arts) and COMAR 10.18.21.13 (Miscellaneous Metal Coating, Interior Sheet Drum Lining). COMAR 10.18.21 has been modified to remove a "grandfather" provision adopted several years ago for graphics arts sources that allowed the use of a condensing precipitator as an acceptable control method. This provision will be eliminated because the equipment is old, needs continuous maintenance and observation, and does not control certain types of hydrocarbons that are now designated as volatile organic compounds (VOC's).

The reform on COMAR 10.18.21.13 establishes an interim and a final coating standard for interior drum liners for reclaimed steel drums and new steel drums and pails. The suggested standards are consistent with EPA's Control Technology Guideline's (CTG) for miscellaneous coating, but provide an interim limit until complying coatings are developed for all applications.
EFFECTIVE DATE: This action will become effective on July 31, 1989 unless notice is received by June 29, 1989 that someone wishes to submit adverse or critical comments. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Written comments on this action should be addressed to David Arnold, Chief, Programs Planning Section, at the EPA Regional Office address listed below. Copies of the documents relevant to this action are available for public inspection during normal business hours at:

U.S. Environmental Protection Agency, Region III, Air Programs Branch, 841 Chestnut Building, Philadelphia, PA 19107.

Maryland Air Management Administration, Department of the Environment, 201 W. Preston Street, Baltimore, MD. Attn: George Ferreri.

Public Information Reference Unit, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Ms. Ivette Y. Alamo-Tirado at (215) 597-6863, at the EPA Region III address above. The commercial and FTS numbers are the same.

SUPPLEMENTARY INFORMATION: On June 30, 1987, the State of Maryland submitted Revision 87-01 to the Maryland State Implementation Plan. The submittal concerned regulations for controlling VOCs in the Baltimore Air Quality Control Region (AQCR) and the Maryland portion of the National Capital Interstate AQCR. The submittal was in the form of amendments to Regulation .01 (Definitions) under COMAR 10.18.01 (General Administrative Provisions), Regulation .06 (Volatile Organic Compounds) under COMAR 10.18.06 (General Emission Standards, Prohibitions and Restrictions), Regulation .02 (Applicability and Exemptions) and .04 (Loading Operations in Area III and IV) under COMAR 10.18.13 (Control of Gasoline, and other Volatile Organic Compound Storage and Handling), Regulations .01 (Definitions), .02 (Applicability, Determining Compliance, and Reporting), .10 (Graphic Arts), and .13 (Miscellaneous Metal Coating) under COMAR 10.18.21 (Control of Volatile Organic Compounds from Specific Processes) and the repeal of Regulation .03 (Automotive and Light-Duty Truck Coating and Associated Component Supplies Industries) and adoption of new Regulations .03 and .15 (Paint, Resin and Cessive Manufacturing and Adhesive Application) under COMAR 10.18.21. The amendment to Regulation .01 under COMAR 10.18.21 (Control of Volatile Organic Compounds from Specific Processes) and the definition of a VOC in Regulation .01 under COMAR 10.18.1 (General Administrative Provisions) were withdrawn by the State on August 4, 1987, and June 17, 1987, respectively. The amendments to Regulation .10 and .13 under COMAR 10.18.21 will be the only amendments addressed in this Notice. The remaining amendments will be addressed in separate notices.

COMAR 10.18.21.10 B(1) has been modified to remove a “grandfather” provision adopted several years ago for web printing installations. This provision allowed those installations to use a hot-air high velocity dryer and condensing electrostatic precipitator (ESP), which were installed before January 1, 1979, as an acceptable VOC control. This provision is being deleted because: the equipment (ESP) is at the end of its useful life, (greater than 10 years) needs intensive maintenance by operating personnel and continuous observation by the Air Management Administration, does not regulate alcohol emissions which are VOCs and is in operation in an ozone non-attainment area.

The Air Management Administration amended COMAR 10.18.21.13, establishing an interim and a final coating standard for any epoxy phenolic, or phenolic coating used to line the interior of reclaimed steel drums and new steel drums and pails. Two drum reclaimers and one new drum manufacturer were affected by this change.

The change will set an interim limit of 4.6 pounds of VOC per gallon of coating minus water until July 1, 1987, and a final coating standard of 4.3 pounds of VOC per gallon of coating minus water. This final regulation is consistent with EPA’s Control Technology Guideline which indicates that the maximum VOC content acceptable for miscellaneous metal coating of steel drum interior lining would be equivalent to the clear coating standard of 4.3 pounds of VOC per gallon. The State of Maryland has agreed to revise their definition of VOC in order to bring it into conformance with EPA’s definition of VOC. The revised definition that Maryland is expected to submit will mirror EPA’s current definition of VOC as contained in 40 CFR Part 60.2. In accordance with section 110(a)(2) and section 110(a)(3) of the Clean Air Act, EPA must approve portions of a State’s Implementation Plan, even if not all requirements are met, as long as the partial approval will contribute to the attainment of the ozone standard. Therefore, EPA is proposing to approve COMAR 10.18.21.13 on the basis that it contributes to the attainment of the ozone standard. Therefore, EPA is proposing to approve COMAR 10.18.21.13 on the basis that it contributes to the attainment of the ozone standard.

The implementation of these amendments will not have an adverse economic impact on the State or local agencies.

This revision to the Maryland SIP was adopted by the Secretary of the Department of the Environment on June 10, 1987, in accordance with the requirements of 40 CFR Part 51, Requirements for Preparation, Adoption, and Submittal of Implementation Plans. As required by 40 CFR Part 51.40, the State of Maryland has certified that, after adequate public notice, a public hearing with respect to this SIP revision was held on September 30, 1988.

Final Action

EPA is approving these amendments to COMAR 10.18.21.10 (Graphic Arts) and COMAR 10.18.21.13 (Miscellaneous Metal Coating). This approval is based on a determination that the revision meets the requirements of section 110(a)(2) of the Clean Air Act and 40 CFR Part 51. Requirements for Preparation, Adoption, and Submittal of Implementation Plans.

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial revision and anticipates no adverse comments. This action will be effective 60 days from the date of this Federal Register Notice unless, within 30 days of its publication, notice is received that adverse or critical comments will be submitted. If such notice is received, this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action and the other will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. If no such comments are received, the public is advised that this action will be effective on July 31, 1989.

The Office of Management and Budget has exempted this rule from the requirements of section three of Executive Order 12291.

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 July 31, 1989. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

Under 5 U.S.C. section 505(b), I certify that this SIP revision will not have a significant economic impact on a
substantial number of small entities (see 40 FR 8709).

List of Subjects in 40 CFR Part 2


Note: Incorporation by reference of the State Implementation Plan for the State of Maryland was approved by the Director of the Federal Register on July 1, 1982.

Date: February 2, 1989.

John A. Moore,
Acting Administrator.

Identification of Document

Part 52 of Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

Subpart V—Maryland

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401-7642.

2. Section 52.1070 is amended by adding paragraph (c)(86) to read as follows:

§ 52.1070 Identification of plan.

(c) * * *

(86) Revisions submitted on March 1, 1989 by the Secretary, Maryland Department of the Environment, incorporating the Code of Maryland Air Regulations (COMAR) 10.18.21.10 (Graphic Arts) and COMAR 10.18.21.13 (Miscellaneous Metal Coating, Interior Sheet Drum Lining).

(ii) Incorporation by reference.

(A) Revisions to COMAR 10.18.21.10, pertaining to graphic arts, and COMAR 10.18.21.13, pertaining to miscellaneous metal coating, interior sheet drum lining. These revisions were adopted by the Secretary of Health and Mental Hygiene on June 10, 1987 and became effective on August 10, 1987.

(iii) Additional information.

(A) Letter of June 30, 1987 from George P. Ferreri, Director, Maryland Air Management Administration, to Thomas J. Maslany, EPA Region III, forwarding revisions to COMAR 10.18.21.10 and COMAR 10.18.21.13.

(B) Letter of March 13, 1989 from George P. Ferreri, Director, Maryland Air Management Administration to Stanley L. Laskowski, Acting Regional Administrator, EPA Region III, clarifying information with respect to the adopted and effective dates of the revisions to COMAR 10.18.21.10 and COMAR 10.18.21.13.

[FR Doc. 89-12185 Filed 5-26-89; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 52

[A-1-FRL-3576-6]

Approval and Promulgation of State Air Quality Implementation Plans for Designated Facilities and Pollutants; Maine; Plan for Controlling Sulfuric Acid Mist Emissions From Existing Sulfuric Acid Production Plants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This notice approves Maine's 111(d) plan for the control of sulfuric acid mist (H2SO4) from existing sulfuric acid production plants. The plan was submitted by the Maine Department of Environmental Protection (DEP) on November 10, 1988. The plan consists of a license issued to Delta Chemical in Searsport, Maine. (Delta Chemical is the only existing sulfuric acid production plant in the State of Maine.) The plan satisfies EPA's requirements for adoption and submittal of a plan to control H2SO4 from designated facilities in accordance with section 111(d) of the Clean Air Act.

EFFECTIVE DATE: This action will become effective July 31, 1989 unless notice is received on or before June 29, 1989 that adverse or critical comments will be submitted. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESS: Written comments on this action should be addressed to Louis F. Gitto, Director of the Air Management Division. (See address below.) Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Management Division, U.S. Environmental Protection Agency, Region I JFJK Federal Building, Room 2313, Boston, MA 02203 and the Bureau of Air Quality Control, Department of Environmental Protection, 71 Hospital Street, Augusta, ME 04330.

FOR FURTHER INFORMATION CONTACT: David B. Conroy, (617) 565-3252; FTS 835-3252.

SUPPLEMENTARY INFORMATION: On November 10, 1988, the Maine DEP submitted the State's plan for controlling sulfuric acid mist emissions from existing sulfuric acid production plants. The only existing sulfuric acid production facility in the State of Maine is Delta Chemical in Searsport, Maine. (New sulfuric acid production plants would be subject to 40 CFR Part 60, Subpart H and the Maine’s State Implementation Plan’s permitting regulations for the construction and operation of new and modified sources.) Delta Chemical operates two sulfuric acid production plants. One plant, designated No. 1, has a rated capacity of 70 tons per day of sulfuric acid. The other plant, designated No. 2, has a rated capacity of 100 tons per day of sulfuric acid.

The plan consists of a license issued to Delta Chemical in Searsport, Maine. The State issued the license on February 28, 1979 after conducting a public hearing on February 23, 1979. The plan also contains the most recent license issued to Delta Chemical on April 21, 1988. EPA has reviewed the plan and developed an evaluation report which is based on the requirements of section 111(d) of the Clean Air Act of 1977, as amended; 40 CFR Part 60, Subparts B and C; and an EPA guideline document entitled “Final Guidance Document: Control of Sulfuric Acid Mist Emissions From Existing Sulfuric Acid Production Units.” This evaluation report is available for inspection during normal business hours at the EPA Regional Office listed in the Addresses section of this notice.

The plan meets all of EPA's criteria for approval. The emission limits imposed in the license are the same as the limits prescribed in 40 CFR Part 60. Subpart C for such facilities pursuant to section 111(d) of the Clean Air Act. The Maine DEP has required Delta Chemical to test each of its production units annually, and the company has demonstrated that it is in compliance with the license that is being referenced as the 111(d) plan by this rulemaking.

EPA is approving this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. This action will be effective 60 days from the date of this Federal Register notice unless, within 30 days of its publication, notice is received that adverse or critical comments will be submitted. If such notice is received, this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. If no such comments are received, the public is advised that this action will be effective on July 31, 1989.
Final Action

EPA is approving Maine’s 111(d) plan for the control of sulfuric acid mist from existing plants because the State’s emission limits are the same as the applicable limits of 40 CFR Part 60, Subpart C.

Under 5 U.S.C. 805(b), I certify that this action will not have a significant economic impact on a substantial number of small entities. (See 46 FR 6709).

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291.

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 July 31, 1989. 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 62

Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfuric acid plants, Sulfuric oxides.


Michael R. Deland,
Regional Administrator, Region I.

Title 40 of the Code of Federal Regulations, Chapter I, Part 62, Subpart U is amended as follows:

PART 62—AMENDED

1. The authority citation for Part 62 continues to read as follows:

Authority: 42 U.S.C. 7401-7642.

2. Subpart U is amended by adding an undesignated centerheading Sulfuric Acid Mist From Existing Sulfuric Acid Plants and §62.4900 to read as follows:

Subpart U—Maine

Plan for the Control of Designated Pollutants From Existing Facilities (Section 111(d) Plan)

§62.4845 Identification of plan.

(a) Identification of plan: Maine Plan for the Control of Designated Pollutants From Existing Plants (Section 111(d) Plan).

(b) The plan was officially submitted as follows:

(1) Control of sulfuric acid mist emissions from existing sulfuric acid production units, submitted on November 10, 1988.

(c) Designated facilities: The plan applies to existing facilities in the following categories of sources:

(1) Sulfuric acid plants.

3. Subpart U is further amended by adding an undesignated centerheading §62.4900 and §62.4900 to read as follows:

Sulfuric Acid Mist From Existing Sulfuric Acid Plants

§62.4900 Identification of sources.

The plan applies to the following existing sulfuric acid plants:

(a) Delta Chemical in Searsport, Maine.

§62.4950 [Redesignated from §62.4850]

4. The centerheading “Fluoride Emissions From Phosphate Fertilizer Plants” and §62.4950 are redesignated as “Fluoride Emissions From Phosphate Fertilizer Plants” and §62.4950, respectively.

BILLING CODE 6560-50-M

40 CFR Part 180

[PP 6F3377/R1023; FRL-3577-6]

Isomate-M (Pheromone Dispensers); Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption for an insecticide from the requirement of a tolerance for residues of the insect pheromone isomate-M (pheromone dispensers) containing the active ingredients Z-8-dodecen-1-yl acetate, E-8-dodecen-1-yl acetate, Z-8-dodecen-1-ol in or on raw agricultural commodities (RACs) nectarines, peaches, and macadamia nuts. This rule amends 40 CFR Part 180 to include nectarines, peaches, and macadamia nuts. This exemption is for an oriental fruit moth pheromone which acts to control the oriental fruit moth by mating disruption. The pheromone is a synthetic replica of the naturally occurring pheromone. This pheromone product is impregnated in a 6-inch flexible polyethylene tube which has an aluminum wire that runs along the length of the tube to allow the tube to be tied to the lateral branches of the fruit trees. The pheromone permeates the surrounding area giving off an olfactory stimulus which disrupts the mating pattern of the oriental fruit moth and diminishes its ability to reproduce, by reportedly causing a false trail in the orchard air so as to interrupt the reproductive cycle. Isomate-M is selective for the oriental fruit moth. It appears to have no influence on other insects, which means that beneficial insects, such as those that prey on mites, are not affected.

The recommended application rates are:

Four (4) dispensers/tree in standard orchard spacing or 400 dispensers/acre, or 1000 dispensers/hectare. Normally two applications per season will suffice; the first application should be prior to the emergence of the moths (in late February), and the second application should be 90 days later, preferably in late May.

The data submitted in the petition and other relevant material have been evaluated. The toxicology data performed with the active ingredient, considered in support of the exemption from the requirements of a tolerance included: an acute oral LD₅₀, rat, with no observed effect level (NOEL) = >20 mg/kg; acute dermal LD₅₀, rat, NOEL = >3000 mg/kg; primary
time for comments is being limited to 15 days in order that the exemption from the requirements of a tolerance can be established in a timely manner.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator had determined that regulations establishing new tolerances or raising tolerance levels, or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950). Effective on: May 30, 1989.

Section 180.1073 Isomate-M; exemption from the requirement of a tolerance.

The oriental fruit moth pheromone (Isomate-M, Z-8-dodecen-1-yl acetate, E-8-dodecen-1-yl acetate, Z-8-dodecen-1-ol) is exempt from the requirement of a tolerance in or on all the raw agricultural commodities (food and feed) including peaches, nectarines, and macadamia nuts when used in orchards with encapsulated polyethylene tubing to control oriental fruit moth.

[FR Doc. 89-12791 Filed 5-26-89; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency.
the community is required to either adopt or show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program. These modified elevations, together with the floodplain management measures required by 60.3 of the program regulations, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State or regional entities.

These modified base flood elevations shall be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for second layer coverage on existing buildings and their contents. These changes in the base flood elevations are in accordance with 44 CFR 65.4. Pursuant to the provisions of 5 U.S.C. 605(b), the Administrator, to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. This rule provides routine legal notice of technical amendments made to designated special flood hazard areas on the basis of updated information and imposes no new requirements or regulations on participating communities.

List of Subjects in 44 CFR Part 65
Flood insurance, Floodplains.

The authority citation for Part 65 continues to read as follows:
§ 65.4 (Amended)
Section 65.4 is amended by adding in alphabetical sequence new entries to the table.

| Florida: Manatee (Docket No. FEMA-6941) | Unincorporated areas | Dec. 9, 1988 and Dec. 18, 1988 Bradenton Herald | The Honorable Kent G. Chetelat, Chairman, Board of County Commissioners, Manatee County, P.O. Box 1000, Bradenton, Florida 33086 | Nov. 29, 1988 | 120173 |
| Tennessee: Shelby (Docket No. FEMA-6941) | City of Germantown | Dec. 22, 1988 and Dec. 29, 1988, Germantown News | The Honorable Warner Hodges III, Mayor, City of Germantown, 196 South Germantown Road, P.O. Box 38809, Germantown, Tennessee 38138-0809 | Dec. 12, 1988 | 470063 |


DEPARTMENT OF TRANSPORTATION
Research and Special Programs Administration
49 CFR Part 107
[Docket No. 640; Amdt. No. 107-19]
Settlements and Compromises of Civil Penalty and Compliance Order Cases
AGENCY: Research and Special Programs Administration (RSPA), DOT.
ACTION: Final rule.
SUMMARY: RSPA is amending its procedural rules for civil penalty and compliance order cases under the Hazardous Materials Transportation Act (HMTA), 49 App. U.S.C. 1801 et seq., to facilitate expeditious compromises and settlements of such enforcement cases. Under this rule, parties may compromise or settle any of those enforcement cases without the approval of an administrative law judge (ALJ) even when the case is pending before an ALJ.

EFFECTIVE DATE: These regulations are effective May 30, 1989. The good cause authority has been delegated by the Chief Counsel of RSPA and the respondent without order of the ALJ to compromise or settle the case, under 49 CFR 107.327, without order of the ALJ. In addition, this amendment specifically authorizes the voluntary dismissal of a case by the Chief Counsel of RSPA and the respondent without order of the ALJ pursuant to Rule 41(a)(1) of the Federal Rules of Civil Procedure (FRCP). Section 107.321 makes the FRCP generally applicable in these cases. In the event of such a compromise, settlement or voluntary dismissal of a case pending before an ALJ, the Chief Counsel expeditiously will notify the ALJ before whom the case is pending of such compromise, settlement or voluntary dismissal. Finally, this amendment specifically authorizes a respondent to withdraw, in writing, a request for a formal administrative hearing. Such a withdrawal constitutes an irrevocable waiver of respondent's right to such a hearing on the facts, allegations, and proposed sanction presented in the notice of probable violation to which the request for hearing relates.

These changes are intended to expedite and facilitate compromise and settlement of HMTA enforcement cases by specifically authorizing the parties to those cases to compromise or settle
them without involvement of, or approval by, an ALJ. Because these amendments are procedural in nature, no prior notice of proposed rulemaking (NPRM) is required under 5 U.S.C. 553.

Administrative Notices

RSPA has determined that this final rule (1) is not "major" under Executive Order 12291; (2) is not "significant" under DOT's regulatory policies and procedures (44 FR 11034); (3) will not affect not-for-profit enterprises, or small governmental jurisdictions; and (4) does not require an environmental impact statement under the National Environmental Policy Act (40 U.S.C. 4321 et seq.). A final regulatory evaluation was not prepared as these amendments are not substantive changes. I certify that these amendments will not, as promulgated, have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. I have reviewed this regulation in accordance with Executive Order 12612 ("Federalism"). It has no substantial direct effects on the States, on the Federal-State relationship or on the distribution of power and responsibilities among levels of government. Thus, this regulation contains no policies that have Federalism implications as defined in Executive Order 12612.

List of Subjects in 49 CFR Part 107

Administrative practice and procedure.

In consideration of the foregoing, 49 CFR Part 107 is amended as follows:

PART 107—HAZARDOUS MATERIALS PROGRAM PROCEDURES

1. The authority citation for Part 107 is revised to read as follows:


2. In §107.319, the last sentence in paragraph (c) is revised and a new paragraph (d) is added to read as follows:

§107.319 Request for a hearing.

(c) * * * * Upon assignment of an ALJ, further matters in the proceeding generally are conducted by and through the ALJ, except that the Chief Counsel and respondent may compromise or settle the case under §107.327 of this subpart without order of the ALJ or voluntarily dismiss the case under Rule 41(a)(1) of the Federal Rules of Civil Procedure without order of the ALJ; in the event of such a compromise, settlement or dismissal, the Chief Counsel expeditiously will notify the ALJ thereof.

(d) At any time after requesting a formal administrative hearing but prior to the issuance of a decision and final order by the ALJ, the respondent may withdraw such request in writing, thereby terminating the jurisdiction of the ALJ in the case. Such a withdrawal constitutes an irrevocable waiver of respondent's right to such a hearing on the facts, allegations, and proposed sanction presented in the notice of probable violation to which the request for hearing relates.

National Highway Traffic Safety Administration

49 CFR Part 531

[Docket No. FE-88-01; Notice 5]

RIN No. 2127-AB73

Passenger Automobile Average Fuel Economy Standards, Model Year 1989

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Denial of petition for reconsideration.

SUMMARY: On September 30, 1988, NHTSA issued a final rule setting the passenger automobile average fuel economy standard for model year 1989 at 26.5 miles per gallon (mpg). The standard represented an increase of 0.5 mpg over the 1988 level, and a decrease of 1.0 mpg from the statutory level of 27.5 mpg. The Center for Auto Safety and Public Citizen jointly submitted a petition requesting the agency to reconsider its decision to lower the statutory standard. This notice denies the petition.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: Title V of the Motor Vehicle Information and Cost Savings Act specifies a CAFE standard of 27.5 mpg for each model year after 1994. (Title V was added to that Act by the Energy Policy and Conservation Act.) However, the Act permits NHTSA to regulate the statutory standard to a level determined to be the "maximum feasible average fuel economy level." 15 U.S.C. 2022(a)(4). In determining the "maximum feasible average fuel economy level," the agency is required to consider the following four factors: technological feasibility, economic practicability, the effect of other Federal motor vehicle standards on fuel economy, and the need of the nation to conserve energy.

NHTSA commenced the rulemaking proceeding regarding the model year (MY) 1989 standard on August 25, 1988 with the issuance of a notice proposing to reduce the standards for MY's 1989-90 from the statutory level of 27.5 mpg to some level from 26.5 mpg to 27.5 mpg (53 FR 33080, August 29, 1988).

On September 30, 1988, NHTSA issued a final rule (53 FR 39275, October 6, 1988) setting the MY 1989 corporate average fuel economy (CAFE) standard for passenger cars at 26.5 mpg. While this level represented a lowering of the statutory standard, it also represented a first step in returning to the statutory level of 27.5 mpg. NHTSA noted that its raising of the standard from the MY 1986-88 level of 26.0 mpg was thus consistent with the fact that the nation's conservation needs were greater then than they had been in 1985, when the agency first set the standard at 26.0 mpg.

On November 7, 1988, the Center for Auto Safety (CFAS) and Public Citizen (PC) jointly submitted a petition requesting the agency to reconsider its decision to lower the statutory standard. The petitioners alleged that NHTSA erred in reducing the standard for a number of reasons, including "(1) erroneously finding that Congress' energy conservation goals have been met, (2) finding General Motors maximum feasible fuel economy as 26.5 mpg when it is at least 27.5 mpg, (3) falsing (sic) blaming General Motors' declining sales on CAFE standards, (4) misconstruing the Energy Policy and Conservation Act (EPCA) and its requirement that manufacturers split their fleet into domestic and foreign, and (5) erroneously finding CAFE standards will result in foreign companies selling more large cars."

The petitioners’ arguments regarding the reduction of the MY 1989 standard are addressed below. The agency notes that in MY 1990 the standard will return to the statutory level of 27.5 mpg. See NHTSA's notice terminating its rulemaking regarding the proposed reduction of the MY 1989 standard (54 FR 21285, May 22, 1989).
NHTSA relied, in large measure, on the continuing increase in imports of foreign petroleum in taking this action.

Energy Conservation Goals

CFAS/PC's first contention is that "NHTSA incorrectly stated that Congress' energy conservation goals have been met since 1988 overall CAFE was 28.7 mpg." The petitioners argued that Congress intended energy conservation to be maximized by setting CAFE standards higher than 27.5 mpg if feasible. CFAS/PC also argued that even the statutory 27.5 mpg has not been met in actual use because actual on-road CAFE is at least 15 percent below that calculated under the statute. Finally, citing legislative history, the petitioners asserted that, at the time EPICA was adopted, Congress' express purpose was to improve actual on-road new car fuel efficiency over 1974 levels by 100% to 27.5 mpg by 1985 and reduce U.S. oil consumption by 3 million barrels per day (MMB/D) by 1985. CFAS/PC contended that the actual savings in 1985 when new car CAFE averaged 27.6 mpg was 1 MMB/D less than that, and that even the 1987 vehicle fleet with a CAFE of 28.3 mpg still missed Congress' 3 MMB/D goal and consumed 2.35 MMB/D less gasoline than what it would have if the fleet had the same fuel economy as in 1975.

NHTSA believes its statements that Congress' statutory goal of reaching an average fuel economy of 27.5 mpg for new cars has been met and exceeded are correct, given that MY 1988 industrywide CAFE is 28.7 mpg. In setting the 27.5 mpg goal, Congress included a requirement that CAFE be measured according to "the procedures utilized by the EPA Administrator for model year 1975 (55 percent urban cycle, and 45 percent highway cycle), or procedures which yield comparable results." 18 U.S.C. 2003(c). The agency's statements that Congress' statutory goal has been met and exceeded were made in the context of that "measuring stick." Use of that measuring stick in gauging progress is common. NHTSA has previously noted that the 27.5 mpg goal is roughly twice the MY 1974 CAFE. Even Clarence M. Ditlow, Executive Director of CFAS, stated in the 1989 edition of The Car Book that "Federal gas mileage standards are one of the most successful government sticks in gauging progress, with 1989 cars getting more than twice the fuel economy of 1974 cars." Thus, in at least one context, one of the petitioners apparently embraced the use of that measuring stick.

NHTSA notes that the primary purpose of its statements was to draw attention to two points: (1) The significant progress that has been made in improving automotive fuel efficiency since 1975, and (2) the fact that GM's and Ford's achieving the 27.5 mpg statutory standard are partly an artifact of the "two fleet rule." As discussed below, the two fleet rule prevents GM and Ford from including their smallest, most fuel-efficient cars in their domestic CAFE (since those cars are largely imports). The country of origin of a car, however, has no effect on its contribution to energy conservation.

NHTSA notes that the point made in the MY 1989 decision that Congress' statutory goal of reaching an average fuel economy of 27.5 mpg for new cars has been met and exceeded should not be confused with a belief that energy conservation is no longer important. That decision expressly recognized that there is a continuing need to conserve energy. 53 FR 39227. In addition, contrary to the implication of the CFAS/PC petition, the decision to reduce the MY 1989 standard was not based on the point that Congress, 1975 energy conservation goals have been met. Even if there is more than one reasonable interpretation concerning how those goals should be quantified, this is not an issue that was material to the agency's MY 1989 decision.

GM's MY 1989 CAFE Capability

CFAS/PC's second contention is that NHTSA erred in finding that General Motors' CAFE capability was 26.5 mpg instead of at least 27.6 mpg, the level that company achieved in MY 1988. The petitioners made several arguments in support of this position.

First, CFAS/PC argued that NHTSA relied on a net CAFE reduction of 0.5 mpg for use of airbags and daytime running lights. According to the petitioners, however, GM is not offering daytime running lights on any MY 1989 models, and the market penetration of optional airbags is not projected to reach the 33 percent level that would trigger inclusion of an option in fuel economy ratings. According to the petitioners, however, GM is not offering daytime running lights on any MY 1989 models, and the market penetration of optional airbags is not projected to reach the 33 percent level that would trigger inclusion of an option in fuel economy ratings. (See 40 CFR Part 86.) The petitioners also argued that even if actual sales of an option unexpectedly exceed 33 percent, there is no adjustment to CAFE for that model year.

Second, CFAS/PC argued that NHTSA erroneously lowered GM's fuel economy capability by at least 0.3 mpg on the grounds that GM has been wrong about CAFE projections by this magnitude in the past. The petitioners stated that NHTSA should only look at those years where GM was requesting a CAFE relaxation to "avoid letting GM stack the deck by submitting arbitrarily low estimates." In addressing the petitioners' arguments concerning GM's MY 1989 fuel economy capability, it is again helpful to review the agency's presentation of the issue in the MY 1989 preamble. A portion of that discussion follows (53 FR 39289-90):

NHTSA has analyzed GM's MY 1989 CAFE projection and underlying plan. As discussed above, GM indicated in its September 1988 comment that its current product plan is expected to result in a MY 1989 CAFE level of 27.2 mpg. If NHTSA focused narrowly on GM's MY 1989 CAFE projection and its MY 1988 CAFE achievement, it would presumably conclude that GM's MY 1989 capability is above that of Ford. While manufacturer product plans are subject to risks, GM's 27.2 mpg projection reflects that company's best estimate of its MY 1989 CAFE in light of its current product plan. As discussed above, however, NHTSA believes that too narrow a focus on GM's MY 1988 CAFE achievement and MY 1989 CAFE projection could have the effect of ratifying the significant loss in market share that company has experienced over the past several years and the significant job losses that accompanied that market loss. The agency believes that its analysis of GM's capability should also consider the CAFE level that company might achieve if it more aggressively seeks to regain, in MY 1989, a portion of its lost market share. As indicated above, GM's current product plan reflects the constraints of a 27.5 mpg standard, and the agency does not believe that it reflects the kinds of actions GM might wish to take to restore market share and jobs if there were a lower MY 1989 CAFE standard.

NHTSA recognizes that it is difficult to estimate what GM's CAFE capability would be under a scenario of seeking to regain lost market share and jobs. Ford's recent CAFE
experience suggests that a full line manufacturer can achieve approximately 26.5 mpg while remaining fully competitive in all market segments. The agency has analyzed GM's product plan and concluded that efforts by that company to increase its market share in less fuel-efficient market segments could, consistent with its capacity restraints, result in a MY 1989 CAFE of 26.5 mpg or below. These efforts could include pricing and other actions to promote sales of compact, intermediate and luxury cars. In light of Ford's experience and NHTSA's analysis of the kinds of actions GM might take to restore lost market share and jobs, the agency concludes that 26.5 mpg appropriately represents GM's MY 1989 CAFE capability."

NHTSA believes that in order for GM to be able to adequately compete in today's intensely competitive market, it must be able to accommodate consumer demand for such attributes as larger engines and larger interior space. These actions come at a CAFE price; however, since they generally reduce the fuel efficiency of a model, to the extent that GM is able to so accommodate consumer demand or otherwise increase the sales of its less fuel-efficient vehicles, including less fuel-efficient compacts as well as larger vehicles, its CAFE will decline, relative to what it achieved in MY 1988. This decline is in addition to that portion of the decline that reflects unexpectedly high EPA test results in MY 1988.

NHTSA believes that several points should be made concerning the petitioners' arguments about GM's MY 1989 CAFE capability. First, the petitioners are incorrect in asserting that the agency lowered GM's CAFE capability by 0.5 mpg due to airbags and daytime running lights and another 0.3 mpg on the grounds that GM has been wrong about CAFE projections by this magnitude in the past. The Final Regulatory Impact Analysis's (FRIA) discussion of GM's MY 1989 CAFE capability did cite possible increased use of daytime running lights and airbags, as well as the uncertainty associated with GM's MY 1989 CAFE projection, including past forecasting errors by that company. However, the FRIA also listed other factors that could result in GM achieving a MY 1989 CAFE below its 27.2 mpg projection, including greater sales of large cars and higher performance compact cars as part of an effort to regain lost market share. Following this discussion, the FRIA noted that "[i]f GM realizes even a portion of the CAFE penalty the agency postulates for increased performance of compact cars or more large cars sales as described above, voluntarily adopts half its safety improvements described above, and realizes its historic CAFE prediction error by overestimating its CAFE, its CAFE could actually be below 26.5 mpg." FRIA, p. V-101. The FRIA then stated that "[r]ecognizing that the actual product and market decisions of GM are likely to differ from the illustrative examples given above, and that the effect on fuel economy may likewise differ from the agency's example, the agency believes its analysis is nevertheless reasonable, given historical inaccuracies in projecting CAFE, the current dictates of consumer demand, and the agency's policy not to have CAFE standards adversely affect safety." NHTSA thus did not determine GM's MY 1989 CAFE capability by means of a formula that ascribed specific values to the factors cited by the petitioners. The agency also notes that the two factors cited by the petitioners were not even included in the preamble's discussion of GM's capability. (Elsewhere in the preamble, however, the agency noted the potential CAFE impact of airbags and daytime running lights and expressed concern that overly stringent CAFE standards might discourage manufacturers from these and other voluntary safety actions. See 33 FR 39296. Also, the agency has long recognized the uncertainties associated with manufacturer CAFE projections.)

On the issue of uncertainties associated with manufacturer CAFE projections, the FRIA included an analysis of GM's pre-model-year reports. Like other manufacturers, GM is required to submit the pre-model-year report during December, and include, among other information, the company's projected CAFE, vehicle configuration, base level and model type. These data are submitted to the agency some months into the model year in question. The FRIA's analysis showed that, over a 10-year period, GM missed its estimated CAFE projection by an average of more than 0.3 mpg. Sometimes GM underestimated its CAFE, and other times underestimated its CAFE. The basic point is that, given the broad range of product offerings sold by GM and the many factors affecting the sales of its different models, that company is unable to predict its exact CAFE even at the time of the pre-model-year report. The petitioners argued that NHTSA "should only look at those years where GM was requesting a CAFE relaxation to avoid letting GM stack the deck by submitting arbitrarily low estimates," or "[a]t the very least ... average the differences rather than use the absolute value." The petitioners also stated that NHTSA should "incorporate the differences for 1987 and 1988 where GM underestimated its CAFE by 0.4 and 0.7 mpg respectively." NHTSA notes that there is no basis to support the petitioners' suggestion that GM may have submitted arbitrarily low CAFE estimates in support of its request for a lower CAFE standard. In addition, the agency did not merely accept GM's CAFE projections but instead analyzed a great deal of supporting data, including GM's detailed product plan and analyses provided by that company concerning how its plan differed from prior model years and why it had exceeded its CAFE estimates for prior model years. Since the purpose of the FRIA's analysis of GM's pre-model-year reports was to show the uncertainties associated with CAFE projections, the agency sees no basis to adopt the petitioners' suggestion to average the differences rather than use the absolute value. The issue is not whether, over a long period, the differences tend to average out but instead to recognize the inherent uncertainty associated with any CAFE projection for a particular model year. With respect to the petitioners' suggestion that NHTSA include the differences for 1987 and 1988, the agency notes that the two differences cited by CAFE/PC in fact illustrate the uncertainties associated with CAFE projections. GM exceeded the particular CAFE projections cited by the petitioners. However, NHTSA has always recognized that the uncertainties associated with CAFE projections go in both directions.

NHTSA believes that the preamble's discussion of GM's capability is clear and adequate. The agency noted the difficulty in estimating what GM's CAFE capability would be under a scenario of seeking to regain lost market share and jobs, recognized that Ford's CAFE experience suggests that a full line manufacturer can achieve approximately 26.5 mpg while remaining fully competitive in all market segments and that efforts by GM to restore its market share in less-fuel-efficient market segments could, consistent with its capacity restraints, result in a MY 1989 CAFE of 26.5 mpg or below, and concluded that 26.5 mpg appropriately represents GM's MY 1989 CAFE capability.

NHTSA disagrees with the petitioners' argument that the agency did not adequately assess improving fuel economy by use of multi-valve engines. The FRIA discusses multi-valve engines in its section on technology (at p. IV-12). The agency notes that this technology is one of several means of achieving more efficient fluid flow and combustion in an engine and that the improvement that can be obtained from this technology is also included in Table IV-2 of the FRIA under the more general listings of reduced friction, mechanical and pumping losses.
GM's 4-valve-per-cylinder engine, the "Quad 4," is already providing fuel economy gains in the Pontiac Grand Am, Oldsmobile Cutlass Calais, and Buick Skyhawk. The agency notes that this engine reflects a number of technology improvements in addition to multi-valve technology. The Quad 4 was introduced in MY 1988, and GM noted in an earlier proceeding that it provides a major advance in fuel economy. With the exception of the MY 1989 Ford Taurus SHO, a lower volume premium performance-oriented car, and the high-performance, low-volume Corvette ZK-1, the Quad 4 is the only 4-valve engine offered in domestic cars.

The use of the Quad 4 was, of course, reflected in GM's MY 1989 product plan and considered by NHTSA in its evaluation of GM's capability. The Quad 4 was discussed in several places in the agency's FRIA. With respect to whether GM could make greater use of multi-valve engines instead of 6- or 8-cylinder engines during MY 1989, the agency notes that leadtime constraints prevent use of the Quad 4 in any models beyond those already included in GM's plans. For the three models where the Quad 4 is offered, the vast majority of the cars already use either the Quad 4 or a less expensive [base] 4 cylinder engine. While GM also offers a 6 cylinder option or turbo 4 cylinder option for these cars, the volumes for these options are sufficiently small that there would be little CAFE impact even if those engines could be replaced by the Quad 4.

NHTSA believes that the Quad 4 represents a significant fuel economy accomplishment for GM and considers its development and use to be part of the reasonable efforts made by that company to achieve the statutory 27.5 mpg standard. The agency recognizes that the introduction of a major new engine involves significant risks, especially if it incorporates new technologies, and that a manufacturer typically needs to ensure its acceptability at low volumes and with a small number of models prior to expanding its use. Accordingly, the agency does not believe that further use of this engine or technology for MY 1989, beyond what GM currently plans, should be expected as part of an assessment of GM's "reasonable efforts." (A complete discussion of the "reasonable efforts" test was provided in the MY 1988 preamble. 53 FR 32084-36. 39320-39.)

With respect to whether a portion of the decline in GM's projected CAFE for MY 1989, as compared to MY 1988, appropriately reflected uncertainty in EPA testing, CFAS/PC asserted that comparison of the 1988 and 1989 EPA test car lists do not show fuel economy reductions for the same vehicle which can be attributed to EPA testing variation. NHTSA notes that in comparison of the two test car lists shows that of the domestic GM cars that carried over from MY 1988 to MY 1989 with the same specifications, 17 tests showed lower fuel economy, 16 showed higher fuel economy, and 6 were unchanged. The value of such an exercise is limited, however, since the impact on CAFE depends on the relative production volume of each configuration. NHTSA notes that it considered this issue during the MY 1989 proceeding (see FRIA, pp. V-88 to V-89) and does not believe that further evaluation of this issue is warranted at this time.

GM's Loss in Market Share

CFAS/PC's third contention is that NHTSA erroneously concluded that GM's CAFE of 27.6 mpg in MY 1988 caused it to lose sales. The petitioners asserted that GM's lower sales in recent years including MY 1988 are due not to CAFE but instead "to well known GM mistakes including poor quality, failure to differentiate its models in the marketplace, [and] poor styling compared to its competitors." The petitioners are incorrect in asserting that NHTSA concluded that GM's high domestic CAFE of 27.6 mpg in MY 1988 caused company to lose domestic sales. The agency did recognize that GM's achievement of 27.6 mpg in MY 1988 "can be traced in part to its smaller share of the large car market." 53 FR 39277. In making this point, the agency stated the following:

While the market share loss may have occurred for a variety of reasons, the results were nonetheless dramatic. The decline in market share led both to a high CAFE last year and to the laying off thousands of workers, estimated by GM to be a loss of 75,000 workers in the past three years.

NHTSA also recognized that it is likely that GM plant closings and the other GM product decisions over the past few years are due in part to overcapacity in the auto industry generally and in part to the market converging on the medium, 'compact' car." 53 FR 39278. The agency emphasized, however, that "the larger car market, while shrinking, is not disappearing. NHTSA notes that a and it is clear from Ford's experience that the CAFE of a company that serves that segment will be lower than if the company does not serve that market." 53 FR 39278

With respect to GM's MY 1989 CAFE capability, the key point is that efforts by that company to regain a portion of its lost market share would come at a CAFE price. This is particularly true given current consumer demand for larger engines (in cars of all sizes), and since part of the market share lost by GM is in the larger car market, a market segment where that company is traditionally very competitive but which is inherently less fuel-efficient than other market segments. As NHTSA concluded in the MY 1989 proceeding, "[t]he extent that GM is able to so accommodate consumer demand or otherwise increase the sales of its less fuel-efficient vehicles, including less fuel-efficient compacts as well as larger vehicles, its CAFE will decline, relative to what it achieved in MY 1988." 53 FR 39290 (emphasis added).

Impact of the Two Fleet Rule

CFAS/PC's fourth contention is that NHTSA was incorrect in concluding that EPCA's requirement that manufacturers separate their fleets into two categories—domestic and not domestically manufactured (i.e., imported)—creates a threat to American jobs. The petitioners asserted that Congress established the two fleet rule to protect domestic jobs and that it does just that if NHTSA does not relax CAFE standards. CFAS/PC stated that Congress amended the CAFE law in 1980, at a time well after Japanese imports began capturing a larger market share and started to upscale in the vehicles they were producing, and that "surely" Congress would have amended this provision if it were costing U.S. jobs. The petitioners also asserted that UAW President Owen Bieber "pointed out . . .[that] relaxing CAFE standards costs jobs as it permits the domestic manufacturers to build small cars abroad rather than produce them in the U.S."

NHTSA believes that this issue was fully addressed in the MY 1989 preamble and will not repeat all of that discussion. With respect to Mr. Bieber's comments, the agency notes that while he did state that "[t]he lowering of the standards should not provide the companies with an incentive to outsource smaller vehicles," he also urged the agency "to consider both the implications of not lowering the standards and of lowering the standards." (Emphasis his.) Mr. Bieber recognized that the manufacturers have said that one option for meeting the standards would be to outsource large vehicles, and expressed concern that "we are faced with the threat of outsourcing large cars and the good paying jobs the manufacture of such
vehicles provides for American workers with no improvements in overall fuel economy or environmental benefits.”

NHTSA acknowledges, of course, that the purpose of the two fleet rule was to attempt to prevent the fuel economy program from directly encouraging the importation of small, fuel-efficient, foreign-produced cars. In 1975, when CPCA was passed, the domestic manufacturers were already importing some fuel-efficient cars, and Congress was concerned that the manufacturers might decide to meet fuel economy standards largely by increasing such imports.

NHTSA does not agree, however, that the two fleet rule is currently meeting its intended purpose. Today, the domestic manufacturers are importing substantial numbers of smaller, fuel-efficient cars for reasons unrelated to CAFE. The introduction of low-priced, entry-level cars from countries with low costs has precluded the domestic manufacturers from competing in this segment of the market with domestically produced cars. These low-priced models are produced in such countries as Korea, Mexico, Brazil and Yugoslavia. This competition has affected import manufacturers as well as domestic manufacturers.

Western European manufacturers have not competed in the American entry-level market for several years, and Japanese manufacturers are now beginning to lose market share to Korean cars. For example, Mitsubishi is now importing a Korean-produced Hyundai as its lowest priced Mitsubishi Precis.

Since the domestic manufacturers will necessarily continue to import small, fuel-efficient cars in order to remain in that segment of the market, notwithstanding the two fleet rule, the current primary effect of the rule is to create an incentive for the domestic manufacturers to transfer the production of their larger, less fuel-efficient cars to production facilities outside of the United States, in order to meet CAFE standards. This action would result in a higher domestic CAFE value for these manufacturers, making it easier for them to meet CAFE standards, and would not create a compliance problem for the manufacturers’ import fleets since the larger, less fuel-efficient cars would be averaged in with the small, more fuel-efficient cars being imported for competitive reasons. Ford commented in the MY 1988 proceeding, for example, that it could improve its domestic CAFE by 0.6 mpg by sourcing sufficient LTD Crown Victoria and Mercury Grand Marquis components outside the United States to transfer these vehicles into its import CAFE fleet. While such outsourcing would increase the manufacturers’ domestic CAFE values, it would reduce the number of American jobs while having no effect on energy conservation.

With respect to the petitioners’ suggestion that Congress would “surely” have amended this provision in 1980 if it were costing U.S. jobs, NHTSA observes that the inability of the domestic manufacturers to compete in the entry level small car market with domestically produced cars has primarily occurred after 1980. For example, GM produced the fuel-efficient Chevette from 1975 to 1987. As discussed in the MY 1989 preamble, GM stated at NHTSA’s September 14, 1988 public hearing that the Chevette was not redesigned because GM could no longer compete in that market. GM emphasized that its inability to compete in that market is the reason it is working on Saturn at this point in time, and that it has increased its import fleet from zero in 1984 to over 300,000 in 1986 to maintain a presence in that market until it can get Saturn on the street.

Competitive Impacts

CFAS/PC’s fifth contention is that NHTSA erroneously concluded that CAFE standards will result in foreign companies selling more large cars. The petitioners argued that the CAFE standards do not give foreign companies an unfair advantage and that the upscale mid-size and luxury cars being sold by foreign manufacturers are priced above comparable domestic cars and compete on the basis of quality.

NHTSA addressed the issue of competitiveness at considerable length in the MY 1989 preamble and will not repeat all of that discussion. A portion of the agency’s presentation follows (53 FR 38276):

...(T)he fleet averaging requirement... was originally intended to ensure that manufacturers could continue to offer consumers a wide choice of makes and models, because compliance with the standard would be measured on a fleet average basis. In other words, a manufacturer could continue to offer models that achieved fuel economy levels below the standard, as long as it sold a sufficient number of models that exceeded the standard. While intended as a means to preserve consumer choice, the provision gives a real advantage to Asian and some European manufacturers that generally have not been manufacturing large, family-size or luxury vehicles. The setting of the standards largely based on the capabilities of the major domestic manufacturers results in standards that are well below the capabilities of these foreign manufacturers, giving them substantial latitude in designing and introducing new models to take advantage of changing consumer preferences. While the full-line U.S. manufacturers must struggle to adjust their fleet mixes to meet the standard on a fleet average basis, these other companies are manufacturing fleets that are automatically more fuel efficient by virtue of their sales mix, but not by virtue of any inherent fuel efficiency superiority of their individual models. Thus, they need not be concerned with the adverse CAFE effects of their new, higher performing, less fuel-efficient models that the market now demands. And, as discussed below, they are actively entering the larger and luxury car markets in the U.S., poses a real competitive threat to the U.S. manufacturers in this segment.

NHTSA believes that it is obvious that CAFE standards result in uneven impacts on different manufacturers, depending on the market segments they serve. Since the Japanese and other Asian manufacturers have traditionally specialized in smaller cars and, as a practical matter, are not affected by the two fleet rule, they can freely introduce new, higher performance large or luxury models without fear of CAFE noncompliance. Since GM and Ford have traditionally been full-line manufacturers, and cannot average together their most fuel-efficient cars (which are imports) with their larger cars, they have lower (domestic) CAFE values than the Japanese and other Asian manufacturers. Thus, overly stringent CAFE standards could make it difficult or impossible for GM and Ford to adequately compete with the new, higher performance large or luxury Japanese models, since such standards could constrain the domestic manufacturers from selling competitive models.

Conclusion

After carefully considering the arguments raised by CFAS/PC, NHTSA has decided to deny their petition for reconsideration. None of the arguments lead the agency to believe that, on the basis of the record before the agency at the time, it should have declined to exercise its discretion to reduce the MY 1989 passenger car standard, or that the standard should have been set a level other than 28.5 mpg.


Issued on May 23, 1989.

Jeffrey R. Miller,
Acting Administrator.

[FR Doc. 89-12712 Filed 5-24-89; 9:54 am]

BILLING CODE 4910-59-M
Federal Motor Vehicle Safety Standards, Hydraulic Brake Systems

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Final rule.

SUMMARY: Standard No. 105, Hydraulic Brake Systems, requires a vehicle to have one or more brake system indicator lamps, to warn its driver about certain types of brake failure and to indicate application of the parking brake. Section S5.3.2 of the standard requires that the brake system indicator lamps be activated automatically either when the ignition switch is turned to the "on" position or to a position between "on" and "start," to check whether the lamp bulbs are burned out. This notice amends the standard to provide that the activation as a check of lamp function is not required when a starter interlock is in operation.

DATES: The amendments made by this rule are effective June 29, 1989. Petitions for reconsideration must be received by June 29, 1989.

SUPPLEMENTARY INFORMATION: Standard No. 105, Hydraulic Brake Systems, requires vehicles to have one or more brake system indicator lamps, to provide a warning to drivers about certain types of brake failure and to indicate application of the parking brake. Section S5.3.2 of the standard requires that the brake system indicator lamps be activated automatically either when the ignition switch is turned to the "on" position or to a position between "on" and "start," to check whether the lamp bulbs are burned out. This notice amends the standard to provide that the activation as a check of lamp function is not required when a starter interlock is in operation.

On August 18, 1988, NHTSA published in the Federal Register (53 FR 31379) a notice of proposed rulemaking (NPRM) to amend Standard No. 105 to provide that activation as a check of lamp function not be provided under any condition in which a vehicle cannot be started due to operation of an interlock switch. The proposal represented an extension of an existing provision. For many years, section S5.3.2 has provided that activation as a check of lamp function is not required for automatic transmission vehicles when the transmission shift lever is in a forward or reverse drive position. In the NPRM, the agency explained the rationale for the existing provision as follows: "Since the purpose of section S5.3.2 of Standard No. 105 was to provide an automatic check of lamp function each time the vehicle was started, it was unnecessary to require the check function in situations where the vehicle could not be started. Section No. 102, Transmission Shift Lever Sequence, Starter Interlock, and Transmission Braking Effect, requires for vehicles equipped with automatic transmissions that the engine starter be inoperative when the transmission shift lever is in a forward or reverse drive position. Since vehicles equipped with automatic transmissions could not be started when the transmission shift lever is in a forward or reverse drive position, it was unnecessary to require the check function when the transmission shift lever is in either of those positions. S5 FR 31380.

As discussed in the NPRM, Mazda submitted a petition for rulemaking requesting an amendment of section S5.3.2's provision limiting the conditions under which the lamp check function must be provided. That company stated that the provision, which applied only to automatic transmission vehicles, should also apply to manual transmission vehicles which are equipped with a clutch pedal interlock switch. Mazda stated that this type of interlock switch prevents the engine from starting unless the clutch pedal is fully depressed, and is analogous to the starter interlock required by Standard No. 105 for automatic transmission vehicles.

Mazda also asserted that overall cost effectiveness, and to a lesser degree, safety, would be enhanced by its requested amendment. According to the petitioner, the amendment would enable manufacturers to employ a single wiring harness for the brake system indicator lamp circuit for vehicles equipped with both manual and automatic transmissions. That company stated that it currently designs, produces and installs two separate brake system indicator lamp wiring harnesses, one for manual transmission vehicles and the other for automatic transmission vehicles, which results in unnecessary additional costs. Mazda also stated that its requested amendment would provide an incentive for manufacturers to provide clutch pedal starter interlock switches for vehicles not so currently equipped. That company stated that unexpected motion of the vehicle during engine activation would be reduced as the clutch pedal would be depressed more often in a wider variety of vehicles prior to engine activation.

In the NPRM, NHTSA stated that it agreed with the petitioner that, for purposes of section S5.3.2's provision limiting the conditions under which the lamp check function must be provided, a clutch pedal interlock switch for manual transmission vehicles is analogous to the starter interlock required by Standard No. 102 for automatic transmission vehicles. Since the purpose of section S5.3.2 of Standard No. 105 is to provide an automatic check of lamp function each time the vehicle is started, the agency tentatively concluded that it was unnecessary to require the check function under any condition where a vehicle cannot be started due to operation of an interlock switch. The agency therefore granted Mazda's petition and proposed to amend Standard No. 105 accordingly. NHTSA stated that it believed that the proposed amendment would increase manufacturer flexibility without any adverse impact on safety.

NHTSA received comments on the NPRM from General Motors, Ford, Chrysler, Volkswagen and the Motor Vehicle Manufacturers Association. All of them supported the proposal. Volkswagen also suggested that Standard No. 105 be amended so that the activation of the brake indicator lamp when the parking brake is applied satisfies the check of lamp requirement. NHTSA notes that the amendment suggested by that commenter is not within the scope of this particular rulemaking. However, the agency has proposed a requirement along those lines in its rulemaking to establish an internationally harmonized passenger car brake standard. See 52 FR 1474, 1483, January 14, 1987. NHTSA will continue to handle the issue raised by Volkswagen in the context of that rulemaking.

Based on the reasons discussed above and in the NPRM, and on its consideration of the comments, NHTSA is adopting the proposed amendment as a final rule. Since the amendment imposes no new requirements but instead increases manufacturer flexibility by relieving a restriction, NHTSA has determined that an effective date of 30 days after publication in the Federal Register is in the public interest.

The agency has analyzed this amendment and determined that it is
neither "major" within the meaning of Executive Order 12291 nor "significant" within the meaning of the Department of Transportation regulatory policies and procedures. The agency has determined that the economic effects of this amendment are so minimal that a full regulatory evaluation is not required. Since the amendment imposes no new requirements but simply permits additional flexibility in the design of the wiring harnesses for brake system indicator lamps, any cost impacts will be in the nature of small, nonquantifiable cost savings.

In accordance with the Regulatory Flexibility Act, NHTSA has evaluated the effects of this action on small entities. Based upon this evaluation, I certify that the amendment will not have a significant economic impact on a substantial number of small entities. Small businesses, small organizations, and small governmental units are affected by the amendment only to the extent that they purchase motor vehicles. For the reasons discussed above, the amendments will not significantly affect vehicle price. Accordingly, no regulatory flexibility analysis has been prepared.

The agency has also analyzed this rule for the purposes of the National Environmental Policy Act, and determined that it will not have any significant impact on the quality of the human environment.

Finally, this rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12291, and it has been determined that the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles, Rubber and rubber products, Tires.

PART 571—[AMENDED]

In consideration of the foregoing, 49 CFR Part 571 is amended as follows:

1. The authority citation for Part 571 continues to read as follows:


§ 571.105 [Amended]

2. SS.3.2 of § 571.105 is revised to read as follows:

SS.3.2 [a] Except as provided in paragraph (b) of this section, all indicator lamps shall be activated as a check of lamp function either when the ignition (start) switch is turned to the "on" (run) position when the engine is not running, or when the ignition (start) switch is in a position between "on" (run) and "start" that is designated by the manufacturer as a check position. (b) The indicator lamps need not be activated when a starter interlock is in operation.

Issued on May 24, 1989.

Jeffrey R. Miller,
Acting Administrator.
[FR Doc. 89-12796 Filed 5-26-89; 8:45 am]
BILLING CODE 4910-59-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Addition of the Chinese River Dolphin to the List of Endangered and Threatened Wildlife

AGENCY: Fish and Wildlife Service.

Interior.

ACTION: Final rule.

SUMMARY: The Service is adding the Chinese River Dolphin to the List of Endangered and Threatened Wildlife. This measure, required by section 4(a)(2)(A) of the Endangered Species Act, corresponds with a determination of endangered status by the National Marine Fisheries Service, which has jurisdiction of the Chinese river dolphin pursuant to the Act.

DATES: The effective date of this rule is June 29, 1989.

ADDRESS: Questions regarding the Service's role in this matter may be addressed to the Division of Endangered Species and Habitat Conservation, U.S. Fish and Wildlife Service, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: William E. Knapp (202) 358-2161.

SUPPLEMENTARY INFORMATION: Pursuant to the Endangered Species Act of 1973, as amended, and in accordance with Reorganization Plan Number Four of 1970, responsibility for the Chinese river dolphin [Lipotes vexillifer], as well as most other marine mammals, lies with the National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration. Department of Commerce. Section 4(a)(2)(A) of the Act provides that NMFS must decide whether a species under its jurisdiction should be classified as endangered or threatened. The Fish and Wildlife Service (FWS), however, is responsible for the actual addition of a species to the List of Endangered and Threatened Wildlife in 50 CFR 17.11(h).

In the Federal Register of May 19, 1988, (50 FR 294-298), NMFS proposed a determination of endangered status for the Chinese river dolphin and requested comments from the public by July 18, 1988.

In this issue of the Federal Register, NMFS is publishing its final determination of endangered status for the Chinese river dolphin (see document in Final Rules section under the Department of Commerce, National Oceanic and Atmospheric Administration). Accordingly, the FWS is concurrently adding the Chinese river dolphin as an endangered species to the List of Endangered and Threatened Wildlife. Because this FWS action is nondiscretionary, and in view of the public comment period provided by NMFS on its proposed determination, the FWS finds that good cause exists to omit the notice and public comment procedures of 5 U.S.C. 553(b). The FWS also has determined that an Environmental Assessment, as defined under authority of the National Environmental Policy Act of 1969, does not need to be prepared in regard to regulations adopted pursuant to section 4(a) of the Act. A notice outlining the reasons for this determination was published in the Federal Register of October 25, 1985 (40 FR 49244).

List of Subjects in 50 CFR Part 17

Endangered and threatened wildlife, fish, marine mammals, plants (agriculture).

Regulation Promulgation

Accordingly, Part 17, Subchapter B of Chapter 1, Title 50 of the Code of Federal Regulations, is amended as set forth below:

1. The authority citation for Part 17 reads as follows:


2. Section 17.11(h) is amended by adding the following, in alphabetical order, to the List of Endangered and Threatened Wildlife under "MAMMALS:"

§ 17.11 Endangered and threatened wildlife.

(h) * * *

(h) * * *
Mary Anne Bach, Assistant Secretary for Fish and Wildlife and Parks:

(Addition of Chinese River Dolphin to list of endangered and threatened wildlife)

Department of Commerce.

Assistant Secretary for Fish and Wildlife and Parks:

Dolphin, Chinese river (=whitechin)  Lipotes vexillifer


Mary Anne Bach, Assistant Secretary for Fish and Wildlife and Parks:

National Oceanic and Atmospheric Administration

DEPARTMENT OF COMMERCE

SUMMARY: NOAA Fisheries has determined that the Chinese river dolphin (Lipotes vexillifer) should be listed as an endangered species according to the Endangered Species Act of 1973 (ESA). This determination is based on information contained in a petition to list the species submitted by the Center for Environmental Education to list the Chinese river dolphin (Lipotes vexillifer) as an endangered species. According to the petition, this river dolphin is found primarily in the lower and middle sections of the Chang Jiang (Yangtze) River in the eastern, central region of mainland China.

On February 14, 1987, the Assistant Administrator for Fisheries determined that the petition presented substantial scientific information and solicited information and comments concerning the status of the Chinese river dolphin. On May 18, 1988, NMFS published its status review and proposed to list this species as endangered. Comments were received from the Center for Environmental Education and the Cetacean Society International. Both agencies strongly supported the listing of the Chinese river dolphin (Lipotes vexillifer) as endangered.

Listing Factors

Section 4(a) of the ESA provides that the Secretary of the Interior or Commerce, depending upon the species involved, shall, by regulation, determine if any species is endangered or threatened based upon any one or a combination of the following factors: (1) the present or threatened destruction, modification, or curtailment of its habitat or range; (2) overutilization for commercial, recreational, scientific or educational purposes; (3) disease or predation; (4) inadequacy of existing regulatory mechanisms; or (5) other natural or man-made factors affecting its continued existence. Section 4(b) of the ESA requires that such determinations be made "solely on the basis of the best scientific and commercial data available" and must take into account any efforts being made to protect the species under consideration.

The following discussion considers the history, status and biology of L. vexillifer and current conditions in relation to the listing factors.

(1) The present or threatened destruction, modification, or curtailment of its habitat or range: The banks of the Yangtze River have been extensively modified to prevent floods. Most of the lakes along the river have been isolated by sluice gates to retain the water during the dry season for irrigation and fish culture. Because the lakes are important nursery areas for many fish species, this isolation may have had adverse effects on the Chinese river dolphin by changing fish biomass and species composition in the river. A hydroelectric dam was completed in 1983 below the Three Gorges and another is planned in the Three Gorges region. To date, research has not detected adverse effects of the existing dam on most fish populations. A study of the effects on the proposed new dam on the Chinese river dolphin’s habitat has been carried out, but the report is not yet available in an English translation.

Some fish stocks in the river appear to be greatly reduced due to the loss of nursery areas for migratory species, overfishing, and pollution (Zhou and Li, in press). Thus reduction in prey availability may have played an important role in the decline of the Chinese river dolphin.

(2) Overutilization for commercial, recreational, scientific or educational purposes: The Chinese river dolphin is not directly exploited.

(3) Disease or predation: Nothing is known about these factors. However, based on examination of these dead dolphins recovered, neither appears to be a major problem.

(4) The inadequacy of existing regulatory mechanisms: Information is not available about this factor.

(5) Other natural or man-made factors:

Human use of the Yangtze River is extensive. Over the last 35 years, increasing industrial activity, boat traffic, and exploitation of fish resources have combined to degrade the Chinese river dolphin’s habitat (Zhou, 1986). The Chinese river dolphin suffers from various forms of human-induced mortality, the most serious of which seems to be accidental entanglement in bottom longlines, called "rolling hooks", set to snag bottom-feeding fish such as sturgeon. Chinese river dolphin are also taken incidentally in fish traps and...
Gillnets. Fishing gear may account for almost half the known Chinese river dolphin mortality (Lin, Chen, and Hua, 1985; Zhou and Li, in press).

Some dolphins are killed by boat propellers; this problem appears to be the most serious in the lower reaches of the river where boat traffic is heaviest and expected to double in the next ten years (Zhou and Li, in press).

Explosions, usually associated with construction projects but occasionally with illegal fishing, account for 15-20 percent of known Chinese river dolphin deaths (Zhou and Li, in press; Chen and Hua, in press). Six dolphins were killed in one construction blast.

Conclusion

We believe that the best available scientific and commercial data indicate that the population(s) of the Chinese river dolphin is endangered and should be listed on the U.S. List of Endangered and Threatened Species.

Recommended Critical Habitat

In the final rule regarding listing of species (50 CFR Part 424.12(H)), critical habitat cannot be designated in foreign countries or other areas outside U.S. jurisdiction.

Classification

The 1982 Amendments to the ESA (Pub. L. 97-304), in section 4(b)(1)(A), restrict the information which may be considered when assessing species for listing. Based upon this limitation of criteria for a listing decision and the opinion in Pacific Legal Foundation v. Andrus, 657 F.2d 829 (9th cir. 1981), NOAA Fisheries has categorically excluded all endangered species listings from environmental assessment requirements of the National Environmental Policy Act (40 FR 4113-23; February 6, 1975).

As noted in the Conference report on the 1982 amendments to the ESA, economic considerations have no relevance to determinations regarding the status of a species. Therefore, the economic analysis requirements of Executive Order 12291, the Regulatory Flexibility Act, and the Paperwork Reduction Act are not applicable to the listing process.

List of Subjects in 50 CFR Part 222

Administrative practice and procedure, Endangered and threatened wildlife, Exports, Fish, Import, Marine mammals, Reporting and recordkeeping requirements, Transportation.


Andrew J. Kemmerer, Acting Assistant Administrator for Fisheries.

For the reasons described in the preamble, Part 222 of Title 50 of the Code of Federal Regulations is amended as follows:

PART 222—ENDANGERED FISH OR WILDLIFE

1. The authority citation for Part 222 continues to read as follows:


§ 222.23 [Amended]

2. Section 222.23(a) of Subpart C is amended by adding the phrase "Chinese river dolphin" (Lipotes vexillifer) immediately after the phrase "cochito" (Phocoena sinus) in the second sentence.

[FR Doc. 89-12708 Filed 5-26-89; 8:45 am]
BILLING CODE 3510-22-M
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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 89-NM-50-AD]

Airworthiness Directives; Boeing Model 747-100, 747-200, and 747-SP Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This notice proposes a new airworthiness directive (AD), applicable to certain Boeing Model 747-100, 747-200, and 747-SP series airplanes certified for operation in the autoland system, which would require installation of a placard prohibiting operations under autoland under Category III. Operators would then have the option of either modifying the flight computers so as to restore the airplane to its full autoland capability, or revising the Airplane Flight Manual to indicate that Category II is the highest level of autoland capability. This proposal is prompted by reports of degraded localizer tracking performance during automatic landings. This condition, if not corrected, could lead to a landing approach that is offset from the runway centerline, when the airplane is operated in Category III weather conditions.

DATE: Comments must be received no later than July 17, 1989.


FOR FURTHER INFORMATION CONTACT: Mr. Frank vanLeynseele, Systems and Equipment Branch, ANM-1303; telephone (206) 531-1916. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: 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 should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator 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 post card on which the following statement is made: "Comments to Docket Number 89-NM-50-AD." The post card will be date/time stamped and returned to the commenter.

Discussion

A recent survey of airline operators of Boeing Model 747-100, 747-200, and 747-SP series airplanes, who routinely fly autoland approaches, has revealed several incidents of degraded localizer tracking each month. Research shows that this tracking problem can be brought about by any of the following: (1) Interception of the localizer at an angle greater than 45°; (2) capture at a distance less than 8 miles from runway threshold; (3) capture at speeds greater than V\text{app} + 40; (4) capture at an altitude less than 1,500 feet AGL; or (5) when the airplane is not stabilized on localizer and glideslope before passing the outer marker. The air traffic in Instrument Meteorological Conditions (IMC) has intensified and will continue to intensify; this will create conditions conducive to localizer tracking problems. Failure to properly capture and track the localizer could result in the airplane landing off of the runway surface.

Boeing has designed, and the FAA has certified, a new autoland computer, known as the Advanced Autoland Improvement Program (AAIP) Phase II, which has proven to work satisfactorily.

Since this condition may exist or develop on other airplanes of this same type design, an AD is proposed which would require operators to install a placard advising the crew that autoland under Category III operations is prohibited. Operators then have the option of either modifying the flight computers to meet the AAIP Phase II standards (and thereby restoring the airplane to its full autoland capability); or revising the FAA-approved Airplane Flight Manual to indicate that Category II is the highest level of autoland capability.

There are approximately 169 Model 747-100, 747-200, and 747-SP series airplanes of the affected design in the worldwide fleet. It is estimated that 33 airplanes of U.S. Registry (including 4 U.S. Air Force airplanes) would be affected by this AD, that it would take approximately 1 manhour per airplane to install the (initial) required placard, and that the average labor costs would be $40 per manhour. The placard may be manufactured locally and the cost would be expected to be negligible. Based on these figures, the total initial cost impact of the AD on U.S. operators is estimated to be $1,320.

Should an operator choose to restore the Category III landing capability, it would require from 96 to 446 manhours per airplane, depending upon the autoland computer configuration, at an average labor charge of $40 per manhour. Based on these figures, the cost to U.S. operators would be between $3,840 and $17,840 per airplane.

Should an operator choose to revise the AFM and limit the level of autoland capability to Category II, it would require approximately 1 manhour to accomplish this action, at an average labor cost of $40 per manhour. Based on these figures, the cost to U.S. operators would be $40 per airplane.

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 12866, 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 "major rule" under Executive Order 12866; (2) is not a "significant rule" under 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 evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation 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 as follows.

PART 39—[AMENDED]

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

Authority: 49 U.S.C. 1354(a); 1421 and 1423; 49 U.S.C 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.36.

§ 30.13 [Amended]

2. Section 30.13 is amended by adding the following new airworthiness directive:

Boeing Applies to Model 747-100, 747-200, and 747-SP series airplanes, approved for Category (CAT) III auto-land operations; equipped with analog Landing Control and Logic Unit (LCLU), Boeing Part Number 60B0013-476 through -489, or Landing and Rollout Control Unit (LRCU), Boeing Part Number 60B0013-752 through -756; certificated in any category. Compliance is required as indicated, unless previously accomplished.

To prevent runway off-set errors and possible landing off the runway surface when flying in instrument meteorological conditions, accomplish the following:

A. Within 30 days after the effective date of this AD, install a placard on the autopilot controller, stating: "Category III Operation Prohibited."

B. Within 24 months after the effective date of this AD, accomplish either B.1. or B.2., below:

1. Modify the LCLU or LCRU, as appropriate, to meet the Advanced Autoland Improvement Program (AAIP) Phase II standards, in a manner approved by the Manager of the Seattle Aircraft Certification Office, FAA, Northwest Mountain Region. Once the modification has been accomplished, the placard required by paragraph A., above, may be removed.

2. Revise Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to indicate that CAT II is the highest level of autoland capability.

C. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Seattle Aircraft Certification Office, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment and then send it to the Manager, Seattle Aircraft Certification Office.


Darnell M. Pederson,
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 89-127-3 Filed 5-26-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 89-NM-54-AD]

Airworthiness Directives; British Aerospace Model BAC 1-11 200 and 400 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This notice proposes a new airworthiness directive (AD), applicable to certain British Aerospace Model BAC 1-11 200 and 400 series airplanes, which would limit the number of operations at increased cabin pressure differential, and would require repetitive structural inspections of the fuselage, and repair or replacement, as necessary. This proposal is prompted by the determination that airplanes operating at increased cabin pressure differential are more likely to develop fatigue cracking earlier in their service lives than those airplanes operating at normal cabin differential pressures. This condition, if not corrected, could lead to structural failure of the fuselage and may result in the inability of the airplane structure to carry the required loads.

DATE: Comments must be received no later than July 17, 1989.

ADDRESSES: Send comments on the proposal in duplicate to the Federal Aviation Administration, Northwest Mountain Region, Transport Airplane Directorate, ANM-103, Attention: Airworthiness Rules Docket No. 89-NM-54-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98166. The applicable service information may be obtained from British Aerospace PLC, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. William Schroeder, Standardization Branch, ANM-113; telephone (206) 431-1987. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South C-68966, Seattle, Washington 98166.

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 should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the administrator before taking action on the proposed rule. The proposals contained in this Notice may be changed in light of the comments received. 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.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the FAA, Northwest Mountain Region, Transport Airplane Directorate, ANM-103, Attention: Airworthiness Rules Docket No. 89-NM-54-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98166.

Discussion

The United Kingdom Civil Aviation Authority (CAA), in accordance with existing provisions of a bilateral
airworthiness agreement, has notified the FAA of an unsafe condition which may exist on certain British Aerospace Model BAC 1-11 series airplanes. Analysis by the manufacturer has revealed that Model BAC 1-11 200 and 400 series airplanes operating at increased cabin pressure differential pressures up to a maximum of 8.2 pounds per square inch (psi) are subject to developing fatigue cracking in various components of the fuselage pressure vessel earlier in their service lives than those models operating at normal cabin differential pressures. This condition, if not corrected, could lead to structural failure of the fuselage and may result in the inability of the airplane structure to carry the required loads.

Normal operating cabin pressure differential for Model BAC 1-11 series airplanes is 7.5 psi. Certain operators, however, elected to operate their airplanes at increased cabin pressure differentials (above 7.5 psi) for passenger comfort. Such airplanes are most generally operated as executive transports in accordance with FAR Part 91 operations.

British Aerospace has issued Alert Service Bulletin 53-A-PM5922, Issue 1, dated January 27, 1987, which describes procedures for inspections of the fuselage, and repair or replacement, as necessary. The service bulletin also recommends limiting the number of increased pressure cycles for fuselage structure and reducing operating pressures when those limits are reached, and specifies special repetitive inspections for the structure during its remaining service life. The United Kingdom CAA has classified this service bulletin as mandatory.

This airplane model is manufactured in the United Kingdom and type certificated in the United States under the provisions of Section 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement.

Since this condition is likely to exist or develop on airplanes of this model registered in the United States, an AD is proposed that would limit the number of operations at increased cabin pressure differential, and would require repetitive structural inspections of the fuselage, and repair or replacement, as necessary, in accordance with the service bulletin previously described.

It is estimated that 30 airplanes of U.S. registry would be affected by this AD, that it would take approximately 67 manhours per airplane to accomplish the required actions, and that the average labor cost would be $40 per manhour.

Based on these figures, the total cost impact of this AD to U.S. operators is estimated to be $80,400.

The regulations proposed herein would not have substantial direct effects on the States, or 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, the FAA has determined that this document (1) involves a proposed regulation which is not major under Executive Order 12291 and (2) is not a significant rule under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and it is further certified under the criteria of the Regulatory Flexibility Act that this proposed rule, if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities because few, if any, British aerospace Model BAC 1-11 200 and 400 series airplanes are operated by small entities. A copy of a draft regulatory evaluation prepared for this action is contained in the regulatory docket.

List of Subjects in 14 CFR Part 39
Aviation safety, Aircraft.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

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


2. By adding the following new airworthiness directive:

British Aerospace: Applies to Model BAC 1-11 200 and 400 series airplanes, Post-Modification PM5240 and PM5187, or PM4686 (excluding airplanes modified to PM5232, cabin freight door), certified in any category. Compliance is required on the airplanes of this category up to the relationship between the number of landing shown for initial inspection in the "NE period" column of Table AA in the service bulletin, or within 15 months after the effective date of this AD, whichever occurs later.

3. At or prior to the accumulation of 55,000 landings, or within 30 days after the effective date of this AD, whichever occurs later, reduce the aircraft maximum cabin pressure differential to 7.5 psi by system modification, in a manner approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

4. For airplanes which have had the cabin pressure differential reduced from 8.2 psi to 7.75 psi as specified in paragraph 2.2.3 of the service bulletin, perform repetitive inspections at intervals specified in the "NE period" column of Table AA of the service bulletin.

5. At or prior to the accumulation of 60,000 landings, or within 30 days after the effective date of this AD, whichever occurs later, reduce the aircraft maximum cabin pressure differential to 7.5 psi by system modification, in a manner approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.
date of this AD, whichever occurs later, the airplane cabin maximum operating pressure differential must be reduced to 7.8 psi by modification as specified in paragraph 2.2.7 of the service bulletin, in a manner approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

6. For airplanes modified for 8.2 psi maximum cabin operating pressure differential and operated for a period in excess of any Table AA inspection threshold in the service bulletin, perform one additional inspection at or prior to the Table AA "NE period" column interval after limiting operation to 7.5 psi, as specified in Paragraph 2.2.5 of the service bulletin.

C. If defects are found during the inspections required by this AD, prior to further flight:

a. Replace with a serviceable part of the same part number;

b. For damage within the limits specified in the BAC 1-11 Structural Repair Manual, repair in accordance with the Structural Repair Manual;

c. Repair in accordance with a method approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

D. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment and then send it to the Manager, Standardization Branch, ANM-113.

E. Special flight permits may be issued in accordance with FAR 21.127 and 21.139 to operate airplanes to a base for the accomplishment of the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to British Aerospace PLC, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. These documents may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or at the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

Issued in Seattle, Washington, on May 19, 1989.

Darrell M. Pederson,
Acting Manager, Transport Aircraft Directorate, Aircraft Certification Service.

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 89-NM-41-AD]

Airworthiness Directives; McDonnell Douglas Model DC-9-10, -20, -30, -40, -50, and C-9 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This notice proposes to revise an existing airworthiness directive (AD), applicable to McDonnell Douglas Model DC-9-10, -20, -30, -40, -50, and C-9 series airplanes, which currently requires external eddy current inspections for cracks in certain longerons on airplanes that have accumulated more than 45,000 landings. This action would reduce the initial inspection compliance threshold to 30,000 landings and would add a requirement to perform internal visual inspections. This action is prompted by reports of fuselage skin and longeron cracks found in the upper fuselage over the wing. This condition, if not corrected, could result in degradation of the structural integrity of the fuselage and lead to rapid decompression of the airplane.

DATE: Comments must be received no later than June 29, 1989.

ADDRESSES: Send comments on the proposal in duplicate to the Federal Aviation Administration, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington 98168. The applicable service information may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846. Attention: Director, Publication and Training, C1-750 (54-60). This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or at 3229 East Spring Street, Long Beach, California.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Salas, Aerospace Engineer, Airframe Branch, ANM-122L, FAA, Northwest Mountain Region, 3229 East Spring Street, Long Beach, California 90806-2425; telephone (213) 988-8324.

SUPPLEMENTARY INFORMATION: 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 should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator 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 post card on which the following statement is made: "Comments to Docket Number 89-NM-41-AD." The post card will be date/time stamped and returned to the commenter.

Discussion

On November 8, 1988, the FAA issued AD 88-24-08, Amendment 39-6071 (53 FR 46433; November 17, 1988), to require external eddy current inspections for fuselage skin and longeron cracks on McDonnell Douglas Model DC-9 series airplanes prior to the accumulation of 55,000 landings. On December 28, 1988, the FAA issued AD 88-24-08, Revision 1 (R1), Amendment 39-6108 (54 FR 1975; January 17, 1989), which revised the existing AD to require external eddy current inspections for fuselage skin and longeron cracks on McDonnell Douglas Model DC-9 series airplanes prior to the accumulation of 45,000 landings. Those actions were prompted by reports of skin and longeron cracks at various overwing fuselage stations. This condition, if not corrected, could degrade the structural integrity of the fuselage and lead to possible rapid decompression.

Since the issuance of that revised AD, there have been additional reports of cracked or failed longerons on airplanes with fewer than 35,000 landings. One operator has reported finding skin and longeron cracks on three airplanes having accumulated between 32,745 and 39,823 landings.

In addition, the FAA has determined that internal visual inspections are more effective for detecting cracks on certain locations than are the eddy current inspections currently required.
The FAA has reviewed and approved McDonnell Douglas DC-9 Service Bulletin Bulletin A53-230, Revision 2, dated April 21, 1989, which recommends a revised (lower) threshold for initial inspections, describes procedures for internal visual inspections, and provides instructions for interim and permanent repairs.

Since this condition is likely to exist on other airplanes of the same type design, this action proposes to revise AD 88-24-08-R1 to lower the threshold for initial external eddy current inspections for skin and longeron cracks on airplanes, prior to the total accumulation of 30,000 landings, and to require visual internal inspections and repair, if necessary, in accordance with the service bulletin previously described.

On December 28, 1988, the FAA issued a Supplemental Notice of Proposed Rulemaking, Docket 88-NM-176-AD (54 FR 17228; January 17, 1989), which proposed to require repetitive visual inspections of the longerons from longeron 10 left through 10 right fror inside the fuselage, and repair, if necessary. The FAA has now determined that it is more appropriate to include those inspection requirements in this proposed action; consequently, the FAA intends to withdraw Docket 88-NM-176-AD.

There are approximately 732 Model DC-9 series airplanes of the affected design in the worldwide fleet. It is estimated that 578 airplanes of U.S. registry would be affected by this AD, that it would take approximately 100 manhours per airplane to accomplish the required action, and that the average labor cost would be $40 per manhour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $2,312,000 for the initial inspection cycle.

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 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures, 49 FR 18154; February 28, 1984; 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 evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained from the Rules Docket.

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 as follows:

PART 39—[AMENDED]

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


§ 39.13 [Amended]

2. Section 39.13 is amended by adding AD 88–24–08–R1, Amendment 39–6108 (54 FR 1675; January 17, 1989), as follows:


To prevent fatigue cracking and subsequent failure of the fuselage skin and longerons, accomplish the following:

A. Prior to the accumulation of 45,000 landings, or 30 days after January 28, 1989 (the effective date of Amendment 39–6108), whichever occurs later, unless accomplished within the last 2,500 landings, perform external eddy current inspections of the fuselage skin and longerons from longeron 7 left through 7 right, in accordance with the accomplishment instructions of McDonnell Douglas DC–9 Alert Service Bulletin AS3–230, Revision 2, dated April 21, 1989, within the range of fuselage stations for the particular series airplanes as specified in Table 1 of that service bulletin.


F. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Regional Maintenance Inspection (PMI), who will either concur or comment and then send it to the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

G. Special flight permits may be issued in accordance with FAR 21.190 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director, Publication and Training, 750 (54–66). These documents may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or 3229 East Spring Street, Long Beach, California.
14 CFR Part 71
[Airspace Docket No. 89-ACE-14]

Proposed Alteration of Transition Area; LeMars, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This notice proposes to alter the 700-foot transition area at LeMars, Iowa, to provide additional controlled airspace for aircraft executing a new instrument approach procedure to Runway 36 at the LeMars, Iowa, Municipal Airport utilizing the Sioux City VOR as a navigational aid.

DATE: Comments must be received on or before July 5, 1989.

ADDRESSES: Send comments on the proposal to: Federal Aviation Administration, Manager, Traffic Management and Airspace Branch, Air Traffic Division, ACE-540, 601 East 12th Street, Kansas City, Missouri 64106, Telephone (816) 426-3408.

FOR FURTHER INFORMATION CONTACT: Lewis G. Earp, Airspace Specialist, Traffic Management and Airspace Branch, Air Traffic Division, ACE-540, FAA, Central Region, 601 East 12th Street, Kansas City, Missouri 64106, Telephone (816) 426-3408.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties may participate in the proposed rulemaking by submitting such written data, views or arguments as they may desire. Communications should identify the airspace docket number, and be submitted in duplicate to the Traffic Management and Airspace Branch, Air Traffic Division, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106. All communications received on or before the closing date for comments will be considered before action is taken on the proposed amendment. The proposal contained in this Notice may be changed in light of the comments received. All comments received will be available both before and after the closing date for comments in the Rules Docket for examination by interested persons.

Availability of NPRM

Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Traffic Management and Airspace Branch, 601 East 12th Street, Kansas City, Missouri 64106, or by calling (816) 426-3408.

Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for further NPRMs should also request a copy of Advisory Circular No. 11-2A which describes the application procedure.

The Proposed Amendment

The FAA is considering an amendment to Subpart G, § 71.181 of the Federal Aviation Regulations [14 CFR Part 71] by altering the 700-foot transition area at LeMars, Iowa. To enhance airport usage, Runway 36 at the LeMars, Iowa, Municipal Airport will have additional controlled airspace for aircraft executing a new VOR/DME instrument approach procedure utilizing the Sioux City VOR. The establishment of this new instrument approach procedure, based on this approach aid, entails alteration of the transition area at LeMars, Iowa, at and above 700 feet above ground level, within which aircraft are provided air traffic control service. The intended effect of this action is to ensure segregation of aircraft using the approach procedure under instrument flight rules (IFR) from other aircraft operating under visual flight rules (VFR). Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.82 dated January 3, 1989.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. If, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71
Aviation safety, Transition areas.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the FAA proposes to amend Part 71 of the FAR [14 CFR Part 71] as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

§ 71.181 [Amended]

1. The authority citation for Part 71 continues to read as follows:


2. Section 71.181 is amended as follows:

LeMars, Iowa [Revised]

That airspace extending upward from 700 feet above the surface within a 5-mile radius of the LeMars, Iowa, Municipal Airport (lat. 42°11’37” W.), and within 3 miles each side of the 358° bearing from the airport extending from the 5-mile radius to 6 miles north of the airport, within 2.5 miles each side of the 193° bearing from the airport extending from the 5-mile radius to 0.3 miles south of the airport.

Issued in Kansas City, Missouri, on May 16, 1989.

Clarence E. Newbern,
Manager, Air Traffic Division.

[FR Doc. 89-12731 Filed 5-26-89; 8:45 am]
BILLING CODE 4910-15-M
The FAA is considering an amendment to Subpart G, §71.181 of the Federal Aviation Regulations (14 CFR Part 71) to designate a 700-foot transition area at Winterset, Iowa. To enhance airport usage, a new VOR/DME-A instrument approach procedure is being developed for the Winterset-Madison County Airport, Winterset, Iowa, utilizing the Des Moines VORTAC as a navigational aid. This navigational aid will offer new navigational guidance for aircraft utilizing the airport. The establishment of a new instrument approach procedure, based on this navigational aid, entails designation of a transition area at Winterset, Iowa, at and above 700 feet above ground level, within which aircraft are provided air traffic control service. Transition areas are designed to contain IFR operations in controlled airspace during portions of the terminal operation and while transiting between the terminal and en route environment. The intended effect of this action is to ensure segregation of aircraft using the approach procedure under IFR from other aircraft operating under VFR. This action will change the airport status from VFR to IFR.

Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6E, dated January 3, 1989.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a “major rule” under Executive Order 12291; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71
Aviation safety, Transition areas.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the FAA proposes to amend Part 71 of the FAR (14 CFR Part 71) as follows:

**PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS**

1. The authority citation for Part 71 continues to read as follows:

   Authority: 49 U.S.C. 1340(a), 1354(a), 1510;
   Executive Order 10854; 49 U.S.C. 106(g)

   §71.181 [Amended]
   2. Section 71.181 is amended as follows:

   **Winterset, Iowa [New]**

   That airspace extending upward from 700 feet
   above the surface within a 5-mile radius of
   the Winterset-Madison County Airport
   (lat. 41°21'50"N. long. 94°01'15"W.), and
   within 2.5 miles each side of the 227° bearing
   from Winterset-Madison County Airport
   extending from the 5-mile radius to 6.5 miles
   southwest of the airport; excluding that
   portion which overlaps the Des Moines, Iowa,
   transition area.

   Issued in Kansas City, Missouri on May 15,
   1989.

   Clarence E. Newbern,
   Manager, Air Traffic Division
   [FR Doc. 89-12752 Filed 5–26–89; 8:45 am]

   BILLING CODE 4910–13–M

**14 CFR Part 71**

[Airspace Docket No. 69–AGL–11]

**Proposed Alteration to Transition Area; Eagle River, WI**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This notice proposes to alter
the existing Eagle River, WI, transition area to accommodate a new VOR/DME
Runway 04 Standard Instrument Approach Procedure (SIAP) to Eagle
River Union Airport, Eagle River, WI. The intended effect of this action is to
ensure segregation of the aircraft using approach procedures in instrument
conditions from other aircraft operating under visual weather conditions in
controlled airspace.

**DATE:** Comments must be received on or before July 6, 1989.

**ADDRESSES:** Send comments on the proposal in triplicate to: Federal
Aviation Administration, Asst. Chief Counsel, AGL–7, Attn: Rules Docket No.
69–AGL–11, 2300 East Devon Avenue,

The official docket may be examined in the Office of the Regional Counsel,
Federal Aviation Administration, 2300
The Proposed Amendment
Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) as follows:

PART 71—[Amended]
1. The authority citation for Part 71 continues to read as follows:

§ 71.181 [Amended]
2. Section 71.181 is amended as follows:

Eagle River, WI [Revised]
That airspace extending upward from 700 feet above the surface within a 5-mile radius of Eagle River Union Airport (Lat. 45°55'55" N., Long. 89°16'04" W.) and within 3 miles of each side of the 63° bearing from the airport, extending from the 5-mile radius area to 6 miles southwest of the airport.


Teddy W. Burcham,
Manager, Air Traffic Division.

[FR Doc. 89-12750 Filed 5-26-89; 8:45 am]
BILLING CODE 4910-13-M

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 52
[FRI-3573-5]

Approval and Promulgation of Implementation Plans; Ohio

AGENCY: U.S. Environmental Protection Agency (USEPA).

ACTION: Proposed rulemaking.

SUMMARY: On April 9, 1988, the State of Ohio Environmental Protection Agency (OEPA), submitted amendments to Ohio Administrative Code (OAC) Chapter 3745-21 to USEPA as proposed revisions to the State Implementation Plan (SIP) for Ozone. OAC Chapter 3745-21 consists of emission limitation and control requirements for sources of volatile organic compounds (VOC). The amendments to OAC Chapter 3745-21 involve certain compliance deadlines and source specific exemptions from otherwise applicable emissions limitations.

USEPA is proposing approval and disapproval of specific portions of the OEPA submittal as a revision to the Ohio SIP. The intent of this notice is to discuss the results of USEPA's review of the State's amendments to the VOC control portion of its SIP and to solicit
public comments on the revisions and USEPA's proposed action. Ohio's April 9, 1986, State Submittal included new VOC regulations for additional source categories not specifically covered by Ohio's existing rules and a site-specific revision for the Huffy Corporation. USEPA's will propose rulemaking on these other elements of the April 9, 1986, submittal in other Federal Register notices. Today's Federal Register notice also does not address those amendments to the ozone SIP that were previously submitted on March 23, 1983, to USEPA, and were addressed in a March 6, 1985, Federal Register notice of proposed rulemaking (50 FR 9862).

Final rulemaking has not as yet been completed on these previously submitted amendments.

**DATE:** Comments on this revision and on the proposed USEPA action must be received by June 29, 1989.

**ADDRESSES:** Copies of the SIP revision are available at the following addresses for review: (It is recommended that you telephone Uylaine E. McMahan, at (312) 886-6031, before visiting the Region V office.)

- U.S. Environmental Protection Agency, Region V, Air and Radiation Branch, 230 South Dearborn Street, Chicago, Illinois 60604
- Ohio Environmental Protection Agency, Office of Air Pollution Control, 361 East Broad Street, Columbus, Ohio 43216

Comments on this proposed rule should be addressed to: (Please submit an original and three copies, if possible.) Cary Couble, Chief, Regulatory Analysis Section, Air and Radiation Branch (5AR-26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604.

**SUPPLEMENTARY INFORMATION:** On April 9, 1986, the OEPA submitted amendments to OAC Chapter 3745-21 and supporting data to USEPA as a proposed revision to the ozone portion of its SIP. OEPA adopted these rules in final form on May 9, 1986. OAC Chapter 3745-21, entitled, "Carbon Monoxide, Photochemically Reactive Materials, Hydrocarbons, and Related Materials Standards," includes Ohio's VOC reasonably available control technology (RACT I and II) regulations.

The regulations being discussed today are embodied in the OAC Chapter 3745-21 as follows: averaging period, Rule 3745-21-09(B); can regulations, Rules 3745-21-09(D)(1)(e), (D)(2)(e), and (D)(3); metal furniture, Rule 3745-21-09(I)(3)(i); cutback and emulsified asphalt, Rules 3745-21-09(N)(3)(a) and (N)(4); bulk gasoline terminal, Rule 3745-21-09(Q)(4); miscellaneous metals, Rule 3745-21-09(U)(1)(viii); and best available technology (BAT), Rule 3745-21-09(U)(2)(f); and gasoline tank trucks, Rule 3745-21-09(V)(1)(i). USEPA initially approved these regulations and others as part of Ohio's SIP for ozone in separate rulemaking actions on October 31, 1980 and June 29, 1982 (45 FR 72122 and 47 FR 23607).

For the reader's convenience, the following discussion presents a summary of the changes to the existing rules. Where appropriate, the discussion presents the results of USEPA's analysis and USEPA's conclusion as to whether or not the change should be approved. USEPA's complete analysis is contained in a document entitled, "Technical Support Document for Revisions to Ohio RACT I and II VOC Regulations," dated July 14, 1986. This document is available for review at the Region V office listed above. For further details, the reader is referred to this document, and the State submittal of April 9, 1986, which includes the adopted Amendments to 3745-21 and supporting documentation.

1. Averaging Period—Rule 3745-21-09(B)

**Proposed Approval**

The first sentence has been changed to "Compliance with the limitations specified in paragraphs (C) to (K), (S), (U), and (Y) of this rule is based upon a weighted average by volume of all coating materials employed in the coating line or printing line in any one day."

**USEPA Position**

This revision is generally consistent with suggested wording in USEPA's September 17, 1985, letter commenting on Ohio's draft RACT I and II revisions. The revision as submitted is approvable because it specifies that the limitations are weighted averages that are applicable to the coatings materials employed in the coating line or printing line each day. This is preferable to a determination of emissions for each applicator, which was previously required.

2. Can Regulations—Rules 3745-21-09(D)(1)(e) and (D)(2)(e)

**Proposed Disapproval**

OEPA proposed a relaxation (from 3.7 pounds of VOC per gallon of coating (lbs VOC/gallon)) to 4.4 lbs VOC/gallon of coating, excluding water, for food can ends from an end sealing compound coating line. OEPA's basis includes a September 13, 1985, letter and testimony from Heekin Can, an April 13, 1984, submittal from the Can Manufacturers Institute to USEPA, and testimony presented by Campbell Soup Company. The basis of the can industries' request for a relaxation is the purported unavailability of complying end sealing compounds for food can ends as well as the infeasibility of add-on control.

**USEPA Position**

USEPA investigated the can industries' contentions (1) that add-on controls are infeasible and (2) that complying end sealing compounds for food can ends are unavailable. USEPA found the following information which appears to refute both contentions. This information was presented by Michael Lake of the San Diego County Air Pollution Control District as a paper at the 1985 Air Pollution Control Association (APCA) conference. (The paper is included in the docket on this rulemaking action.)

The San Diego District's limit is 440 grams per liter (g/l), which is essentially equivalent to 3.7 pounds per gallon (lbs/gal). During 1984, a San Diego source, Van Camp, studied the feasibility of add-on control. Van Camp's study provided a strong indication that it may be feasible and cost-effective to control VOC emissions at the line with carbon adsorption or incineration. This control methodology could achieve a 76 percent overall reduction (80 percent capture, 95 percent control).

During 1984, Van Camp also started testing a compliance end sealing compound. This solventless, waterborne compound is Darenex Compound AD 408T, by the Dewey & Almy Division of W.R. Grace. This testing was successful on their pet food line, and Van Camp subsequently switched over to use of this waterborne compound on pet foods. This amounted to 35 percent of their operations and resulted in emissions equivalent to 440 g/l. Van Camp's other products (e.g., tuna cans) have a longer shelf life and testing for these other products is still in progress.

Therefore, a permanent relaxation of Ohio's can end sealing regulations is not approvable because the Van Camp data indicates possible feasibility of both add-on control equipment and low solvent coatings, and Ohio has not considered this information. Thus, Ohio has not demonstrated that the current emission limits are infeasible.
3. Can Regulation—Rule 3745-21-09(D)(3)

Proposed Approval

OEPA revised the equation for the alternative daily emission limitation for can plants. This equation has been revised so that it is now based on a constant volume solids basis.

USEPA Position

This revision is approvable as it corrects a serious deficiency in Ohio’s SIP. In its previous equation, the calculations were incorrectly performed on a volume basis.

4. Metal Furniture—Rule 3745-21-09(U)(3)(b)

Proposed Approval

This provision exempts “Any application of a coating to a part not defined as metal furniture” from the 3.0 lbs/gallon limitation in 3745-21-09(I)(1).

USEPA Position

This provision is approvable. However, any metal part not defined as metal furniture would be considered a “miscellaneous metals” and would be subject to 3745-21-09(U).

5. Cutback and Emulsified Asphalt—Rule 3745-21-09(U)(3)(e)

Proposed Disapproval

This paragraph states that the control requirements of (U)(1) and (U)(2) shall not apply:

To the use or application by hand of any cutback asphalt or emulsified asphalt for patching or crack sealing, provided the maximum daily usage is less than one thousand gallons for any work crew.

USEPA proposed to disapprove this exemption (without the underlined words) on March 6, 1985 and is now proposing to disapprove the rule as revised.

This exemption is supported by a November 3, 1982, letter from the Ohio Department of Transportation which states that “Our attempts at using emulsified asphalts as crack sealers have not generally been satisfactory.”

The County Engineers Association of Ohio, in a June 22, 1982, requested OEPA to “Permit use of cutback asphalt for patching up to a usage not to exceed 2000 gallons per day at any time of the year.” The County Engineers stated that this requested change “would improve the efficiency and economy of road paving and maintenance work.”

USEPA Position

The language added to the end of (U)(3)(e) clarifies the exemption. However, this clarifying language could result in substantially increased VOC emissions. This clarifying language, and the supporting documentation, does not result in a change in USEPA’s position on this exemption (a proposed disapproval) as stated in the March 6, 1985, notice of proposed rulemaking. An adequate basis has not been provided for this exemption. USEPA informed OEPA of this in its September 17, 1985, comment letter.

6. Cutback and Emulsified Asphalt—Rule 3745-21-09(N)(4)

Proposed Disapproval

This paragraph has been added to establish recordkeeping requirements for those persons using or applying cutback asphalt or emulsified asphalt during the period from May 15 through September 15.

USEPA Position

These recordkeeping requirements are inadequate in that they do not apply to the period of April 15 through October 15. USEPA does not agree with Ohio’s exemption period of September 15 through May 15. USEPA previously proposed to disapprove this exemption period in its March 6, 1985, notice of proposed rulemaking (50 FR 9052). The reasons for disapproval stated in the March 6, 1985, notice still stand.

Under the current USEPA’s approved regulations, the use or application of cutback asphalt or emulsified asphalt during October 14 through April 15 is exempt from limitations. Thus, the recordkeeping requirements may be necessary for the remaining period: April 15 through October 15. Ohio previously increased the exemption period to September 15 through May 15, and as a result seeks to establish recordkeeping requirements for the remaining period of May 15 through September 15.

7. Bulk Gasoline Terminal—Rule 3745-21-09(U)(1)(vii)

Proposed Disapproval

This paragraph establishes a limitation of 4.8 lbs VOC/gal of coating, excluding water, for a heat resistant, anti-corrosion coating applied to the interior of a motor vehicle directly above the catalytic converter.

USEPA Position

This revision is not approvable because it is a relaxation of approved VOC emission limits in Ohio’s ozone SIP and Ohio has not made a demonstration that this relaxation will not interfere with attainment and/or maintenance of the ozone National Ambient Air Quality Standards (NAAQS). Furthermore, the July 29, 1983 memorandum titled “Source Specific SIP Revisions” by Sheldon Meyers, former Director of the Office of Air Quality Planning and Standards, addresses the issue of VOC SIP relaxations. This memorandum states that approval of such a relaxation would require a data base and modeling demonstration consistent with that applied in extension areas. The sources subject to this relaxation are located in Lordstown and Dayton, Ohio. There have not been any revised attainment demonstrations, consistent with those done for extension areas, submitted for these areas.

8. Miscellaneous Metals—Rule 3745-21-09(U)(1)(vii)

Proposed Disapproval

This paragraph establishes a limitation of 4.8 lbs VOC/gal of coating, excluding water, for a heat resistant, anti-corrosion coating applied to the interior of a motor vehicle directly above the catalytic converter.

USEPA Position

This revision is not approvable because it is a relaxation of approved VOC emission limits in Ohio’s ozone SIP and Ohio has not made a demonstration that this relaxation will not interfere with attainment and/or maintenance of the ozone National Ambient Air Quality Standards (NAAQS). Furthermore, the July 29, 1983 memorandum titled “Source Specific SIP Revisions” by Sheldon Meyers, former Director of the Office of Air Quality Planning and Standards, addresses the issue of VOC SIP relaxations. This memorandum states that approval of such a relaxation would require a data base and modeling demonstration consistent with that applied in extension areas. The sources subject to this relaxation are located in Lordstown and Dayton, Ohio. There have not been any revised attainment demonstrations, consistent with those done for extension areas, submitted for these areas.


Proposed Disapproval

The VOC requirement in this paragraph establishes a limitation of 6.2 lbs VOC/gal of coating, excluding...
This relaxation is not approvable because OEPA has neither documented the infeasibility of add-on control nor the potential use of powder coatings. There are several suppliers of powder coatings. Three of these suppliers Armstrong Products, Fuller O'Brien, and Polymer Corporation expect their coatings to pass the 5 year exposure test. Some of these are currently in the third or fourth year of their 5 year testing period. Therefore, a permanent relaxation for high performance architectural aluminum coatings, is not approvable.

Summary
OEPA has proposed a number or revisions to its RACT I, RACT II, and general VOC Rules. These are contained in OAC Chapter 3745-21-01, Definitions; OAC Chapter 3745-21-04, Compliance and schedules; OAC Chapter 3745-21-09. Emission Limits; and OAC Chapter 3745-21-10, Test Methods. A listing and short description of all of these revisions is in USEPA's technical support documents, dated July 14, 1986. September 23, 1986 and July 27, 1988. Many of these revisions are minor. USEPA is proposing to approve Ohio's revisions, with the following exceptions:

1. USEPA is proposing to disapprove the proposed relaxation for food end sealing compounds in 3745-21-09(D)(1)[e] and (D)(2)[e] (from 3.7 to 4.4 lbs VOC/gal).

2. USEPA is proposing to disapprove the proposed revision to the exemption, as well as the entire exemption in 3745-21-09(N)(3)[e] for the application by hand of any cutback asphalt or emulsified asphalt for patching or crack sealing. In addition, USEPA is proposing to disapprove the recordkeeping requirements in 3745-21-09(N)(4) because they are inadequate with respect to the time period during which records are required.

3. USEPA is proposing to disapprove the relaxation (from 3.5 to 0.2 lbs VOC/gal) for high performance architectural aluminum coatings in 3745-21-09(U)(1)(a)(v).

4. USEPA is taking no action on the exemption for new sources in 3745-21-09(U)(2)[f].

5. USEPA is proposing to disapprove the proposed VOC emission limitation for miscellaneous metals 3745-21-09(U)(1)(vii) of 4.8 lbs VOC/gal of coating, excluding water.

As stated earlier, Ohio's April 9, 1986, State Submittal included more stringent emission limitations than those contained in this rule.

11. Gasoline Tank Trucks—Rule 3745-21-09(U)(1)[f]

Proposed Approval
This paragraph has been added to require the owner or operator of a gasoline tank truck to properly hook up to a vapor balance system or vapor control system at a bulk gasoline terminal, bulk gasoline plant, or gasoline dispensing facility.

USEPA Position
This paragraph requires proper operation of emission control systems, for gasoline tank trucks and is, therefore, approvable.

10. BAT "Permit to Install" New Sources—Rule 3745-21-09(U)(2)[f]

USEPA is taking no action on this rule.

This paragraph has been revised to indicate that coating lines, for which construction or modification commenced on or after March 27, 1981 (the effective date of (U)(1)), and which are subject to Best Available Technology (BAT) requirements under a "Permit to Install", may be exempted from the "Voluntary Deterioration (PSD) program. USEPA is proposing to disapprove the proposed relaxation for high performance architectural aluminum coatings, is not approvable.

USEPA is continuing to take no action on this section as it applies to new sources of VOC, because new sources continue to be regulated by Ohio's new source review (NSR) program and USEPA's Prevention of Significant Deterioration (PSD) program. USEPA notes that NSR and PSD may require

* * *

A Publication No. AAMA 2-85, "Voluntary Specifications for High Performance Organic Coatings on Architectural Extrusions and Panels", describes test procedures and requirements for high performance organic coatings applied to aluminum extrusions and panels for architectural products. High performance architectural aluminum coatings are required to meet the requirements in AAMA 605 t. which includes a 5 year weathering test.
SUMMARY: USEPA is proposing to disapprove a revision to the Illinois State Implementation Plan (SIP) for Ozone. The revision pertains to a temporary relaxation of Reasonably Available Control Technology (RACT) requirements for Classic Finishing Company (Classic) in Cook County. USEPA’s action is based upon a revision request which was submitted by the State under the Clean Air Act (Act).

DATES: Comments on this revision and on the proposed USEPA action must be received by June 29, 1989.

ADDRESSES: Copies of the SIP revision are available at the following addresses for review. (It is recommended that you telephone Randolph O. Cano, at (312) 889-6036, before visiting the Region V Office.]

U.S. Environmental Protection Agency, Region V, Air and Radiation Branch, 230 South Dearborn Street, Chicago, Illinois 60604

Illinois Environmental Protection Agency, Division of Air Pollution Control, 2200 Churchill Road, Springfield, Illinois 62706.

Comments on this proposed rule should be addressed to: (Please submit an original and three copies, if possible.)


SUPPLEMENTARY INFORMATION: Under Section 107 of the Act, USEPA has designated certain areas in each State as not attaining the National Ambient Air Quality Standards (NAAQS) for ozone. See 40 CFR 5092 (March 3, 1978) and 43 CFR 45993 (October 5, 1978). For these areas, Part D of the Act requires that the State revise its SIP to provide for attaining the primary NAAQS by December 31, 1985, or, in certain cases, e.g., Cook County, Illinois, by December 31, 1987, for ozone). These SIP revisions must also provide for attaining the secondary NAAQS as soon as practicable. The requirements for an approved SIP are described in a “General Preamble” for Part D rulemakings published at 44 FR 20372 (April 4, 1979), 44 FR 38983 (July 2, 1979), 44 FR 50371 (August 28, 1979), 44 FR 53761 (September 17, 1979), and 44 FR 67182 (November 23, 1979).

On November 19, 1986, the State of Illinois submitted a proposed revision to the Illinois SIP in the form of a June 29, 1986, Final Opinion and Order of the Board PCB 64-174, Docket B. This proposed SIP revision, if approved by USEPA, would grant Classic a retroactive variance from the requirements of 35 Illinois Administrative Code (IAC) 215.204(C).1 Classic is located in Chicago, Cook County, Illinois, which is designated as not attaining the national ambient air quality standards (NAAQS) for ozone. Classic coats and laminates printed paper and vinyl sheets. Classic currently operates seven roll coaters, four laminating machines, and one surlyn coater. These lines are subject to the control requirements contained in SIP Rule 206(n)(1)[c] and the compliance schedule contained in Rule 203(i). These rules require that the coatings used on paper coating lines meet a volatile organic compound (VOC) limit of 2.9 pounds of VOC per gallon of coating, excluding water, by December 31, 1992. Classic has been in compliance with Rule 206(n)(1)[c] since January 1, 1986, through the use of specialized coatings cured with ultraviolet (UV) light, water-based coatings, and coatings containing exempt solvent. However, for the period prior to coming into compliance, Classic requested a variance for these lines. By means of a June 20, 1986, order of the Illinois Pollution Control Board (IPCB), Classic was granted a retroactive variance from Rule 206(n)(1)[c] for the period between March 4, 1986, and January 1, 1996.

Evaluation of the Proposed Revision

A relaxation of this type constitutes a compliance date extension. A detailed discussion of the rationale for proposing disapproval of a State submission and of the Clean Air Act and USEPA policy related to compliance date extensions appears in Appendix A of the proposed rulemaking published on November 8, 1988 at 53 FR 45103.

USEPA policy indicates that two tests must be met before a compliance date extension can be approved. First, a State must demonstrate that the extension will not interfere with timely attainment and maintenance of the ozone standard and, where relevant, “reasonable further progress” (RFP) toward timely attainment. This demonstration may be based on a comparison between the margin for attainment predicted by the approved attainment demonstration and the increase in emissions caused by the relaxation. Because this is an extension until the end of 1985, and because an extension of the attainment date for the Chicago area to December 31, 1987, has been granted, it is not necessary to demonstrate that the revision will not interfere with attainment or maintenance of the ozone standard. However, it is necessary to demonstrate that the revision will not interfere with RFP. Illinois has made no such demonstration.

Second, extensions must also be consistent with the requirement that nonattainment area SIPs provide for the implementation of all reasonably available control measures as expeditiously as practicable. Expeditiousness is demonstrated by determining the time that has elapsed since the source was first notified of the applicable requirements. Compliance date extensions for periods longer than 3 years after the adoption of the rule by the State are to be scrutinized to determine whether or not they are truly expeditious.

IEPA has not adequately addressed the expeditiousness of the compliance plan. Because it has not been shown that the original timeframe in the SIP did not allow sufficient time for an economically and technologically feasible compliance plan to be implemented, this extension cannot be approved.

Proposed Rulemaking Action

USEPA proposes to disapprove this requested SIP revision for Classic for two reasons. The State failed to demonstrate that the revision will not interfere with RFP, and that the requested SIP revision was expeditious. Public comment is solicited on the requested SIP revision and on USEPA’s proposed disapproval. Public comments received by the above indicated date...
will be considered in the development of USEPA's final rulemaking action.

Under the Regulatory Flexibility Act, 5 U.S.C. 603(b), USEPA must assess the impact of proposed or final rules on small entities. If USEPA takes final action to disapprove this requested SIP revision, it will not have a significant impact on a substantial number of small entities. Only a single entity, Classic, is affected.

Under Executive Order 12231, this action is not "Major." It has been submitted to the Office of Management and Budget (OMB) for review.

Authority: 42 U.S.C. 7401-7442.

Valdas V.Adamkus,
Regional Administrator:

Regional Administration:

[FR Doc. 89-12700 Filed 5-28-89; 8:45 am]

BILLING CODE 6560-5Q-M

40 CFR Part 60

[AD-FRL-3576-5]

Standards of Performance for New Stationary Sources; Test Methods

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and notice of public hearing.

SUMMARY: Method 21 applies to the determination of volatile organic compounds (VOC) leaks from process equipment such as valves, flanges and connections, pumps and compressors, and pressure relief devices. Since Method 21 was promulgated in 1983, several deficiencies in the method that could lead to inconsistencies in the determination of VOC leaks from such devices have come to the attention of EPA in the form of questions as to the proper application of the method. This action remedies those deficiencies by making appropriate additions and revisions to the method.

A public hearing will be held, if requested, to provide interested persons an opportunity for oral presentation of data, views, or arguments concerning the proposed rule.

DATES: Comments. Comments must be received on or before August 14, 1989.

Public Hearing. If anyone contacts EPA requesting to speak at a public hearing by June 20, 1989, a public hearing will be held July 14, 1989 beginning at 10:00 a.m. Persons interested in attending the hearing should contact the Regional Administrator's Office by June 20, 1989.

ADDRESSES: Comments. Comments should be submitted (in duplicate if possible) to: Central Docket Section (LE-331), Attention: Docket Number A-88-29, U.S. Environmental Protection Agency, South Conference Center, Room 401 M Street, SW., Washington, DC 20460.

Public Hearing. If anyone contacts EPA requesting a public hearing, it will be held at EPA's Emission Measurement Laboratory Building, Research Triangle Park, North Carolina. Persons interested in attending the hearing or wishing to present oral testimony should notify William Grimley, Emission Measurement Branch (MD-19), Technical Support Division, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone (919) 541-1065.

Docket. Docket Number A-88-29, containing material relative to this rulemaking, is available for public inspection and copying between 8:00 a.m. and 3:30 p.m., Monday through Friday, at EPA's Central Docket Section, South Conference Center, Room 401 M Street, SW., Washington, DC 20460. A reasonable fee may be charged for copying.


SUPPLEMENTARY INFORMATION:

1. The Rulemaking

Section 2.4 is being revised to remove a description of the leak determination procedure, which is already given, and more properly belongs, in Section 4.3.2. The exclusion of an acceptable increase in surface concentration versus local concentration is incorrect, and is being removed, as all existing regulatory subparts state that any reading less than 500 ppm constitutes "no detectable emissions." The definition is now expressed in terms of the instrument readability specification.

Section 3.1.1(a) is being revised because it is important to call attention to the possibility that the leak definition concentration may be beyond the linear response range of some instruments for some VOC. This potential problem is not identified by the existing calibration procedure, which specifies a single upscale VOC calibration gas. An argument could be made that a multipoint calibration should, therefore, be required. However, adding that requirement would increase the method's performance burden and cost.

Section 3.1.1(c) is being revised in consideration of existing regulatory subparts, where the intention is for the readability to be to the nearest 500 ppm. Since the leak definition in existing subparts is 10,000 ppm, the nearest 500 ppm represents ±2.5 percent, not ±5 percent.

Section 3.1.1(d) is being revised to prevent any flow interruption, such as could occur if a manually operated device was used for a pump, from occurring. The minimum flow rate specification of 0.50 liter per minute is reduced to 0.10 liter per minute to prevent the exclusion of some instruments that do meet the response time specification and could be acceptable if this change was made. The flow rate specification has been qualified as to where, and under what conditions, it applies in order to prevent misunderstandings that it might apply at the instrument detector, or with no flow restriction in the probe. The upper flow rate specification of 3.0 liters per minute is retained because some upper limit on flow rate is required to prevent dilution of any leaking VOC to a concentration below the definition of a leak.

Section 3.1.1(e) is being revised in consideration of comments that have been made to EPA that the existing wording is not clear and should be more specific. In addition, it has been reported that inexperienced sampling personnel have been observed to use a portable flame ionization analyzer with the exhaust flame arrestor not replaced after removal for cleaning.

Section 3.1.1(f) is being added to emphasize that the instrument is meant to sample a discrete area. Some probes have been observed to have a relatively large inlet area. The addition is necessary so as to provide as much consistency in the identification of leaks as is reasonably possible. All measurements made by EPA in support of its VOC-leaks regulatory development activities have been made with probes not over 1/4 in. in outside diameter.

Section 3.1.2(a) is being revised to include a procedure that is needed for those instances where an instrument is not available that meets the response factor criteria when calibrated with the specified VOC calibration gas. The proposed procedure should meet the spirit of existing VOC-leak regulations.

Finally, Section 3.1.2(b) is being revised by replacing the term "configuration" with all of the items of sampling equipment that might be
between the probe tip and the detector during testing.

II. Administrative Requirements

A. Public Hearing

A public hearing will be held, if requested, to discuss the proposed test method in accordance with Section 307(d)(5) of the Clean Air Act. Persons wishing to make oral presentations should contact EPA at the address given in the ADDRESSES section of this preamble. Oral presentations will be limited to 15 minutes each. Any member of the public may file a written statement with EPA before, during, or within 30 days after the hearing. Written statements should be addressed to the Central Docket Section in Washington, D.C. (see ADDRESSES section of this preamble).

A verbatim transcript of the hearing and written statements will be available for public inspection and copying during normal working hours at EPA’s Central Docket Section in Washington, D.C. (see ADDRESSES section of this preamble).

B. Docket

The docket is an organized and complete file of all the information submitted to or otherwise considered by EPA in the development of this proposed rulemaking. The principle purposes of the docket are: (1) To allow interested parties to identify and locate documents based on interagency review (except for interagency review of the rules) and (2) to serve as the record in case of judicial review (except for interagency review materials) (Section 307(d)(7)(A)).

C. Office of Management and Budget Review

Executive Order 12291 Review. Under Executive Order 12291, EPA must judge whether a regulation is "major" and, therefore, subject to the requirement of a regulatory impact analysis. This rulemaking is not major because it will not have an annual effect on the economy of $100 million or more; it will not result in a major increase in costs or prices; and there will be no significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

D. Regulatory Flexibility Act Compliance

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this attached rule, if promulgated, will not have an economic impact on small entities because no additional costs will be incurred.

This rule does not contain any information collection requirements subject to OMB review under Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

List of Subjects in 40 CFR Part 60

Air pollution control.

Intergovernmental relations, Synthetic Organic Chemicals Manufacturing Industry, Reporting and recordkeeping requirements, and Incorporation by reference.

Date: May 5, 1989.

Don R. Clay,
Acting Assistant Administrator for Air and Radiation.

It is proposed that Method 21, Appendix A of 40 CFR Part 60 be amended as follows:

PART 60—APPENDIX A [AMENDED]

1. The authority for 40 CFR Part 60 continues to read as follows:

Authority: Sections 101, 111, 114, 116, and 301 of the Clean Air Act, as amended (42 U.S.C. 7401 et seq.

Method 21 [Amended]

2. By revising Section 2.4 as follows:

2.4 No Detectable Emission. Any VOC concentration at a potential leak source (adjusted for local VOC ambient concentration) that is less than a value corresponding to the instrument readability specification of Section 3.1.1(c) indicates that a leak is not present.

3. By revising Section 3.1.1(b), (c), (d), and (e) and adding (f) to read as follows:

3.1.1 Specifications.

(a) Both the linear response range and the measurable range of the instrument for each of the VOC to be measured, and for the VOC calibration gas that is used for calibration, shall encompass the leak definition concentration specified in the regulation. A dilution probe assembly may be used to bring the VOC concentration within both ranges; however, the specifications for instrument response time and sample probe diameter shall still be met.

(b) The scale of the instrument meter shall be readable to ±2.5 percent of the specified leak definition concentration when performing a no detectable emission survey.

(c) The instrument shall be equipped with an electrically driven pump to insure that a sample is provided to the detector at a constant flow rate. The nominal sample flow rate, as measured at the sample probe tip, shall be 0.10 to 0.30 liters per minute when the probe is fitted with a glass wool plug or filter that may be used to prevent plugging of the instrument.

(d) The instrument shall be intrinsically safe as defined by the applicable U.S.A. standards (e.g., National Electric Code by the National Fire Prevention Association) for operation in any explosive atmospheres that may be encountered in its use. The instrument shall, at a minimum, be intrinsically safe for Class 1, Division 1 conditions, and Class 2, Division 1 conditions, as defined by the example Code.

The instrument shall not be operated with any safety device such as an exhaust flame arrester, removed.

(f) The instrument shall be equipped with a probe or probe extension for sampling not to exceed 1/4 in. in outside diameter, with a single end opening for admission of sample.

4. By revising Section 3.1.2(a) and (b) to read as follows:

3.1.2 Performance Criteria.

(a) The instrument response factors for each of the VOC to be measured shall be less than 10. When no instrument is available that meets this specification when calibrated with the reference VOC specified in the applicable regulation, the available instrument may be calibrated with one of the VOC to be measured, or any other VOC, so long as the instrument then has a response factor of less than 10 for each of the VOC to be measured.

(b) The instrument response time shall be equal to or less than 30 seconds. The instrument pump, dilution probe (if any), sample probe, and probe filter, that will be used during testing, shall all be in place during the response time determination.

5. By revising Section 3.1.3(a), (b), and (c) as follows:

3.1.3 (a) The instrument pump shall be capable of providing a minimum of 0.10 liters per minute when the probe is fitted with a glass wool plug or filter.

(b) The instrument pump shall be capable of providing a minimum of 0.10 liters per minute when the probe is fitted with a glass wool plug or filter.
that the agency will update these appendices annually, shortly after A.M. Best publishes its revised listings, to reflect changes in premium shares for the insurance companies. (55 FR 62). This rulemaking action implements that pledge. The agency would like to emphasize that this rulemaking does not affect its prior determination that those insurance companies that are statutorily eligible to be exempted from these reporting requirements should, in fact, be exempted therefrom. Instead, this rulemaking simply uses more current data to determine which insurance companies are eligible for such exemptions.

The 1987 calendar year. A.M. Best data for market shares shows that for Appendix A, listing companies which must report. Based on the fact that they had at least one percent of the national market for motor vehicle insurance premiums, the listing remained the same as for the September 1988 final listing. One company, previously identified as "CNA Insurance Group" is now "CNA Insurance Companies." It is proposed that each of these twenty companies be required to file a report not later than October 25, 1989, setting forth the information required by Part 544 for each State in which it did business in the 1988 calendar year.

Appendix B lists those insurers required to report for particular States for 1987, because they had a 10 percent or greater market share of motor vehicle insurance premiums in those States. The 1987 calendar year. A.M. Best data for market shares shows that all set forth the insurance groups listed in the September 1988 final listing for Appendix B would again be required to report on their activities in those States in which they had a 10 percent or greater market share. One group, formerly the Alabama Farm Bureau Group, changed its name to Alfa Insurance Group. One additional insurance group, the Concord Group Insurance Company, which would report on its 1988 activities in the State of Vermont, would be added to Appendix B. Accordingly, it is proposed that, for calendar year 1988, each of these eight groups report on their activities in every State in which they had a 10 percent or greater market share, pursuant to section 612 of the Cost Savings Act.

These reports must be filed no later than October 25, 1989, and set forth the information required by Part 544.
NHTSA has analyzed this proposal and determined that it is neither "major" within the meaning of Executive Order 12291 nor "significant" within the meaning of the Department of Transportation regulatory policies and procedures. If adopted as a final rule, this listing would ensure that all insurance companies that are statutorily eligible for exemption from the insurer reporting requirements are in fact exempted from those requirements. On the other hand, those companies that are not statutorily eligible for an exemption would be expressly required to file reports.

NHTSA does not believe that this proposed rulemaking to reflect more current A.M. Best data would affect the impacts described in the final regulatory evaluation prepared for Part 544. Accordingly, a separate regulatory evaluation has not been prepared for this proposal. Using the cost estimates in the final regulatory evaluation for Part 544, the agency estimates that it would cost the company that would be added to Appendix B about $20,000 to file a report. Thus, the net total impact of these changes is estimated to be a cost increase of about $30,000 for insurance companies. This is well below the threshold of $100 million for classifying a rulemaking action as "major" under the Executive Order.

As noted above, a full regulatory evaluation was prepared for the final rule establishing Part 544. Interested persons may wish to examine that evaluation in connection with this proposal. Copies of that evaluation have been placed in Docket No. T86-01; Notice 2. Any interested person may obtain a copy of this evaluation by writing to: NHTSA Docket Section, Room 5108, 400 Seventh Street SW., Washington, DC 20590, or by calling the Docket Section at 202-366-9949.

The agency has also considered the effects of this proposed rulemaking under the Regulatory Flexibility Act. I certify that this proposed action would not have a significant economic impact on a substantial number of small entities. This proposed action simply applies more current information to determine which insurance companies are statutorily eligible to be exempted from these reporting requirements. NHTSA believes that any insurance company that does not qualify as a "small insurer" within the meaning of section 612 of the Act would also not qualify as a small entity within the meaning of the Regulatory Flexibility Act.

In accordance with the National Environmental Policy Act, the agency has considered the environmental impacts of this proposed rule and determined that, if adopted as a final rule, it would not have a significant impact on the quality of the human environment.

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 on "Federalism," and it has been determined that the proposed rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Interested persons are invited to submit comments on the proposal. It is requested but not required that 10 copies of the comments be submitted. If applicable, it is requested that 2 copies of films, tapes, and other similar materials be provided.

All comments must not exceed 15 pages in length (49 CFR 553.21). Necessary attachments may be appended to these submissions without regard to the 15-page limit. The limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential business information, should be submitted to the Chief Counsel, NHTSA, at the street address given above, and seven copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. A request for confidentiality should be accompanied by a cover letter setting forth the information specified in the agency's confidential business information regulation. 49 CFR Part 512.

All comments received before the close of business on the comment closing date indicated above for the proposal will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Comments received too late for consideration in regard to the final rule will be considered as suggestions for further rulemaking action. Comments on the proposal will be available for inspection in the docket. The NHTSA will continue to file relevant information as it becomes available in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material. Those persons desiring to be notified upon receipt of their comments in the rules docket should enclose a self-addressed, stamped postcard in the envelope with their comments. Upon receiving their comments, the docket supervisor will return the postcard by mail.

List of Subjects in 49 CFR Part 544

Crime insurance, Insurance, Insurance companies, Motor vehicles, Reporting and recordkeeping requirements.

In consideration of the foregoing, it is proposed that 49 CFR Part 544 be amended as follows:

PART 544—[AMENDED]

1. The authority citation for Part 544 would continue to read as follows:


2. Appendix A to Part 544 would be revised to read as follows:

Appendix A to Part 544—Issuers of Motor Vehicle Insurance Policies Subject to the Reporting Requirements in Each State in Which They Do Business

State Farm Group
Allestate Insurance Group
Farmers Insurance Group
Nationwide Group
Aetna Life & Casualty Group
Liberty Mutual Group
Travellers Insurance Group
Harford Insurance Group
USA Group
United States F & G Group
Geico Corporation Group
American International Group
GIGNA Group
Continental Group
FIREMAN'S FUND GROUP
CNA Insurance Companies
California State Auto Association
American Family Group
Progressive Group
Crua & Forster Companies

3. Appendix B to Part 544 would be revised to read as follows:

Appendix B to Part 544—Issuers of Motor Vehicle Insurance Policies Subject to the Reporting Requirements Only in Designated States

Alfa Insurance Group (Alabama)
Island Insurance Group (Hawaii)
Kentucky Farm Bureau Group (Kentucky)
Commercial Union Assurance Group (Maine)
Auto Club of Michigan Group (Michigan)
Southern Farm Bureau Group (Mississippi)
Amica Mutual Insurance Company (Rhode Island)
Concord Group Insurance Company (Vermont)

Issued on May 23, 1989.

Barry Felrice,
Associate Administrator for Rulemaking.

BILLING CODE 4910-59-M
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
Federal Grain Inspection Service

Standards for Rapeseed

AGENCY: Federal Grain Inspection Service, USDA.

ACTION: Request for public comment.

SUMMARY: Notice is hereby given that the Federal Grain Inspection Service (FGIS) is considering proposing official United States standards for common rapeseed (Brassica napus L.) and turnip rapeseed (Brassica campestris L.). Individuals or parties interested in this action are requested to submit comments. Official standards should facilitate and enhance trade of rapeseed and rapeseed products in domestic and international markets. Additionally, official standards should provide uniformity in marketing.

DATE: Comments must be submitted on or before August 28, 1989.

ADDRESS: Comments must be submitted in writing to Lewis Lebakken, Jr., Resources Management Division, USDA, FGIS, Room 0628 South Building, P.O. Box 96454, Washington, DC 20090-6454. Alternatively, telemail users may respond to [IRSTAFF/FGIS/USDA] telemail. Telex users may respond as follows: to Lewis Lebakken, Jr., TLX:7607351, ANS:FGIS UC. Telecopy users may send responses to the automatic telecopier machine at (202) 475-1800.

All comments received will be made available for public inspection at room 0628 South Building, 1400 Independence Avenue SW., Washington, DC, during regular business hours (7 CFR 1.27(b)).

For further information contact: Lewis Lebakken, Jr., address as above, telephone (202) 475-3428.

Supplementary Information: Annual world production of major oils and fats has increased by 52 percent between 1975 and 1985 (from 44,000,000 tons to 66,800,000 tons). Sources of edible oils in the past decade have shifted from animal to plant products. As a result, common rapeseed and turnip rapeseed production has increased by 138 percent. Rapeseed oil imports are projected to increase from the estimated 330 million pounds in the 1987/1988 crop year to 440 million pounds in the 1988/1989 crop year. No statistics are available concerning domestic production.

Rapeseed is increasing in economic importance as an oilseed crop in the United States and may be produced and processed for either industrial or edible oils. Rapeseed oil with greater than 40 percent erucic acid is used for industrial purposes, whereas, rapeseed oil with no greater than 2 percent erucic acid is edible. Rapeseed oil which contains over 2 percent and less than 40 percent erucic acid is not known to have commercial value.

The rapeseed industry in Canada adopted the name “Canola” to refer to those varieties of Brassica napus L. and Brassica campestris L. which are genetically low in erucic acid and glucosinolates. The Food and Drug Administration (FDA) included low erucic acid rapeseed oil (LEAR oil or canola oil) containing no greater than 2 percent erucic acid as safe for use as fats and oils in foods for human consumption except in infant formulas (21 CFR 164.1555(c)); 50 FR 3755 amended at 53 FR 52681). FGIS is considering using the term “Canola” in standards for rapeseed varieties from which canola oil is derived.

As part of its review of this matter, FGIS will evaluate all information including comments received, to determine whether standards, if adopted, should be promulgated pursuant to the U.S. grain standards Act (USGSA; 7 U.S.C. 71 et seq.) or the Agricultural Marketing Act of 1946 (AMA; 7 U.S.C. 1621 et seq.).

The USGSA provides for a national inspection and weighing system for grain which is voluntary for domestic shipments and mandatory for export shipments. Inspection and weighing services under the AMA are provided on request for both domestic and export shipments. Public comments are requested regarding the need for rapeseed standards.

On May 11, 1989 (54 FR 20408), FGIS announced a planned implementation of an updated Hard Red Winter wheat protein calibration for NIR instruments which was to begin on May 15, 1989. The implementation of an updated calibration has been delayed until June 19, 1989, due to technical problems discovered in the transfer of the new calibration to official inspection instruments. The existing calibration and the existing NIR values for the national standard reference samples will continue to be used until June 19, 1989. Since the differences between the existing and new calibrations are very small, this delay should have minimal impact on the national system.


W. Kirk Miller,
Administrator.

Forest Service

Columbia River Gorge National Scenic Area; Minor Boundary Revision

AGENCY: Forest Service, USDA.

ACTION: Notice of final decision on boundary change.

SUMMARY: The Forest Service has made a decision to change the Special Management Area (SMA) boundary of the Columbia River Gorge National Scenic Area (NSA) so that the SMA boundary will coincide with the...
boundary of the Rowena Rural Service Center. To comply with the direction contained in section 4 of the Columbia River Gorge National Scenic Area Act of November 17, 1986 (Pub. L. 99-663), which established the Scenic Area, notice of the boundary change is being published in the Federal Register. The revision involves approximately 11.82 acres of land that was previously SMA and is now reclassified as General Management Area (GMA) land. Notice of the proposed revisions was published in the Federal Register, Vol. 53, No. 230, Wednesday, November 30, 1988.

ADDRESS: Copies of the analysis and decision are available from Columbia River Gorge National Scenic Area, 902 Wasco Ave., Suite 200, Hood River, Oregon 97031.

FOR FURTHER INFORMATION CONTACT: Jurgen Hees, Land Use Coordinator, Hood River, Oregon (503) 386-2333.

SUPPLEMENTARY INFORMATION: The subject parcels are located seven miles northwest of The Dalles, Oregon. The description of the property is the northern part of Tax Lots 100, 400, and 500. The areas are a portion of Government Lot 4 and Donation Claim 37 in Section 11, T. 2 N., R. 12 E., W.M.

500 acres of land that was previously SMA and is now reclassified as General Management Area (GMA) land. Notice of the proposed revisions was published in the Federal Register, Vol. 53, No. 230, Wednesday, November 30, 1988.

The Committee has established the following rules for public participation: After the Board has completed discussion of each topic, the public will be allowed time for questions or comments.

Date: May 19, 1989.

Dennis W. Martin.
Forest Supervisor and Chairman.
[FR Doc. 89-12700 Filed 5-26-89; 8:45 am]
BILLING CODE 3410-11-M

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

Endangered and Threatened Species, Listing and Recovery Priority Guidelines

AGENCY: National Marine Fisheries Service (NOAA Fisheries), NOAA, Commerce.

ACTION: Notice and request for comments.

SUMMARY: NOAA Fisheries has developed draft guidelines governing both the assignment of priorities to species for listing, delisting, and threatened species under the Endangered Species Act of 1973 (Act) and the development and implementation of recovery plans for species that are listed under the Act. Comments are requested from the public.

DATE: Comments on the draft guidelines must be received by July 31, 1989.

ADDRESS: Comments should be sent to Dr. Nancy Foster, Director, Office of Protected Resources and Habitat Programs, National Marine Fisheries Service, 1335 East West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Patricia Montanio, Protected Species Management Division, Office of Protected Resources and Habitat Programs (301/427-2322).

SUPPLEMENTARY INFORMATION:

Background

For those species under the jurisdiction of the Secretary of Commerce, section 4(a) of the Act requires NOAA Fisheries to determine whether any species of wildlife or plant should be: (1) Listed as an endangered or threatened species (listing); (2) changed in status from threatened to endangered (reclassification); or (3) removed from the list (delisting). Section 4(h) of the Act requires that NOAA Fisheries establish agency guidelines which include a priority ranking system for listing, reclassification, or delisting.

Section 4(f) of the Act requires NOAA Fisheries to develop and implement recovery plans for the conservation and survival of all endangered or threatened species, unless such a plan will not promote the conservation of the species. In general, listed species which occur entirely outside U.S. jurisdiction are not likely to benefit from recovery plans. Foreign species are more likely to benefit from bilateral or multilateral agreements under Section 8 of the Act and other forms of international cooperative efforts. Section 4(f) of the Act also requires NOAA Fisheries to give priority to those endangered or threatened species (without regard to taxonomic classification) which are more likely to benefit from such plans, particularly those species that are, or may be, in conflict with construction or other developmental projects or other forms of economic activity. Section 4(h) of the Act requires that NOAA Fisheries establish a system for developing and implementing recovery plans on a priority basis.

The assignment of priorities to listing, reclassification, delisting, and recovery actions will allow NOAA Fisheries to use the limited resources available to implement the Act in the most effective way. These proposed guidelines establish priority systems based on: (1) Magnitude of threat; (2) immediacy of threat; (3) recovery potential of the species; (4) conflict status of the species; (5) management impact; and (6) petition status. Inasmuch as such assessments are subjective to some degree and individual species may not be comparable in terms of all considerations, the proposed priority systems must be viewed as guidelines and should not be interpreted as inflexible frameworks for making such determinations.

These proposed guidelines are based primarily on guidelines published by the U.S. Fish and Wildlife Service (FWS) on September 21, 1983 (48 FR 43098). NOAA Fisheries believes that, to the extent practical, both agencies should follow similar priority guidelines for listing, reclassification, delisting, and recovery. To the extent possible, NOAA Fisheries has adopted the priority guidelines in use by FWS. However, due to the smaller number of listed species and the anticipated smaller number of candidate species under NOAA Fisheries jurisdiction, NOAA Fisheries believes that fewer priority categories are
necessary and the FWS guidelines have been modified accordingly.

A. Listing, Reclassification, and Delisting Priorities

1. Listing and Reclassification from Threatened to Endangered

In considering species to be listed or reclassified from threatened to endangered, two criteria will be evaluated to establish four priority categories as shown in Table 1.

Table 1.—Priorities for Listing or Reclassification from Threatened to Endangered.

<table>
<thead>
<tr>
<th>Magnitude of Threat</th>
<th>Immediacy of Threat</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Imminent</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Non-Imminent</td>
<td>2</td>
</tr>
<tr>
<td>Low to Moderate</td>
<td>Non-Imminent</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4</td>
</tr>
</tbody>
</table>

The first criterion, magnitude of threat, gives a higher listing priority to species facing the greatest threats to their continued existence. Species facing threats of low to moderate magnitude will be given a lower priority. The second criterion, immediacy of threat, gives a higher listing priority to species facing actual threats than to those species facing threats to which they are intrinsically vulnerable, but which are not currently active.

2. Delisting and Reclassification from Endangered to Threatened

NOAA Fisheries currently reviews listed species at least every five years in accordance with section 4(c)(2) of the Act to determine whether any listed species qualify for recategorization or removal from the list. When a species warrants recategorization or delisting, priority for developing regulations will be assigned according to the guidelines given in Table 2. Two criteria will be evaluated to establish six priority categories.

Table 2.—Priorities for Delisting and Reclassification from Endangered to Threatened.

<table>
<thead>
<tr>
<th>Management Impact</th>
<th>Petition Status</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Petitioned Action</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Unpetitioned Action</td>
<td>2</td>
</tr>
<tr>
<td>Moderate</td>
<td>Petitioned Action</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Unpetitioned Action</td>
<td>4</td>
</tr>
<tr>
<td>Low</td>
<td>Petitioned Action</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Unpetitioned Action</td>
<td>6</td>
</tr>
</tbody>
</table>

The priorities established in Table 2 are not intended to direct or mandate decisions regarding a species’ recategorization or removal from the list. The priority system is intended only to set priorities for developing rules for species that no longer satisfy the listing criteria for their particular designation under the Act. The decision regarding whether a species will be retained on the list, and in which category, will be based on the factors contained in section 4(a)(1) of the Act and 50 CFR 424.11.

The first consideration of the system outlined in Table 2 accounts for the management impact entailed by a species’ inclusion on the list. Management impact is the extent of protective actions, including restrictions on human activities, which must be taken to protect and recover a listed species. If the current listing is no longer accurate, continuing protective management actions could divert resources from species more in need of conservation and recovery efforts. Because the Act mandates timely response to petitions, the system also considers whether NOAA Fisheries has been petitioned to remove a species from the list or to reclassify a species from endangered to threatened. Higher priority will be given to petitioned actions than to unpetitioned actions that are classified at the same level of management impact.

There is no direct relationship between the systems outlined in Tables 1 and 2. Although the same statutory criteria apply in making listing and delisting determinations, the considerations for setting listing and delisting priorities are quite different. Candidate species facing immediate, critical threats will be given a higher priority for listing than species being considered for delisting. Likewise, a delisting proposal for a recovered species that would eliminate unwarranted utilization of limited resources may, in appropriate instances, take precedence over listing proposals for species not facing immediate, critical threats.

B. Recovery Plan Preparation and Implementation Priorities

The proposed recovery priority system will be used as a guide for recovery plan development, recovery task implementation and resource allocation. It consists of two parts—species recovery priority and recovery task priority. Species recovery priority will be used for recovery plan development. Recovery task priority, together with species recovery priority, will be used to set priorities for funding and performance of individual recovery tasks as explained below.

1. Species Recovery Priority

Species recovery priority is based on three criteria—magnitude of threat, recovery potential and conflict. These criteria are arranged in a matrix yielding twelve species recovery priority numbers (Table 3).

Table 3.—Species Recovery Priority

<table>
<thead>
<tr>
<th>Magnitude of Threat</th>
<th>Recovery Potential</th>
<th>Conflict</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Conflicting</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No conflicts</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Low to Moderate</td>
<td>Conflicting</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No conflicts</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>Conflicting</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No conflicts</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>Conflicting</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No conflicts</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>9</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>10</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>11</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>12</td>
<td></td>
</tr>
</tbody>
</table>

The first criterion, magnitude of threat, is divided into three categories: high, moderate, and low. The high category means extinction is almost certain in the immediate future because of a rapid population decline or habitat destruction. Moderate means the species will not face extinction if recovery is temporarily held off, although there is a continuing population decline or threat to its habitat. Taxa in the low category are rare, or are facing a population decline which may be a short-term, self-correcting fluctuation, or the impacts of threats to the species’ habitat are not fully known.

The second criterion, recovery potential, assesses that resources are used in the most cost effective manner within each magnitude of threat ranking. Priority for preparing and implementing recovery plans would go to species with the greatest potential for success. Recovery potential is based on how well biological and ecological limiting factors and threats to the species’ existence are understood, and the extent of management actions needed. The recovery potential of a species will be determined by consideration of the criteria given in Table 4.
The third criterion, conflict, reflects the Act’s requirement that recovery priority be given to those species that are, or may be, in conflict with construction or other developmental projects or other forms of economic activity. Thus, species judged as being in conflict with such activities will be given higher priority for recovery plan development and implementation than non-conflict species within the same magnitude of threat/recovery potential ranking. Species in conflict with construction or other developmental projects or other forms of economic activity would be identified in large part through consultations conducted with Federal agencies under section 7 of the Act.

2. Recovery Task Priority

Recovery plans will identify specific tasks that are needed for the recovery of a listed species. Recovery tasks will be assigned priorities of 1 to 3 based on the criteria set forth in Table 5.

Table 5. Recovery Task Priority.

<table>
<thead>
<tr>
<th>Priority</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Priority 1</td>
<td>An action that must be taken to prevent extinction or to prevent the species from Declining irreversibly.</td>
</tr>
<tr>
<td>Priority 2</td>
<td>An action that must be taken to prevent a significant decline in species population, habitat quality, and/or other significant negative impacts Short of extinction.</td>
</tr>
<tr>
<td>Priority 3</td>
<td>All other actions necessary to provide for full recovery of the species.</td>
</tr>
</tbody>
</table>

It should be noted that a Priority 1 ranking is not necessarily given to the highest priority tasks within a plan, rather it is given to those actions, if any, necessary to prevent a species from declining irreversibly. Priority 1 tasks should only apply to species facing a high magnitude of threat (species recovery priority 1–4).

Priority 2 tasks would rank higher than a Priority 3 task for a species with a recovery priority of 1; and, a Priority 1 task for a species with a recovery priority of 2 would rank higher than a Priority 2 task for a species with a recovery priority of 1. For tasks with the same priority ranking, the Assistant Administrator will determine the appropriate allocation of available resources.

C. Recovery Plans

As recovery plans are developed for each species, specific recovery tasks are identified and prioritized according to the criteria discussed above. As new information warrants, these plans, including tasks and priorities, will be reviewed and revised. In addition, funding and implementation of the tasks identified in recovery plans will be tracked in order to aid in effective management of the recovery program. NOAA Fisheries believes that periodic review and updating of plans and tracking of recovery efforts are important elements of a successful recovery program. Information from tracking and implementing recovery actions and other sources will be used to review plans and revise them as necessary. These and other elements of NOAA’s recovery planning process will be discussed in more detail in the draft Recovery Planning Guidelines that the agency is developing.

Classification

The General Counsel of the Department of Commerce certified to the Small Business Administration that these draft guidelines, if adopted, would not have a significant economic impact on a substantial number of small entities because they do not direct or mandate decisions on a species’ listing, recategorization or delisting. Rather, they set up priorities for later decisions as to agency review of species, recovery plan development and recovery task implementation. As a result, a regulatory flexibility analysis was not prepared.

Date: May 23, 1989.

Andrew J. Kemmerer,
Acting Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration.

[FR Doc. 89-12747 Filed 5-26-89; 8:45 am]
BILLING CODE 3510-22-M

Availability for Licensing

AGENCY: National Oceanic and Atmospheric Administration.

ACTION: Notice of availability.

SUMMARY: The invention disclosed and claimed in the U.S. patent application listed below is owned by the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of the results of federally funded research and development.


ADDRESSES: Technical and licensing information may be obtained by writing to: Dr. Mel Eklund, Director, Utilization Research Division, Northwest Fishery Center, National Marine Fisheries Service, 2725 Montlake Boulevard, East, Seattle, Washington 98112

FOR FURTHER INFORMATION CONTACT:
Edward Tierman, 763–4240.
Melvin N.A. Peterson, Chief Scientist.
[FR Doc. 89-12794 Filed 5-26-89; 8:45 am]
BILLING CODE 3510-12-M

Marine Mammals; Application for Permit; Dolphin Services (P324A)

Notice is hereby given that an Applicant has applied in due form for a Permit to take marine mammals as authorized by the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361–1407), and the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216).

1. Applicant: Dolphin Services, Mill Farm, Hurst Green, Brightlingsea, Colchester, Essex CO7 OEH, England.

2. Type of Permit: Public display.
3. Name and Number of Animals: California sea lion (Zalophus californianus).
4. Type of Take: Beached/stranded or captive born.
5. Location of Activity: Sea World, Orlando.
6. Period of Activity: 2 years.

As a request for a permit to take living marine mammals to be maintained in areas outside the jurisdiction of the United States, this application has been submitted in accordance with National Marine Fisheries Service policy concerning such applications (40 FR 11619, March 12, 1975). In this regard, no application will be considered unless:
(a) It is submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, through the appropriate agency of the foreign government;
(b) It includes:
 i. A certification from such appropriate government agency verifying the information set forth in the application;
 ii. A certification from such government agency that the laws and regulations of the government involved permit enforcement of the terms of the conditions of the permit, and that the government will enforce such terms;
 iii. A statement that the government concerned will afford comity to a National Marine Fisheries Service decision to amend, suspend or revoke a permit.

In accordance with the above cited policy, the certification and statements of the Department of the Environment have been found appropriate and sufficient to allow consideration of the permit application.

The arrangements and facilities for transporting and maintaining the marine mammals requested in the above described application have been inspected by a licensed veterinarian, who has certified that such arrangements and facilities are adequate to provide for the well-being of the marine mammals involved.

Concurrent with the publication of this notice in the Federal Register, the Secretary of Commerce is forwarding copies of this application to the Marine Mammal Commission and the Committee of Scientific Advisors.

Written comments and recommendations on the proposed information collection should be sent to Ms. Eyvette R. Flynn at Office of Management and Budget, Desk Officer, Room 3235, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Ms. Pearl Rascoe-Harrison.

Written requests for copies of the information collection proposal may be obtained from Ms. Rascoe-Harrison, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, Virginia 22202-4302.

L.M. Bynum, Alternate OSD Federal Register Liaison Officer, Department of Defense, May 24, 1989.

BILLING CODE 3510-01-M

Office of the Secretary

Defense Manufacturing Board; Meeting

AGENCY: Under Secretary of Defense (Acquisition).

ACTION: Notice of open meeting.

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Office of the Under Secretary of Defense for Acquisition announces a forthcoming meeting of the Defense Manufacturing Board (DMB).


ADDRESS: Hotel de Ville, 80 State Street, Binghamton, NY 13901. The agenda for the meeting will focus on manufacturing technology research.

FOR FURTHER INFORMATION CONTACT: Ms. Grace Shriargian of the DMB Secretariat, (202) 696-7500.

L.M. Bynum, Alternate OSD Federal Register Liaison Officer, Department of Defense, May 24, 1989.

BILLING CODE 3150-01-M

Department of the Army

Science Board; Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following Committee Meeting:

Name of the Committee: Army Science Board (ASB).


Time of Meeting: 0830-1630 hours.

Place: The Pentagon, Washington, DC.
CORPS of Engineers, Department of the Army

Intent To Prepare a Supplement to the Final Environmental Impact Statement, Beach Erosion Control Study, Manatee County, Florida

AGENCY: U.S. Army Corps of Engineers, DOD.

ACTION: Notice of intent.

SUMMARY: The proposal consists of restoration and maintenance at 9-year intervals of 4.2 miles of beach on Anna Maria Key, Manatee County, Florida, to protect threatened upland structures and oceanfront property from wave damage and beach erosion.

FOR FURTHER INFORMATION CONTACT: Questions about the proposed action and the Supplement can be addressed to: Dr. Gerald Atmar, Chief, Environmental Studies Section, U.S. Army Corps of Engineers, P.O. Box 4970, Jacksonville, Florida 32232; 904-791-2615.

SUPPLEMENTARY INFORMATION: 1. The Manatee Beach Erosion Control Project was approved by public works committees of the House and Senate in 1974 and 1975. The project has been coordinated with interested Federal, State, and local agencies and the public since 1970 during feasibility phase studies and development of the preconstruction reports of 1978, 1980, and 1989. A Final Environmental Impact Statement was filed with the Council on Environmental Quality in May 1973. A supplement to the FEIS was filed in September 1978.

2. The 3.9 mile recommended plan presented in the 1978 FEIS supplement has been changed to provide for nourishing 4.2 miles of beach by extending the project at the northern end at Holmes Beach. In addition, two groins would be constructed at the south end of the project to stabilize the shoreline. The initial nourishment will now require 1,704,000 cubic yards of sand and renourishment would occur at 9-year intervals instead of 10-year intervals.

3. Coordination with appropriate Federal and State agencies is required under provisions of the Endangered Species Act and the National Historic Preservation Act.

4. Comments on alternatives and environmental concerns are invited from any affected Federal, State, and local agency, private groups, and individuals. Significant concerns to be addressed in the supplement to the FEIS include alternative borrow sites, presence of historical and/or archeological sites in the project area, impacts on near-shore and offshore rocks, effect on the nearby bait fishery and overall water quality, and status of protected species. Scoping will be conducted by letter. No scoping meeting is scheduled.

5. The Supplement to the FEIS is expected to be available for review in the 4th quarter of 1989.


Mann G. Davis, 
Acting Chief, Planning Division.

BILLING CODE 3710-00-M

Technical Assistance Demonstration Program

AGENCY: Corps of Engineers, Department of the Army, DOD.

ACTION: Notice of availability.

SUMMARY: The purpose of this notice is to inform potential applicants of a Corps of Engineers (Corps) Technical Assistance Demonstration Program. The purpose of the Program is to provide non-exclusive technical assistance to United States firms that are competing for or have been awarded a contract for the planning, design or construction of a project outside the United States. Technical Assistance may be provided to firms operating outside the United States in accordance with the provisions of the Endangered Species Act and the National Historic Preservation Act.


FURTHER INFORMATION CONTACT: Requests for assistance and/or information should be addressed to: Technical Assistance Demonstration Program Manager, HQU/SACE, Attn: CERD-C; 20 Massachusetts Avenue NW., Washington, DC 20314-1000.

SUPPLEMENTAL INFORMATION: Subject to the following criteria, non-exclusive Technical Assistance may be provided on a cost-reimbursable basis to any United States firm which is competing for or has been awarded a contract for the planning, design or construction of a project outside the United States.

- Performance of the work will not interfere with performance of services essential to the mission of the Corps.
- The work is within the scope of authorized activities of the Corps Field Operating Agency (FOA) at which the work is to be performed.
- Technical Assistance will not be provided to a firm which has been debarred or suspended by any agency of the United States Government.
- Technical Assistance will not be provided to a firm which has been awarded a contract for work outside the United States which is being financed directly by the United States Government.
- To request Technical Assistance, a senior executive of a requesting firm will contact HQU/SACE, in writing, at the following address: Technical Assistance Program Manager, CERD-C.
Once the Technical Assistance Program Manager has determined the appropriate FOA to provide assistance, the requesting firm will contact the FOA Commander, either verbally or in writing, to determine the feasibility of the FOA providing assistance. If the FOA Commander determines that the requested assistance is feasible within the mission, resources, and workload of the FOA, the Commander will require the firm to submit a written proposal which includes:

- Description of the assistance required and the anticipated schedule of performance.
- Certification that the assistance and expertise being sought is necessary to effectively compete for or execute the mission, resources, and workload of the FOA for review and approval.
- Firms who are already under contract for a project outside the United States which qualifies for assistance under the Technical Assistance Demonstration Program.

The FOA Commander may not resolve a conflict by accepting the proposal of one United States firm and excluding other United States firms bidding on the same contract, where the other firms have also requested assistance under this Program.

The draft Technical Assistance Program will be submitted to HQUSACE by the FOA for review and approval/disapproval. The draft Technical Assistance Agreement, after coordination with the appropriate staff organizations, will be approved/disapproved by HQUSACE within fifteen (15) working days of receipt from the FOA. Upon approval, the FOA will be authorized to execute the Technical Assistance Agreement when funds are received from the United States firm. In the event the draft Technical Assistance Agreement is not approved, the FOA will notify the requesting firm of the reason(s) for disapproval. The United States firm shall have thirty (30) calendar days from the notification to renegotiate, if possible, the proposed Technical Assistance Agreement or terminate the Technical Assistance request.

The United States firm must provide, in advance of fiscal obligations by the United States, funds to cover all direct and indirect costs of the Technical Assistance. No obligations or expenses will be incurred in connection with the work in excess of funds on deposit with the FOA performing the work. Financial reports covering funds expended and remaining will be provided. Unused funds will be returned to the sponsoring firm by the FOA upon completion or termination of the project. Travel by FOA personnel required by the Technical Assistance Agreement will be performed under Government travel policy and regulations.

If an invention is made or conceived by a Federal Employee while providing assistance pursuant to this Program, the Government will retain, as a minimum, a non-exclusive, non-transferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world. The Government may also:

- Retain all or any rights to such invention as the Secretary deems appropriate.
- Grant or agree to grant to a United States firm an exclusive or non-exclusive patent license or an option there to.
- Waive in whole or in part any right which the United States may have to such invention subject to the license described above.

Intellectual property rights described above may be negotiated and granted or agreed to be granted through a licensing agreement at any time, including as a term of the Technical Assistance Agreement. All licensing agreements, including the collection and distribution of royalties pursuant to such agreement, are subject to the legal authorities and restrictions covered by 35 U.S.C. 207, 15 U.S.C. 371a, and 15 U.S.C. 3710c and implementing regulations.

Information of a confidential nature, such as proprietary or classified information, provided to a United States firm pursuant to this Technical Assistance Demonstration Program shall be protected. Such information may be released by a United States firm only after written approval by the Government. A United States firm’s proposal may include information (data) that the firm does not want disclosed for any purpose other than evaluation and negotiation. If the firm wishes to restrict the dissemination of information (data) presented in the proposal, the proposal must be marked accordingly. Corps employees will not disclose restrictively marked information (data) included in a proposal. The disclosure of such information (data) concerning trade secrets, processes, operations, style of work, apparatus, and other matters, except as authorized by law, may result in criminal penalties under 18 U.S.C. 1905. In any event, information (data) contained in proposals will be protected to the extent permitted by law, but the Government assumes no liability for the use or disclosure of information (data) not restrictively marked.

The United States firm will be provided notice adequate to afford an opportunity to take appropriate action before release of any information (data).
pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. 552; and time permitting, the firm will be consulted to obtain an assistance in determining the eligibility of the information (data) in question as an exception under the Act.

Additional Requirements

Applicants are reminded that a false statement may be grounds for denial or termination of assistance and grounds for possible punishment by a fine or imprisonment. Except where declared by law or approved by the head of an agency, no assistance shall be provided to an applicant who is delinquent on a Federal debt until the delinquent account is made current or satisfactory arrangements are made between affected agencies and the debtor. No assistance will be provided to debarred or suspended contractors.

Classification

This document is not a major rule requiring a regulatory analysis under Executive Order 12291 because it will not have an annual impact on the economy of $100 million or more, nor will it result in a major increase in costs or prices for any group, nor have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. It is not a major Federal action requiring an environmental assessment under the National Environmental Policy Act. The Technical Assistance Demonstration Program does not involve the mandatory payment of any matching funds from a State or local government. Accordingly, the Corps determined that Executive Order 12291 is not applicable to the Program. This notice does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612. The Technical Assistance Demonstration Program is being carried out under the authority of section 9, Water Resources Development Act of 1988 (Pub. L. 100-676) (102 Stat. 4012).


Frank R. Finch,
Colonel, Corps of Engineers, Executive Officer, OASA (C&W).

DEPARTMENT OF ENERGY

Financial Assistance Award; Intent To Award Grant to Albert Engineering

AGENCY: U.S. Department of Energy.

ACTION: Notice of Unsolicited Financial Assistance Award.

SUMMARY: The U.S. Department of Energy (DOE) announces that pursuant to 10 CFR 800.14, it is making a financial assistance award based on a unsolicited application under Grant Number DE-FC01-88CE13312 to Albert Engineering to assist in the development of an invention entitled "A Device for Well Site Monitoring and Control of Rod-Pumped Wells."

Scope: The objectives of this grant are to design, build and install 15 monitoring and control units on operating wells in Oklahoma that are owned by Chevron Oil Company. The proposed technology develops stress data on the above-ground drive unit with a very reliable strain gauge and an inclinometer, both placed in a unitized package with a computer at the fulcrum of the drive. The computer uses these above-ground data in well-known and accepted formulas to continually determine forces on the pump at the bottom of the well. When these forces become too great, the computer stops the drive unit to prevent damage from pump-off or other causes. The computer also continuously adjusts pumping time as a function of down-time to continuously reoptimize pumping economics. Mr. Glenn Albert has a licensing agreement with the University of Oklahoma, to whom the patent was assigned to Dr. John Purcupile, the inventor, who was involved in the initial grant proceedings with the DOE before his death.

Mr. Albert has a degree in Computer Sciences. The Office of Oil and Gas in Fossil Energy of DOE believes this technology is needed, especially if it is reliable. They believe that pumping economics are important to the entire oil industry and especially to the stripper-well segment.

Eligibility: Based on receipt of an unsolicited application, eligibility of this award is being limited to Mr. Albert of Albert Engineering. The market for this technology is the approximately $1 million operating wells in the United States, as mentioned in the evaluation report of the National Institute of Standards and Technology (NIST), formerly the National Bureau of Standards.

The term of this grant shall be two years from date of award.


Thomas S. Keefe,
Director, Contract Operations Division "B", Office of Procurement Operations.

BILLING CODE 5450-01-M

Idaho Operations Office; Intent To Negotiate a Cost-Sharing Grant With American Iron and Steel

AGENCY: Department of Energy.

ACTION: Intent to negotiate a cost-sharing Grant With American Iron and Steel Institute, Washington, DC.

SUMMARY: Direct Steel Making Research

The U.S. Department of Energy (DOE), Idaho Operations Office, has accepted an unsolicited proposal and intends to negotiate, on a noncompetitive basis, a cost-share grant for approximately $30,000,000 with the American Iron and Steel Institute (AISI), Washington DC. AISI will provide cost share equal to thirty percent (30%) of the Government cost. This action is prompted by Pub. L. 99-190 with supplemental appropriations provided under Pub. L. 99-591, and Pub. L. 100-202. The legislation includes a provision that funding be made "available for a research and development initiative * * * to increase significantly the energy effectiveness of processes that produce steel." This project will seek a replacement for the coke-oven, blast-furnace, and basic-oxygen process technology now in use. The objective of the work is to develop a coal based (cokeless), continuous steelmaking process that: requires less energy and lower capital investment; produces steel at a significantly reduced cost; and is a logical step in process development. The authority and justification for determination of noncompetitive financial assistance is DOE Financial Assistance Rules 10 CFR Part 600.14(e)(1) in that the unsolicited application represents a unique and innovative approach that is not the subject of a recent, current, or planned solicitation and DOE has determined that a competitive solicitation would not be appropriate. The work at AISI definitely meets the purpose of Public Law 99-190, which in turn, addresses a public need (viz. increase significantly the energy efficiency of processes that produce steel). In serving this need, the U.S. Steel industry will strengthen its competitive position internationally.
Public response may be addressed to the contract specialist below.


H. Brent Clark,
Director, Contracts Management Division.

Date: April 25, 1989.

[FR Doc. 89-12802 Filed 5-26-89; 8:45 am]
BILLING CODE 6450-01-M

Financial Assistance Award; Intent To Award a Grant to the University of Oklahoma

AGENCY: U.S. Department of Energy.

ACTION: Acceptance of an unsolicited application for a grant award.

SUMMARY: The Department of Energy (DOE), Bartlesville Project Office announces that pursuant to 10 CFR 600.14 (D) and (E), it intends to award a Grant based on an unsolicited application submitted by the University of Oklahoma, for “A Study of Surfactant-Assisted Waterflooding.”

Scope: The objective of this grant project is to increase oil recovery by improving the volumetric sweep efficiency of the recovery process, where the efficiency is a measure of how well the injected fluids are distributed throughout the oil bearing regions of the reservoir. The intended research will (1) perform core floods in reservoirs of varying characteristics, (2) define the viability of the process in the presence of oil, (3) incorporate these results into the reservoir simulator model to further utilize the experimental results that have been utilized in the anionic/cationic surfactants used, and (4) transfer the learned technologies to the oil operators through publications and workshops.

In accordance with 10 CFR 600.14 (D) and (E), the University of Oklahoma has been selected as the grant recipient. This activity would be conducted by the University of Oklahoma based on the meritorious application of the general evaluation. DOE support of the activity would enhance the public benefits to be derived by allowing further coverage of the state’s reservoirs. This activity represents a unique and innovative idea and method which would not be eligible for financial assistance under solicitation, or if, as determined by DOE, a competitive solicitation would be inappropriate.

The term of the grant is for a six month period at an estimated value of $24,850.00. The cost to DOE is anticipated at $24,850.00. There will be no cost sharing.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Energy, Pittsburgh Energy Technology Center, Acquisition and Assistance Division, P.O. Box 10940, MS 921,168, Pittsburgh, PA 15236, Attn: Norey B. Laug, Telephone: (412) 892-4827.

Date: May 15, 1989.

Gregory J. Kawalkin,
Director, Acquisition and Assistance Division, Pittsburgh Energy Technology Center.

[FR Doc. 89-12803 Filed 5-26-89; 8:45 am]
BILLING CODE 6450-01-M

Financial Assistance Award; Intent To Award Grant to Utah Transmission Corporation

AGENCY: U.S. Department of Energy.


SUMMARY: The U.S. Department of Energy announces that pursuant to 10 CFR 600.14, it is making a financial assistance award based on an unsolicited application under Grant Number DE-FG01-89CE15420 to Utah Transmission Corporation (UTC) in the development of an invention entitled “The Utah Transmission.”

Scope: This grant will assist UTC by supporting the engineering and construction of a prototype which will be test under an existing agreement between UTC and the U.S. Postal Service (USPS).

The invention is a continuously variable transmission (CVT) which utilizes a one-way clutch principle and a variable cam drive. Two or more variable-lift cam-and-lever arrangements are used to transmit power to a single output shaft. Speed changes are accomplished by moving a cam, which varies continuously in diameter longitudinally, under the cam followers to achieve changes in the throw of the follower levers.

The successful development of the Utah transmission for automotive applications holds the prospect of very substantial improvements in vehicle fuel economy because current transmission designs are inefficient translators of power. The advantages of the Utah transmission are particularly impressive in their application to delivery type vehicles which operate on short, urban driving cycles involving many stops in a short distance. It is estimated that use of this transmission in the USPS fleet of delivery vehicles would result in fuel savings of up to 28 million gallons of fuel annually.

The probability of fulfilling the objectives of the grant is high as the grantee has demonstrated, through prior investment of resources and reduction of the design concept to practice, commitment and capability. The principal investigator under the grant is the inventor of the technology.

Eligibility: Based on receipt of an unsolicited application, eligibility for this award is being limited to Utah Transmission Corporation. Mr. Laird Coggin, president of UTC, is the inventor of the technology. UTC’s unique experience in working with this technology will be applied to the efforts foreseen under this grant as will its technical data base and human resources. The same toolmaking resources that have been utilized in reduction of this technology to a five horsepower prototype will be employed in scaling the technology up to the 95 horsepower model envisioned herein.

The term of this grant shall be for two years from the effective date of award.


Thomas S. Keefe,

[FR Doc. 89-12804 Filed 5-26-89; 8:45 am]
BILLING CODE 6450-01-M

Voluntary Agreement and Plan of Action to Implement the International Energy Program; Meetings

In accordance with section 252(c)(1)(A)(i) of the Energy Policy and Conservation Act (42 U.S.C. 6272(c)(1)(A)(i)), the following meeting notices are provided:

I. A meeting of the Industry Advisory Board (IAB) to the International Energy Agency (IEA) will be held on Tuesday, June 6, 1989, at the offices of the Organization for Economic Cooperation and Development, Chateau de la Muette, 2, rue Andre Pascal, Paris, France, beginning at 8:30 a.m. The purpose of this meeting is to permit attendance by representatives of U.S. company members of the IAB at (i) a meeting of the IEA’s Standing Group on Emergency Questions (SEQ) which is scheduled to be held at the aforesaid location on that date, beginning at 9:00 a.m., and (ii) a preliminary meeting among IAB members, which is scheduled to begin at 8:30 a.m. on the same date and at the same location, at which IAB members will have an opportunity to comment on...
the items on the agenda for the SEQ meeting. The agenda for the meeting is under the control of the SEQ. It is expected that the following draft agenda will be followed:

1. Adoption of the Agenda
2. Summary Record of the 61st Meeting
3. Report on IEA Governing Board Meeting at Ministerial Level
4. 1990 Program of Work
5. Future Testing of IEA Emergency Response Systems
   - Emergency Management Manual Update; Points Arising from Allocation Systems Test No. 6 (AST-6)
   - Coordinated Emergency Response Measures Test 2: Questionnaire A/Questionnaire B Submission; Allocation Systems Test No. 7
   - Other Training Operations
7. Summary of Energy Emergency Legislation of Countries
   - Report on IEA Governing Board
   - Draft Questionnaire and Work Program
   - Tentative Calendar for Reviews
   - Summary of Emergency Response Issues in Standing Group on Long Term Cooperation/Committee on Research and Development Country Reports
   - Summary of Energy Emergency Legislation of IEA Member Countries
   - Review of Member Countries' Emergency Response Programs
   - Draft Questionnaire and Work Program
   - Tentative Calendar for Reviews
   - Summary of Emergency Response Issues in Standing Group on Long Term Cooperation/Committee on Research and Development Country Reports
   - Summary of Energy Emergency Legislation of IEA Member Countries
   - Review of Member Countries' Legislation
   - Administrative Procedures and Policy Attitudes Concerning the Use of Stocks in Supply Disruptions
   - Demand Restraint
8. AST-6 Follow-up
   - AST-6 Appraisal Report by the Secretariat
9. Emergency Reserve Situation of IEA Countries
   - IEA Country Emergency Reserve—Calculation Method Chosen
   - Emergency Reserve and Net Import Situations of IEA Member Countries
   - Bilateral Stocks—Review of Legislation of Countries' Government Stocks Held Abroad and the Status of Stocks Held in Countries with Bilateral Agreements
10. Emergency Data Systems
    - Review of Questionnaire A/Questionnaire B Reporting Instructions
    - Base Period Final Consumption 1Q88–4Q88
    - Monthly Oil Statistics (MOS) to February 89 MOS to March 89 Questionnaire C Data to June 89
    - Availability of Oil Trade Statistics for Individual EEC Countries Post 1982
    - Workshop on Practical Aspects of Stockholding and Stockdraw
    - Progress Report by Chairman of Consultation Group
    - Quarterly Oil Forecast 2Q89/1Q90
    - Normal Domestic Production
    - IAB Issues
    - Any Other Business
    - End-May Monthly Oil Report
    - Industry Restructuring—Oral Report on Standing Group on the Oil Market Discussion
    - Membership of National Emergency Sharing Organizations and ISAG
    - Date of Next Meeting.

II. A meeting of the IAB will be held on Wednesday, June 7, 1989, at 9:30 a.m., at the offices of the IEA, 2, rue Andre Pascal, Paris, France. This meeting is being held to permit attendance by representatives of U.S. company members of the IAB at a meeting of representatives of Participating Countries which is scheduled to be held at the aforesaid location on June 7 for the purpose of advising the IEA Secretariat in its preparations for a workshop on the subject of "Practical Aspects of Stockholding and Stockdraw." The principal participants at the meeting are expected to be representatives of Participating Countries. The agenda for the meeting is under the control of the Secretariat. It is expected that the agenda will cover the following items:

1. Introductory Remarks
2. Draft Agenda for Workshop on Practical Aspects of Stockholding and Stockdraw, Together with Issues Raised by Participants at the Meeting or at the June 6, 1989 Meeting of the Standing Group on Emergency Questions
3. Any Other Business

As provided in section 252(c)(1)(A)(ii) of the Energy Policy and Conservation Act, the foregoing meetings are open only to representatives of members of the IAB, their counsel, representatives of members of the IEA's Standing Group on Emergency Questions (SEQ), representatives of the Departments of Energy, Justice, State, the Federal Trade Commission, and the General Accounting Office, representatives of Committees of the Congress, representatives of the IEA, representatives of the Commission of the European Communities, and invitees of the IAB, the SEQ, or the IEA.

Federal Energy Regulatory Commission

[Docket Nos. ID-1655-000 et al.]

Margaret L. Huber et al.; Electric Rate, Small Power Production, and Interlocking Directorate Filings

Take notice that the following filings have been made with the Commission:

1. Margaret L. Huber
   [Docket No. ID-1655-000]

Take notice that on April 24, 1989, Margaret L. Huber tendered for filing a notice of filing, terminating the following positions:

<table>
<thead>
<tr>
<th>Position</th>
<th>Corporation</th>
<th>Termination date</th>
</tr>
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<tbody>
<tr>
<td>Assistant Secretary, Do.</td>
<td>The Cincinnati Gas &amp; Electric Co.</td>
<td>Apr. 1, 1989.</td>
</tr>
<tr>
<td>Do.</td>
<td>The Union Light, Heat and Power Co.</td>
<td>Do.</td>
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<tr>
<td>Do.</td>
<td>Miami Power Corp.</td>
<td>Do.</td>
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</tbody>
</table>

Comment date: June 5, 1989, in accordance with Standard Paragraph E at the end of this notice.

W. G. Kuhns

[Docket No. ID-1333-001]

Take notice that on May 3, 1989, W. G. Kuhns tendered for filing a notice of terminating the following positions:

General Public Utilitie Corporation
Chairman, Chief Executive Officer
Jersey Central Power & Light Company
Chairman of the Board, Chief Executive Officer and Director
Metropolitan Edison Company
Chairman of the Board, Chief Executive Officer
Pennsylvania Electric Company
Chairman of the Board, Chief Executive Officer
GPU Nuclear Corporation
Director

Comment date: June 5, 1989, in accordance with Standard Paragraph E at the end of this notice.

Iowa Public Service Company

[Docket No. ER89-430-000]

Take notice that Iowa Public Service Company (IPS) on May 11, 1989, tendered for filing an Electric Utility Services Agreement between IPS and the Municipal Electric Utility of Waverly, Iowa (Waverly) and an Interim Wheeling Letter Agreement


Eric J. Fygt,
Acting General Counsel.
whereby IPS will supply intermediate and peaking capacity of Waverly, as well as provide dispatch and transmission services. IPS has requested an effective date of May 1, 1989 for the initial rate, and accordingly seeks waiver of the notice requirements of the Commission's rules.

IPS states that copies of this filing were served on Waverly and the Iowa Utilities Board.

Comment date: June 5, 1989, in accordance with Standard Paragraph E at the end of this notice.

4. New York State Electric & Gas Corporation

[Docket No. ER89-426-000]


Take notice that New York State Electric & Gas Corporation (NYSEG) tendered for filing on May 11, 1989, tendered for filing pursuant to Section 35.12 of the Expansion Power between NYSEG and the Power Authority of the State of New York (the Authority). The agreement sets forth the terms and conditions that govern NYSEG's transmission and delivery of Expansion Power and associated energy to certain of NYSEG's industrial customers.

NYSEG has filed a copy of this filing with the Authority, the Public Service Commission of the State of New York, and with Expansion Power Customers with which NYSEG has signed agreements.

NYSEG states that since the agreement provides for the continuation of a service that has been provided since 1961 and since all parties have agreed to the terms and conditions of the proposed rate schedule, NYSEG requests that the 60-day filing requirement be waived and that April 23, 1989 be allowed as the effective date of the filing.

Comment date: June 5, 1989, in accordance with Standard Paragraph E at the end of this notice.

5. Consumers Power Company

[Docket No. ES89-23-000]


Take notice that on May 17, 1989, Consumers Power Company filed an application pursuant to Section 204 of the Federal Power Act seeking authority to issue and sell up to $750,000,000 unsecured short-term commercial paper notes pursuant to a May 1, 1989 Credit Agreement. The issuance and sale of the unsecured short-term commercial paper notes would be from time to time, during the period June 5, 1988 through June 3, 1990 with maturities of 270 days or less.

Comment date: June 7, 1989, in accordance with Standard Paragraph E at the end of this notice.

6. The University of Texas System (Richardson, Texas)

[Docket No. QF89-217-000]

May 23, 1989.

On May 11, 1989, The University of Texas System (Applicant), of 702 Colorado Street, Suite 400, Austin, Texas 78701 submitted for filing an application for certification of a facility as a qualifying cogeneration facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The topping-cycle cogeneration facility will be located in Richardson, Texas. The facility will consist of a dual fuel engine internal combustion generator and a waste heat recovery boiler. Thermal energy recovered from the facility will be used to heat the campus buildings. The net electric power production capacity is 3,470 kilowatts. The primary energy sources will be natural gas and diesel fuel. The facility was installed in July 1979 and became fully operational in January 1980.

Comment date: Thirty days from publication in the Federal Register, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. 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, 825 North Capital Street N.E., Washington, D.C. 20426 in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. 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 proceeding. 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. 89-12682 Filed 5-26-89; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. QF87-241-002]

Soledad Energy Partnership; Application for Commission Certification of Qualifying Status of a Small Power Production Facility

May 24, 1989.

On May 8, 1989, Soledad Energy Partnership (Applicant), c/o ONSITE
Soledad, Inc., of 306 SW First Avenue, Suite 200, Portland, Oregon 97204 submitted for filing an application for certification of a facility as a qualifying small power production facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing. The biomass-fired small power production facility will be located at Los Coches Industrial Park, Los Coches Drive, Soledad, Monterey County, California. The primary energy source will consist of forest residues, agricultural biomass, plantation wood fuel, and/or urban waste wood. The net electric power production capacity of the facility will be 12 MW.

Any person desiring to be heard or objecting to the granting of qualifying status should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426. In accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such petitions or protests must be filed within 30 days after the date of publication of this notice and must be served on the applicant. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protesters parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,
Secretary.[FR Doc. 89-12864 Filed 5-26-89; 8:45 am]
BILLING CODE 6717-01-M

[Project No. 6623-003]

Hydro-West, Inc.; Availability of the Environmental Assessment

May 24, 1989.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) regulations, 18 CFR Part 380 (Order No. 496, 52 FR 47897), the Office of Hydropower Licensing has reviewed the application for exemption from licensing for the proposed Bridal Veil Water Power Hydropower Project located on Bridal Veil Creek in San Miguel County, Colorado, and has prepared an Environmental Assessment (EA) for the project. In the EA, the Commission's staff has analyzed the potential environmental impacts of the proposed project and has concluded that approval of the proposed project, with appropriate mitigation measures, would not constitute a major federal action significantly affecting the quality of the human environment.

Copies of the EA are available for review in the Public Reference Branch. Room 1000, of the Commission's offices at 825 North Capitol Street NE., Washington, DC 20426.

Lois D. Cashell,
Secretary.

[Docket Nos. RP87-86-009, RP86-11-006, RP85-11-023 (Phase II), RP89-110-003, RP89-111-003]

K N Energy, Inc.; Proposed Changes in FERC Gas Tariff

May 23, 1989.

Take notice that K N Energy, Inc. ("K N") on May 17, 1989 tendered for filing revised tariff sheets in compliance with the Commission's April 12, 1989 Order Accepting for Filing and Suspending Tariff Sheets, Subject to Refund and Conditions, Granting Waiver, and Establishing Hearing Procedures. The proposed effective date for these tariff sheets is April 1, 1989.

Copies of the filing were served upon K N's jurisdictional customers, interested public bodies, and all parties on the official service list.

Any person desiring to protest said filing should, on or before May 31, 1989, file with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, a protest in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 355.211, 355.214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protesters parties to the proceedings. Persons that are already parties to this proceeding need not file a motion to intervene in this matter. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,
Secretary.

[FRC Doc. 89-12864 Filed 5-26-89; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. RP89-137-001]

Northwest Pipeline Corp.; Change in FERC Gas Tariff

May 23, 1989.

Take notice that on May 19, 1989, Northwest Pipeline Corporation [Northwest] filed Second Substitute Ninth Revised Sheet No. 41 to its FERC Gas Tariff, Second Revised Volume No. 1, to be effective March 2, 1989. Northwest states that this tariff sheet is filed in compliance with the Commission's order of May 1, 1989.

Northwest states that this tariff sheet includes in the base tariff rate the interim PGA adjustment which became effective on March 1, 1989 in Docket No. TF89-3-46-000. Northwest states that this filing is being served upon all parties to this proceeding and upon each of its customers and the Public Service Commissions of Kentucky, Pennsylvania and West Virginia.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 355.211, 355.214 (1988)). All such motions or protests should be filed on or before May 23, 1989. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protesters parties to the proceeding. 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.

[FRC Doc. 89-12869 Filed 5-26-89; 8:45 am]
BILLING CODE 6717-01-M
verbal settlement that was retracted by the producer.

Northwest states that the net effect of these corrections is a slight reduction in the total amount of buyout/buydown costs from $70,930.231.58 to $70,017.541.32, or a reduction of $12,690.26. Northwest requests an effective date of April 1, 1989, for this filing.

A copy of this filing is being served on all affected customers, affected state commission, and parties to this proceeding.

Any person desiring to be heard or protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before May 31, 1989. 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 proceeding.

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 in the Public Reference Room.

Lois D. Caswell, Secretary.

[FR Doc. 89-12691 Filed 5-26-89; 8:45 am] BILLING CODE 6717-01-M

[Docket No. RP89-173-000]

Questar Pipeline Co.; Petition for Declaratory Order or, in the Alternative, Petition for Waiver of Regulation


Take notice that on May 12, 1989, Questar Pipeline Company (Questar), 180 East First South Street, Salt Lake City, Utah 84111, filed a petition for an order declaring that §157.206(h) of the Commission's Regulations does not apply to gas storage service that may be rendered under Questar's Rate Schedules S-1 and S-3 using excess capacity at its Clay Basin gas storage field, Daggett County, Utah, pursuant to § 157.213 of the Commission's Regulations and its blanket certificate issued in Docket No. CP82-491-000. However, if the Commission finds that § 157.206(h) is applicable to such storage service, then, in the alternative, Questar Pipeline requests, pursuant to Rule 207[a][5] of the Commission's Rules of Practice and Procedure, 18 CFR 385.207[a][5] (1988), a waiver of the revenue crediting requirement of § 157.206(h) with respect to service under its Rate Schedules S-1 and S-3.

Any person desiring to be heard or to make any protest with reference to said petition should on or before June 21, 1989, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 or 385.211. All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding.

Lois D. Caswell, Secretary.

[Vol. 54, No. 102 / Tuesday, May 30, 1989 / Notices]

[Docket Nos. CP89-1364-000 et al.]

Stingray Pipeline Company et al.; Natural Gas Certificate Filings


Take notice that the following filings have been made with the Commission:

1. Stingray Pipeline Company

[Docket No. CP89-1364-000]

Take notice that on May 12, 1989, Stingray Pipeline Company (Stingray), P.O. Box 1642, Houston, Texas 77251-1642, filed in Docket No. CP89-1360-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to provide an interruptible transportation service for Williams Gas Marketing Company (Williams), a marketer, under the blanket certificate issued by the Commission's Order No. 509, pursuant to Section 7 of the Natural Gas Act, corresponding to the rates, terms and conditions filed in Docket No. RP99-79-000, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Stingray states that pursuant to a transportation agreement dated March 23, 1989, under its Rate Schedule ITS, it proposes to transport up to 100,000 dekatherms (dt) per day equivalent of natural gas for Williams. Stingray states that it would transport the gas from various receipt points on its system as shown in Exhibit "A" of the transportation agreement and would deliver the gas, less fuel used and unaccounted for line loss, to Holly Beach and OXY-NGL plant, both located in Cameron Parish, Louisiana, and Stingray-HIOS Exchange (EHI-A330) located offshore Texas.

Stingray advises that service under § 284.223(a) commenced April 1, 1989, as reported in Docket No. ST89-3153. Stingray further advises that it would transport 25,000 dt on an average day and 9,125,000 dt annually.

Comment date: July 6, 1989, in accordance with Standard Paragraph G at the end of this notice.

2. Stingray Pipeline Company

[Docket No. CP89-1360-000]

Take notice that on May 12, 1989, Stingray Pipeline Company (Stingray), P.O. Box 1642, Houston, Texas 77251-1642, filed in Docket No. CP89-1360-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to provide an interruptible transportation service for Williams Gas Marketing Company (Williams), a marketer, under the blanket certificate issued by the Commission's Order No. 509, pursuant to Section 7 of the Natural Gas Act, corresponding to the rates, terms and conditions filed in Docket No. RP99-70-000, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Stingray states that pursuant to a transportation agreement dated March 23, 1989, under its Rate Schedule ITS, it proposes to transport up to 100,000 dekatherms (dt) per day equivalent of natural gas for Williams. Stingray states that it would transport the gas from various receipt points on its system as shown in Exhibit "A" of the transportation agreement and would deliver the gas, less fuel used and unaccounted for line loss, to Holly Beach and OXY-NGL plant, both located in Cameron Parish, Louisiana, and Stingray-HIOS Exchange (EHI-A330) located offshore Texas.

Stingray advises that service under § 284.223(a) commenced April 1, 1989, as reported in Docket No. ST89-3153. Stingray further advises that it would transport 25,000 dt on an average day and 9,125,000 dt annually.

Comment date: July 6, 1989, in accordance with Standard Paragraph G at the end of this notice.

3. Stingray Pipeline Company

[Docket No. CP89-1361-000]

Take notice that on May 12, 1989, Stingray Pipeline Company (Stingray), P.O. Box 1642, Houston, Texas 77251-1642, filed in Docket No. CP89-1361-000 a request pursuant to §157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for
authorization to provide transportation service for Chevron U.S.A., Inc. (Chevron), a shipper and producer of natural gas, under Stingray's blanket certificate issued by the Commission's Order No. 509 pursuant to section 7 of the Natural Gas Act, with corresponding rates, terms and conditions filed in Docket No. RP89-70-000, all as more fully set forth in the request on file with the Commission and open for public inspection.

Stingray states that it would transport up to 75,000 Dt. equivalent of natural gas per day on an interruptible basis on behalf of Chevron pursuant to a transportation agreement dated March 23, 1989, between Stingray and Chevron. It is stated that the transportation agreements provides for Stingray to receive gas from various existing points of receipt on its system, and then Stingray would then transport and redeliver subject gas, less fuel used and unaccounted for line loss, to Holly Beach and OXY-NGL plant located in Cameron Parish, Louisiana, and Stingray-HIOS Exchange located offshore Texas. It is further stated the estimated daily and estimated annual quantities would be 75,000 Dt and 27,375,000 dt equivalent of natural gas, respectively.

Stingray states that it commenced the transportation of natural gas for Chevron on April 1, 1989, as reported in Docket No. ST89-3145 for a 120-day period, pursuant to § 284.223(a)(1) of the Commission's Regulations. Stingray further states existing facilities would be used in order to provide this transportation service.

Comment date: July 6, 1989, in accordance with Standard Paragraph G at the end of this notice.

4. Stingray Pipeline Company

[Docket No. CP-89-1366-000]

Take notice that on May 12, 1989, Stingray Pipeline Company (Stingray), P.O. Box 1642, Houston, Texas 77251–1642, filed in Docket No. CP89–1366–000 a request pursuant § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to transport natural gas for Brandywine Industrial Gas, Inc. (Brandywine), a marketer of natural gas, under its blanket certificate issued in Docket No. CP88-6–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

United states that it would transport a maximum daily quantity of 18,540 MMBtu for Brandywine pursuant to an interruptible Gas Transportation Agreement dated April 13, 1989, between United and Brandywine. United further states that it would receive the natural gas at an existing point of receipt in offshore Texas and would redeliver the natural gas at existing points of delivery in offshore Texas. United indicates that the estimated average daily and annual quantities to be transported would be 18,540 MMBtu and 8,707,100 MMBtu, respectively.

United states that it commenced the transportation of natural gas for Brandywine on April 1, 1989, as reported in Docket No. ST89–3223–000, for a 120-day period pursuant to § 284.223(a) of the Commission's Regulations (18 CFR 284.223(a)).

Comment date: July 6, 1989, in accordance with Standard Paragraph G at the end of this notice.

7. Texas Gas Transmission Corporation

[Docket No. CP89-1374-000]

Take notice that on May 15, 1989, Texas Gas Transmission Corporation (Texas Gas), 3800 Frederical Street, Owensboro, Kentucky 42301, filed in Docket No. CP89-1374–000 a request pursuant to §§ 157.205 and 284.223 of the Commission's Regulations for authorization to transport natural gas for Special Metals Corporation (Special Metals), under Texas Gas' blanket certificate issued in Docket No. CP88–666–000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with
Texas Gas proposes to transport on an interruptible basis up to 1,000 MMbtu of natural gas on a peak day, 445 MMbtu on an average day and 162,435 MMbtu on an annual basis for Special Metals. Texas Gas states that it would perform the transportation service for Special Metals under Texas Gas' Rate Schedule IT. Texas Gas indicates that it would transport the gas from various receipt points to a delivery point located in Warren County, Ohio.

It is explained that the service commenced April 1, 1989, under the automatic authorization provisions of § 284.223 of the Commission's Regulations, as reported in Docket No. ST89-2978. Texas Gas indicates that no new facilities would be necessary to provide the subject service.

Comment date: July 6, 1989, in accordance with Standard Paragraph G at the end of this notice.

9. Texas Gas Transmission Corporation

[Docket No. CP89-1376-000]

Take notice that on May 15, 1989, Texas Gas Transmission Corporation (Texas Gas), 3800 Frederica Street, Owensboro, Kentucky 42301, filed in Docket No. CP89-1376-000 a request pursuant to §§ 157.205 and 284.223 of the Commission's Regulations for authorization to transport natural gas for PPG Industries, Inc.-Delaware (PPG-Delaware), under Texas Gas' blanket certificate issued in Docket No. CP88-686-000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Texas Gas proposes to transport on an interruptible basis up to 8,500 MMbtu of natural gas on a peak day, 650 MMbtu on an average day and 310,250 MMbts on an annual basis for PPG-Delaware. Texas Gas states that it would perform the transportation service for PPG-Delaware under Texas Gas' Rate Schedule IT. Texas Gas indicates that it would transport the gas from various receipt points to a delivery point located in Warren County, Ohio.

It is explained that the service commenced April 1, 1989, under the automatic authorization provisions of § 284.223 of the Commission's Regulations, as reported in Docket No. ST89-3022. Texas Gas indicates that no new facilities would be necessary to provide the subject service.

Comment date: July 6, 1989, in accordance with Standard Paragraph G at the end of this notice.

10. Texas Gas Transmission Corporation

[Docket No. CP89-1404-000]

Take notice that on May 16, 1989, Texas Gas Transmission Corporation, (Texas Gas), 3800 Frederica Street, Owensboro, Kentucky 42301, filed in Docket No. CP89-1404-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to transport natural gas on behalf of System Supply for End-Users, Inc. (System Supply), under its blanket authorization issued in Docket No. CP88-686-000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Texas Gas would perform the proposed interruptible transportation service for System Supply, pursuant to a gas transportation agreement dated November 11, 1988. The term of the transportation agreement is from the date of execution by System Supply and shall continue in effect month-to-month thereafter, unless terminated upon 30 days written notice by either party. Texas Gas proposes to transport on a peak day up to 30,000 MMbts; an average day up to 20,000 MMbts; and on an annual basis 7,300,000 MMbts for System Supply. Texas Gas proposes to receive the subject gas from exiting points of receipt on its system for transportation and redelivery for System Supply's accounts at existing points of delivery in Arkansas, Louisiana, Tennessee, and Mississippi. The proposed rate to be charged is contained in Texas Gas' currently effective rate schedule. It is stated that the ultimate recipients of the gas are Ralston Purina Co. and E. I. Du Pont De Nemours & Co. It is further stated that the proposed transportation is being rendered through the use of Texas Gas' existing facilities.

It is explained that the proposed service is currently being performed pursuant to the 120-day self-implementing provision of § 284.223(a)(1) of the Commission's Regulations. Texas Gas commenced such self-implementing service on April 1, 1989, as reported in Docket No. ST89-3023-000.

Comment date: July 6, 1989, in accordance with Standard Paragraph G at the end of this notice.

11. Columbia Gulf Transmission Company

[Docket No. CP88-1399-000]

Take notice that on May 15, 1989, Columbia Gulf Transmission Company (Columbia Gulf), 3805 West Alabama, Houston, Texas 77027, filed in Docket No. CP88-1399-000 a request pursuant to §§ 157.205 and 284.223 of the Commission's Regulations (18 CFR 157.205 and 284.223) for authorization to transport on an interruptible basis, on behalf of Exxon Corporation (Exxon), a marketer of natural gas, under its blanket certificate issued in Docket No. CP86-239-000, all as more fully set forth in the request on file with the Commission and open to public inspection.

Columbia Gulf proposes to transport natural gas for Exxon on an interruptible basis, pursuant to a gas transportation agreement dated February 19, 1988, as amended. It is stated that the volume anticipated to be transported on a peak day is a maximum of up to 40,000 MMbts equivalent of natural gas per...
day, an average day of up to 25,000 MMBtu equivalent of natural gas per day, and up to 14,000,000 MMBtu equivalent of natural gas on an annual basis. Columbia proposes to receive the gas in St. Mary, Iberia and Cameron Parishes, Louisiana, and proposes to redeliver the gas for Exxon to points in Vermilion and St. Mary Parishes, Louisiana. Columbia Gulf states that this transportation service commenced for Exxon on February 1, 1989, pursuant to the 120-day automatic provisions of § 284.223(a) of the Commission’s Regulations, as reported in Docket No. ST89–2305–000.

**Comment date:** July 6, 1989, in accordance with Standard Paragraph G at the end of this notice.

12. Stingray Pipeline Company
[Docket No. CP89–1391–000]

Take notice that on May 15, 1989, Stingray Pipeline Company (Stingray), P.O. Box 1842, Houston, Texas 77251–1642, filed in Docket No. CP89–1391–000 a request pursuant to § 157.205 of the Commission’s Regulations under the Natural Gas [18 CFR 157.205] for authorization to provide an interruptible transportation service for Consolidated Fuel Corporation (Consolidated), a marketer, under the blanket certificate issued by the Commission’s Order No. 598, pursuant to Section 7 of the Natural Gas Act, corresponding to the rates, terms and conditions filed in Docket No. RP89–70–000, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Stingray states that pursuant to a transportation agreement dated March 23, 1989, under its Rate Schedule ITS, it proposes to transport up to 50,000 dekatherms (dt) per day equivalent of natural gas for Consolidated. Stingray states that it would transport the gas from various receipt points on its system as shown in Exhibit “A” of the transportation agreement and would deliver the gas, less fuel used and unaccounted for line loss, to Holly Beach and OXY–NGL plant, both located in Cameron Parish, Louisiana, and Stingray–HIOS Exchange (EHII–A330) located offshore Texas.

Stingray advises that service under § 284.223(a) commenced April 1, 1989, as reported in Docket No. ST89–3205. Stingray further advises that it would transport 10,000 dt on an average day and 3,650,000 dt annually.

**Comment date:** July 6, 1989 in accordance with Standard Paragraph G at the end of this notice.

3. El Paso Natural Gas Company
[Docket No. CP89–1391–000]

Take notice that on May 15, 1989, El Paso Natural Gas Company (El Paso), Post Office Box 1492, El Paso, Texas 79978, filed a request for authorization at Docket No. CP89–1391–000, pursuant to § 157.205 and 284.223 of the Commission’s Regulations Under the Natural Gas Act, to provide interruptible transportation service for Meridian Oil Trading Inc. (Shipper), under its blanket certificate issued at Docket No. CP89–433–000, all as more fully set forth in the request for authorization on file with the Commission and open for public inspection.

El Paso requests authority to transport up to 316,500 MMBtu of natural gas per day for Shipper from any point of receipt on El Paso’s system to a point of delivery at the borderline between the States of Arizona and California. El Paso states that the estimated daily and annual quantities would be 316,500 MMBtu and 115,522,500 MMBtu, respectively. El Paso furthers states that transportation service under § 284.223(a) commenced on April 6, 1989, as reported at Docket No. ST89–3332–000.

**Comment date:** July 6, 1989 in accordance with Standard Paragraph G at the end of this notice.

6. El Paso Natural Gas Company

El Paso requests authority to transport 10,000 dt on an average day and 3,650,000 dt annually.

**Comment date:** July 6, 1989 in accordance with Standard Paragraph G at the end of this notice.

Docket Nos. CS73–100–001, et al.)

RAMA Operating Co., Inc. (Kansas Gas Purchasing), et al.; Applications for Small Producer Certificates


Take notice that each of the Applicants listed herein has filed an application pursuant to section 7(c) of the Natural Gas Act and § 157.40 of the Commission’s Regulations thereunder for a small producer certificate of public convenience and necessity authorizing the sale for resale and delivery of natural gas in interstate commerce, all as more fully set forth in the applications which are on file with the Commission and open to public inspection.

Any person desiring to be heard or to make any protest with reference to said applications should on or before June 5, 1989, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a petition to intervene or a protest in accordance with the requirements of the Commission’s Rules of Practice and Procedure (18 CFR 385.11, .214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding.

Any person wishing to become a party in any hearing therein must file a petition to intervene in accordance with the Commission’s rules.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicants to appear or to be represented at the hearing.

Lols D. Cashell
Secretary.

1 This notice does not provide for consolidation for hearing of the several matters covered herein.
the small producer certificate issued in Docket No. CS73-100 that currently covers sales made by Kansas Gas Purchasing be redesignated in the name of RAMA.

By letter dated February 14, 1989, received February 21, 1989, Applicants requested that the small producer certificate in Docket No. CS77-41-000 be amended to reflect the change in name. On April 28, 1989, General Atlantic Rockies Production Co., which, in turn, changed its name to GARI effective January 1,1989.

General Atlantic Resources, Inc. (GARI) requested that the certificate be redesignated in its name, stating that effective July 31, 1987, GAEC changed its name to GARI. The filing date is the date of receipt of the filing fee.

McCabe; Rozene McCabe; Wiltem G. McCabe; and Doris R. McCabe.

Take notice that Algonquin Gas Transmission Company (“Algonquin”) proposed changes in the FERC Gas Tariff. 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, 825 North Capitol Street NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission’s Rules and Regulations. All such motions or protests should be filed on or before May 31, 1989. Protest will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protesters parties to the proceeding. 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 in the Public Reference Room.

Lois D. Cashell,
Secretary.

Algonquin notes that copies of this filing were served upon each affected party and interested state commissions.

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, 825 North Capitol Street NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission’s Rules and Regulations. All such motions or protests should be filed on or before May 31, 1989. Protest will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protesters parties to the proceeding. 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 in the Public Reference Room.

Lois D. Cashell,
Secretary.

[FR Doc. 89-12686 Filed 5-26-89; 8:45 am]
North Penn Gas Co.; Proposed Changes in FERC Gas Tariff

May 23, 1989.

Take notice that North Penn Gas Company (North Penn) on May 18, 1989, tendered for filing Ninety-Third Revised Sheet No. PGA-1 to its FERC Gas Tariff First Revised Volume No. 1.

North Penn states that this tariff sheet is filed pursuant to section 14 of the General Terms and Conditions of North Penn's FERC Gas Tariff to reflect changes in the cost of gas for the period June 1, 1989 through August 31, 1989 and is proposed to be effective June 1, 1989. The proposed change reflects an increase in the average cost of gas for the C-1 Rate Schedule of 90.9734¢ per Mcf.

North Penn requests waiver of the Commission's Rules and Regulations pertaining to the thirty-day notice requirement stating that it did not receive its suppliers' changes in rates in order to make a timely filing.

While North Penn believes that no other waivers are necessary in order to permit this filing to become effective June 1, 1989, as proposed, North Penn respectfully requests waiver of any of the Commission's Rules and Regulations as may be required to permit this filing to become effective June 1, 1989, as proposed.

Copies of this letter of transmittal and all enclosures are being mailed to each of North Penn's jurisdictional customers and State Commissions shown on the attached service list.

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, 825 North Capitol Street NE., Washington, DC 20426, in accordance with 211 and 385.214 of the Commission's Rules of Practice and Procedure. Any person desiring to participate in this proceeding 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.

Transcontinental Gas Pipe Line Corp.; Filing

May 23, 1989.

Take notice that on May 17, 1989, Transcontinental Gas Pipe Line Corporation (Transco) filed a letter stating that it is willing to suspend collection of the transmission gas cost balance effective May 1, 1989, and to defer resolution of the issue of carrying.
charges on such balance until a Commission order addressing carrying charges is issued on its pending Stipulation and Agreement filed April 3, 1989, in Docket Nos. RP88-68, et al. Transco states that by order issued May 10, 1989, the Commission accepted its tariff sheets but rejected Transco's proposal in its April 10, 1989 supplement to suspend the collection of its transition gas cost balance effective May 1, 1989. Transco states that the Commission stated, among other things, that Transco's proposal to accrue carrying charges on the unrecovered transition gas cost balance is inconsistent with Commission practice, but that it would reconsider Transco's proposal if Transco is willing to forgo collection of carrying charges during the period it voluntarily elects to suspend collection of the transition gas cost balance.

Transco states that this instant proposal is contingent upon Commission recognition that Transco shall have a full 12-month collection period remaining to it at such time as Transco is permitted to recommence collection of the transition cost balance subject to the outcome in Docket Nos. TA65-3-29, et al.

Transco states that it is serving copies of this letter to its customers, State Commissions, and interested parties. Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such protests should be filed on or before May 31, 1989. 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. Persons that are already parties to this proceeding need not file a motion to intervene in this matter. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,
Secretary.

[FR Doc. 89-12793 Filed 5-26-89; 8:45 am]
BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3577-8]

Science Advisory Board

Environmental Engineering Committee
Toxics Treatability Subcommittee; Open Meeting, June 22-23, 1989

Under Pub. L. 92-463, notice is hereby given that the Science Advisory Board's Environmental Engineering Committee (EEC), Toxics Treatability Subcommittee, will meet June 22-23, 1989 in the Andrew W. Briedenbach Environmental Research Center, EPA Risk Reduction Engineering Laboratory, Conference Room, Number 107, 28 West Martin Luther King Drive, Cincinnati, Ohio 45218. The meeting will begin at 8:30 a.m. on Thursday, and Friday, and adjourn no later than 6:00 p.m.

The purpose of the meeting is to review the Environmental Protection Agency's, Risk Reduction Engineering Laboratory's Toxics Treatability and Toxicity Reduction Program. Topics to be discussed include aerobic and anaerobic treatability protocols and data on inhibition and degradation of toxic organics, treatability testing procedures and data for sorption and volatilization in conventional wastewater treatment, fate-in-treatment data bases (primary activated sludge treatment and fate in anaerobic digesters), modeling approach for integrating removal mechanisms into an overall predictive model on the activated sludge process, municipal and industrial Toxicity Reduction Evaluation (TRE) and case history data, and TRE proposed health effect toxicity reduction study.

The meeting is open to the public. Any member of the public wishing further information on the meeting or those who wish to submit written comments should contact Dr. K. Jack Kooyoomjian, Executive Secretary, Science Advisory Board, (A101-F), U.S. Environmental Protection Agency, Washington, DC 20460. All protestants parties to the proceeding need not file a motion to intervene in this matter. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,
Secretary.

[FR Doc. 89-12695 Filed 5-26-89; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. TQ89-3-49-001]

Williston Basin Interstate Pipeline Co.; Compliance to Purchased Gas Cost Adjustment Letter Order

May 23, 1989.

Take notice that on May 17, 1989, Williston Basin Interstate Pipeline Company (Williston Basin), Suite 200, 304 East Rosser Avenue, Bismarck, North Dakota 58501, tendered for filing Substitute Third Revised Eighth Revised Sheet No. 11B to Volume No. 2 of its FERC Gas Tariff in compliance with the Commission's Office of Pipeline and Producer Regulation Letter Order issued on April 26, 1989. The Letter Order accepted the instant tariff sheet effective May 1, 1989, but directed the Company to refile said tariff sheet to reflect a change in the tariff sheet pagination.

Any person desiring to protest should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such protests should be filed on or before May 31, 1989. 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. Persons that are already parties to this proceeding need not file a motion to intervene in this matter. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,
Secretary.

[FR Doc. 89-12695 Filed 5-26-89; 8:45 am]
BILLING CODE 6717-01-M

[OPTS-51733; FRL-3577-5]

Toxic and Hazardous Substances; Certain Chemicals Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires anyone who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in the final rule published in the Federal Register of May 13, 1983 (48 FR 21722). This notice announces receipt of 19 such PMNs and provides a summary of each.

DATES: Close of Review Periods:

Written comments by:
P 89-672—June 29, 1989.

P 89-681—July 1, 1989.


ADDRESS: Written comments, identified by the document control number "[OPTS-51734]" and the specific PMN number should be sent to: Document Processing Center (TS-790), Office of Toxic Substances, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 586-0263.


SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the nonconfidential version of the submission provided by the manufacturer on the PMNs received by EPA. The complete nonconfidential document is available in the Public Reading Room NE-G004 at the above address between 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding legal holidays.

P 89-672
Manufacturer. Confidential. Chemical. (G) Polyester polymer. Use/production. (G) Flexibilizer in a general industrial powder coating. Prod. range: 25,000–100,000 kg/yr.

P 89-673

P 89-674

P 89-675

P 89-676
Manufacturer. Arizona Chemical Company. Chemical. (G) C4–C8 naphtha polymer with substituted terpene resin.

Use/production. (G) Resin for use adhesives. Prod. range: Confidential.

P 89-677

P 89-678

Toxicity data: Acute oral toxicity: LD50 > 5,000 MG/KG species (Rat). Skin irritation: negligible species (Rabbit). Mutagenic status: negative.

P 89-679

Toxicity data: Acute oral toxicity: LD50 > 6,900 MG/KG species (Rat). Skin irritation: negligible species (Rabbit). Skin sensitization: none species (Rabbit).

P 89-680

P 89-681
Manufacturer. Confidential. Chemical. (G) Styrenated acrylate methacrylate polymer. Use/production. (G) Dispersively applied coating formulation. Prod. range: 250,000–400,000 kg/yr.

P 89-682

P 89-683

P 89-684
Importer. Nagase America Corporation.

Chemical. (S) 2'-(2-chlorophenyl)aminol-6'-(N-ethoxyaminol-spirto(isobenzofuran-1(3H)-9'(3H)xanthen)-3-one.

Use/import. (G) Color former. Prod. range: Confidential.

P 89-685
Importer. Shin-Etsu Silicones of America, Inc.

Chemical. (G) Organopolysiloxane. Use/import. (S) Coating for release paper & rubber compounds. Prod. range: 500–800 kg/yr.

P 89-686
Importer. Shin-Etsu Silicones of America, Inc.

Chemical. (G) Carboxyl modified organopolysiloxane. Use/import. (S) Textile and lubricant agent. Prod. range: 500–1,000 kg/yr.

P 89-687
Importer. Shin-Etsu Silicones of America, Inc.

Chemical. (G) Modified organo siloxane fluid. Use/import. (G) Addition into plastics for release. Prod. range: 500–1,000 kg/yr.

P 89-688
Importer. Shin-Etsu Silicones of America, Inc.

Chemical. (G) Cured organo polysiloxane. Use/import. (G) Coated silicone film. Prod. range: 500–2,000 kg/yr.

P 89-689
Importer. EM Science.


P 89-690


Steven Newburg-Rinn,
Acting Director, Information Management Division, Office of Toxic Substances.

[FR Doc. 89-12787 Filed 5-26-89; 8:45 am]
Toxic and Hazardous Substances; Certain Chemicals Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in the final rule published in the Federal Register of May 13, 1983 (48 FR 21722). This notice announces receipt of 98 such PMNs and provides a summary of each.

DATES: Close of Review Periods:
- P 89-579—July 1, 1989.
- P 89-599, 89-600—July 6, 1989.
- P 89-661—June 22, 1989.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Assistance Office (TS-790), Office of Toxic Substances, Environmental Protection Agency, 401 M Street, SW., Room L-100, Washington, DC 20460, (202) 382-3532.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the nonconfidential version of the submission provided by the manufacturer on the PMNs received by EPA. The complete nonconfidential document is available in the Public Reading Room NE-G004 at the above address between 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding legal holidays.

P 89-573

Importer. Shin-Estu Silicones of America, Inc.
Chemical. (G) Organosilane.
Use/Import. (G) Contained use in an article. Import range: 200-3,000 kg/yr.

P 89-574

Manufacturer. E.I. Du Pont De Nemours & Co., Inc.
Chemical. (G) Substituted acrylic polymer.
Use/Production. (G) Open, nondispersive use. Prod. range: Confidential.

P 89-575

Manufacturer. E.I. Du Pont De Nemours & Co., Inc.
Chemical. (G) Substituted acrylic polymer.
Use/Production. (G) Open, nondispersive use. Prod. range: Confidential.

P 89-576

Importer. Alcan Chemicals.
Chemical. (G) Metal salt of a complex inorganic oxyacid.
Use/Import. (S) Flame retardant.
Import range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 > 5.0 G/KG species (Rat).

P 89-577

Importer. Alcan Chemicals.
Chemical. (G) Metal salt of a complex inorganic oxyacid.
Use/Import. (S) Flame retardant.
Import range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 > 5.0 G/KG species (Rat).

P 89-578

Manufacturer. Confidential.
Chemical. (G) Polyurethane.
Use/Production. (G) Resin for molded parts. Prod. range: Confidential.

P 89-579

Manufacturer. Confidential.
Chemical. (G) Amine neutralized hydroxyl dialkyl phosphorus dithiate.
Use/Production. (G) Industrial lubricant and engine oil additive. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 > 5.0 G/KG species (Rat). Acute dermal toxicity: LD50 > 2 G/KG species.
[Rabbit], Eye irritation: moderate species [Rabbit]. Skin irritation: strong species [Rabbit]. Mutagenicity: negative.

P 89-580
Manufacturer: Minnesota Mining & Manufacturing Co.
Chemical: (G) Tertiary amine catalyst
Use/Production: (S) Resin catalyst in a tape
Prod. range: Confidential.

P 89-581
Manufacturer: Minnesota Mining & Manufacturing Co.
Chemical: (G) Chloride substituted tertiary amine
Use/Production: (S) Chemical intermediate
Prod. range: Confidential.

P 89-582
Manufacturer: Minnesota Mining & Manufacturing Co.
Chemical: (G) Tertiary amine
Use/Production: (S) Chemical intermediate
Prod. range: Confidential.

P 89-583
Importer: Eastman Kodak Company
Chemical: (G) Substituted polycyclic acid derivative
Use/Import: (G) Chemical intermediate
Import range: 8,000-14,000 kg/yr.

P 89-584
Importer: Confidential
Chemical: (G) Styrene-acrylic copolymer
Use/Import: (S) Acrylic resin
Import range: Confidential.

P 89-585
Manufacturer: Confidential
Chemical: (S) 2,2-methyl-1,3-propanediol; 2-ethyl-2-(hydroxymethyl)-1,3-propanediol; benzene acid; 1,3-benzofuran-2-ol; 1,3-benzenedicarboxylic acid; trans-2-hexanediolic acid; hexadecic acid
Use/Production: (a) Polymer for paint coating
Prod. range: 100,000-250,000 kg/yr.

P 89-586
Manufacturer: Confidential
Chemical: (G) Modified acrylic polymer
Use/Production: (G) Open, nondisperse use
Prod. range: 15,000-100,000 kg/yr.

P 89-587
Manufacturer: E.I. Du Pont De Nemours & Co., Inc.
Chemical: (G) Poly[4-substituted-phenyl]methane dimer
Use/Production: (G) Antihalation masking dye
Prod. range: Confidential.

P 89-588
Manufacturer: Confidential
Chemical: (G) Poly(acrylonitrile-co-styrene-co-vinylidene chloride)
Use/Production: (G) Polyurethane foam
Prod. range: Confidential.

P 89-589
Manufacturer: Confidential
Chemical: (G) Penta-alkylalkylamine substituted piperazinones
Use/Production: (G) Stabilizer
Prod. range: Confidential.

P 89-590
Importer: Confidential
Chemical: (G) Fatty acids, esters with pentaerythritol, reaction products with disocyanate
Use/Import: (S) Transfer agent
Import range: Confidential.

P 89-591
Manufacturer: E.I. Du Pont De Nemours & Co., Inc.
Chemical: (G) Ethylene interpolymer
Use/Production: (S) Polymer for general industrial use
Prod. range: Confidential.

P 89-592
Manufacturer: E.I. Du Pont De Nemours & Co., Inc.
Chemical: (G) Ethylene interpolymer
Use/Production: (S) Polymer for general industrial use
Prod. range: Confidential.

P 89-593
Manufacturer: Confidential
Chemical: (G) Reaction product of sodium methanilulfite with polymer of polyalkylene glycol; alkylidol; and monononyl diglycarboxylic acid, dialkyl ester
Use/Production: (G) Dispersive use
Prod. range: Confidential.

P 89-594
Manufacturer: Confidential
Chemical: (G) Modified polyamide
Use/Production: (G) Coatings and inks
Prod. range: Confidential.

P 89-595
Manufacturer: Confidential
Chemical: (C)
(Alkylaminocarbonyldienyl) pyrazolitone
Use/Production: (G) Coated use
Prod. range: 1,150-1,800 kg/yr.

P 89-596
Manufacturer: E.I. Du Pont De Nemours & Co., Inc.
Chemical: (G) Alkylene glycol teraphthalate and substituted benzate esters
Use/Production: (S) Isolated intermediate
Prod. range: Confidential.

P 89-597
Manufacturer: Confidential
Chemical: (G) Styrene-acrylic modified polyester
Use/Production: (G) Paint
Prod. range: Confidential.

P 89-598
Manufacturer: E.I. Du Pont De Nemours & Co., Inc.
Chemical: (G) Substituted ethylene copolymer
Use/Production: (G) Binder
Prod. range: Confidential.

P 89-599
Manufacturer: Monsanto Company, Inc.
Chemical: (G) Adipic acid hexamethylenediamine polymer mod.
Use/Production: (S) Molded electrical and automotive part
Prod. range: Confidential.

P 89-600
Importer: Wacker Chemicals (USA), Inc.
Chemical: (G) Vinyl alcohol alkendiol alcohol copolymer
Use/Import: (S) Co-binder for paper coatings
Import range: Confidential.

P 89-601
Manufacturer: Confidential
Chemical: (G) Fatty amine condensate
Use/Production: (G) Emulsified additive
Prod. range: Confidential.
**P 89-602**

Manufacturer. Confidential. Chemical. (G) Polyester with propylene glycol. Use/Production. (G) Industrially used coating with an open use. Prod. range: Confidential.

**P 89-604**


**P 89-605**


**P 89-606**

Manufacturer. Confidential. Chemical. (G) Epoxy-phenolic resin. Use/Production. (G) Containing coating. Prod. range: Confidential.

**P 89-607**


**P 89-608**

Manufacturer. Confidential. Chemical. (G) Substituted polyhydroxy aromatic compound. Use/Production. (G) Metal treatment for corrosion protection and paint. Prod. range: Confidential.

**P 89-609**


**P 89-610**


**P 89-611**


**P 89-612**


**P 89-613**


**P 89-614**


**P 89-615**


**P 89-616**


**P 89-617**

Manufacturer. Confidential. Chemical. (S) Di(2-hydroxyethyl trialkylacetaldehyde) adipate with carbon number C38-C50 C26 rich. Use/Production. (G) Plasticizer lubricant. Prod. range: Confidential.

**P 89-618**


**P 89-619**

Importer. Confidential. Chemical. (G) Polyoxymethylene urethane block polymer. Use/Production. (G) Resin coating. Prod. range: Confidential.
P 89-629

Manufacturer. Confidential.
Chemical. (G) Alkanal alkyl substituted oxide.
Use/Production. (S) Site-limited intermediate. Prod. range: Confidential.

P 89-630

Manufacturer. Confidential.
Chemical. (G) 3-(5' -dimethylsulfamyl-benzoxazoly-2')-7-diethylaminocoumarin.
Prod. range: 5,000-20,000 kg/yr.

P 89-631

Importer. GE Plastics.
Chemical. (G) Poly(biphenol-A-carbonate).
Use/Import. (G) Plastic components. Import range: Confidential.

P 89-632

Manufacturer. Confidential.
Chemical. (S) 4-Piperidinamine, N,N'-1,2-ethanediyl bis-
Butyl-2,2,6,6-tetramethyl; 1,3,5-triazine,2,4,6-trichloro-.
Use/Production. (S) Light stabilizer for thermoplastic. Prod. range: Confidential.

P 89-633

Manufacturer. Confidential.
Chemical. (G) Isocyanic acid poly methylene polyphenylene ester polymer with polyether polyol.
Use/Production. (S) Mfr. of polyurethane/polyisocyanate from products. Prod. range: Confidential.

P 89-634

Manufacturer. Confidential.
Chemical. (G) Isocyanic acid poly methylene polyphenylene ester polymer with polyether polyol.
Use/Production. (S) Mfr. of polyurethane/polyisocyanate from products. Prod. range: Confidential.

P 89-635

Importer. Pacific Anchor Chemical Corporation.
Chemical. (G) Polymer of vegetable oil, polyethylene polyamines and a polymeric diglycidyl ether.
Use/Import. (S) Curing agent for epoxy resin coating systems. Import range: Confidential.

P 89-636

Importer. Pacific Anchor Chemical Corporation.
Chemical. (G) Polymer of vegetable oil and polyethylene polyamines.
Use/Import. (S) Curing agent for epoxy resin coating system. Import range: Confidential.

P 89-637

Manufacturer. E.I. Du Pont De Nemours & Co., Inc.
Chemical. (G) Styrene/hydroxyacrylic polymer ammonium salt.
Use/Production. (G) Open, nondispersive use. Prod. range: Confidential.

P 89-638

Manufacturer. H.R. Fuller Company.
Chemical. (G) Methyleneidphenyl dichloroacrylate polymer prepolymer.
Use/Production. (S) Adhesive. Prod. range: Confidential.

P 89-639

Manufacturer. H.B. Fuller Company.
Chemical. (G) Vinyl acetate-hydroxyalkyl acrylate copolymer.
Use/Production. (S) Binder. Prod. range: Confidential.

P 89-640

Manufacturer. Environmental Technology (U.S.), Inc.
Chemical. (G) Sodium polythiocarbonate.
Use/Production. (S) dissolved heavy metal precipitant. Prod. range: Confidential.

P 89-641

Manufacturer. Triazone Corporation.
Chemical. (G) 1,3,5-triazin-2(1H)-one, tetrahydro-5-[2-hydroxyethyl]-.
Use/Production. (S) Specialty fertilizer for lawn and garden use. Prod. range: 100,000-5,000,000 kg/yr.

P 89-642

Manufacturer. Xerox Corporation.
Chemical. (G) Quaternary ammonium salt.
Use/Production. (G) Antistatic for plastics, contained use. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50<5.0 G/KG species(Rat). Skin irritation: slight species(Guinea Pig). Skin sensitization: negative species(Rabbit).

P 89-643

Importer. Hoechst Celanese Corporation.
Chemical. (G) Perfluoropolyether.
Use/Import. (G) Heat transfer fluid. Import range: Confidential.
Toxicity Data. Mutagenicity: negative.

P 89-644

Importer. Hoechst Celanese Corporation.
Chemical. (G) Perfluoropolyether.
Use/Import. (G) Heat transfer fluids. Import range: Confidential.

P 89-645

Manufacturer. Confidential.
Chemical. (G) Silazene.
Use/Production. (G) Destructive use. Prod. range: Confidential.

P 89-646

Manufacturer. Confidential.
Chemical. (G) Poly(silazene).
Use/Production. (G) Precursor to ceramic material. Prod. range: Confidential.

P 89-647

Manufacturer. Sannor Industries, Inc.
Chemical. (G) Polyurethane based on polols, polyisocyanates and polyamines.
Use/Production. (G) Coating. Prod. range: Confidential.

P 89-648

Manufacturer. Milliken & Company.
Chemical. (G) Substituted-phenyl-azopyrazolone.
Use/Production. (G) Open nondispersive use. Prod. range: Confidential.

P 89-649

Importer. Confidential.
Chemical. (G) Aromatic hydrocarbon and aliphatic dicarboxylic acid copolymer.
Use/Import. (G) Paper additives. Import range: Confidential.

P 89-650

Manufacturer. Stephan Company.
Chemical. (G) Quaternary ammonium methosulfate.
Use/Production. (G) Surfactant for fibers. Prod. range: Confidential.

P 89-651

Manufacturer. Confidential.
Chemical. (G) Phenol, 4,4'-oxybis-2,1-ethanediylthio)bis-
Use/Production. (G) Manufacturer office machine paper. Prod. range: 70,000 kg/yr.

P 89-652

Importer. Toyo Ink America, Inc.
Chemical. (G) UV curable resin.
Use/Import. (G) Basse resin for industrial and commercial coatings. Import range: 1,000-10,000 kg/yr.
Toxicity Data. Skin irritation: slight species(Rabbit).
P 89-653
Importer. E.I. Du Pont De Nemours & Co., Inc.
Chemical. (G) Copolymer.
Use/Import. (G) Finished goods.
Import range: Confidential.

P 89-654
Importer. E.I. Du Pont De Nemours and Co., Inc.
Chemical. (G) Polyurethane prepolymer.
Use/Import. (G) Finished goods.
Import range: Confidential.

P 89-655
Importer. Confidential.
Chemical. (G) Direct black dye.
Use/Import. (S) Ink pigment. Import range: Confidential.

P 89-656
Manufacturer. Confidential.
Chemical. (G) Xanthylium, 3, 6-(methoxycarbonyl)phenyl)-chloride.

P 89-657
Manufacturer. Confidential.
Chemical. (G) Dispersive water reactant. Prod, range: Confidential.

P 89-658
Manufacturer. Confidential.
Chemical. (G) Intermediate

P 89-659
Manufacturer. Confidential.
Chemical. (G) Dispersive water treatment. Prod. range: Confidential.

P 89-660
Manufacturer. Confidential.
Chemical. (G) Acrylate terpolymer.
Use/Production. (G) Dispersive water treatment. Prod. range: Confidential.

P 89-661
Importer. Confidential.
Chemical. (G) Azo substituted naphthalene, alkali salt.
Use/Import. (S) Direct dye for textiles. Import range: Confidential.

P 89-662
Manufacturer. Confidential.
Chemical. (G) Fluorinated polyurethane.

P 89-663
Manufacturer. NL Chemicals.
Chemical. (G) Polyurethane resin.
Use/Production. (S) Industrial product finishes. Prod. range: Confidential.

P 89-664
Manufacturer. NL Chemicals.
Chemical. (G) Polyurethane resin.
Use/Production. (S) Industrial product finishes. Prod. range: Confidential.

P 89-665
Manufacturer. Sannocor Industries, Inc.
Chemical. (G) Polyurethane based on polyisocyanates, polyols and polyamines.
Use/Production. (G) Resin. Prod. range: Confidential.

P 89-666
Manufacturer. Lanchem.
Chemical. (G) Polyurethane polyol.
Use/Production. (G) Resin for coating manufacture. Prod. range: Confidential.

P 89-667
Manufacturer. Confidential.
Chemical. (G) Rosin amine derivative.
Use/Production. (G) Destructive use: petroleum corrosion inhibitor. Prod.
range: Confidential.

P 89-668
Manufacturer. Confidential.
Chemical. (G) Acrylate/acrylonitrile/vinylacetat copolymer.
Use/Import. (S) Laminating adhesive. Import range: Confidential.

P 89-669
Manufacturer. Eastman Chemicals.
Eastman Kodak Company.
Chemical. (S) 1,1-Dimethylthyl 3-oxobutanoate.
Use/Production. (S) Industrial reactant. Prod. range: Confidential.

P 89-670
Manufacturer. Sherex Chemical Company.
Chemical. (G) Fatty amine salt.
Use/Production. (S) Floating sand from fla. phosphate rock. Prod. range:
Confidential.

P 89-671
Manufacturer. Confidential.
Chemical. (S) Aromatic hydrocarbon.

P 89-672
Manufacturer. Confidential.

FEDERAL COMMUNICATIONS COMMISSION

Applications for Consolidated Hearing; Aldridge, Joe L., et al.

1. The Commission has before it the following mutually exclusive applications for three new FM stations:

I.

II.

III.

Issue Hearing and Applicants
1. Comparative, All Applicants
2. Ultimate, All Applicants

Federal Register / Vol. 54, No. 102 / Tuesday, May 30, 1989 / Notices
Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set forth in its entirety under the corresponding heading at 51FR19347, May 29, 1986.

III.

Applicant, City, and State File No. MM Docket No.
A. Bluefield Educational Broadcasting Foundation, Bluefield, VA. BPED-860428MG. 89-115
B. Virginia-West Virginia Community Radio, Inc., Bluefield, VA. BPED-860509ME. 89-116
C. Appalachian Educational Communication Corp., Bluefield, VA. BPED-860726MJ. 89-117
D. Golden Rule Workshop, Inc., Galax, Virginia. BPED-861229MB. 89-118

FEDERAL EMERGENCY MANAGEMENT AGENCY

Agency Information Collection Submitted to the Office of Management and Budget for Clearance

The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following information collection package for clearance in accordance with the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Type: New
Title: Expedited Disaster Assistance Delivery System Post-Applicant Preference Survey
Abstract: The Expedited Disaster Assistance Delivery System Post-Applicant Preference Survey, FEMA Form , is a telephone survey designed to determine individuals’ preference for applying for disaster assistance in person or by telephone. No more than 1,000 disaster victims will be telephoned in a 1-year period.
Type of Respondents: Individuals or households
Estimate of Total Annual Reporting and Recordkeeping Burden: 50
Number of Respondents: 1,000
Estimated Average Burden Hours per Response: .05
Frequency of Response: Other. This is a one-time only survey.

Copies of the above information collection request and supporting documentation can be obtained by calling or writing the FEMA Clearance Officer, Linda Shiley, (202) 646-2624, 500 C Street, SW., Washington, DC 20472.

Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to the FEMA Clearance Officer at the above address; and to Pamela Barr, (202) 395-7231, Office of Management and Budget, 3235 NEOB, Washington, DC 20503 within two weeks of this notice.


Wesley C. Moore,
Director, Office of Administrative Support.

[FR Doc. 89-12273 Filed 5-29-89; 8:45 am]
BILLING CODE 6710-01-M

[FEMA-829-DR]
Major Disaster And Related Determinations; Louisiana

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Louisiana (FEMA-829-DR), dated May 20, 1989, and related determinations.


NOTICE: Notice is hereby given that, in a letter dated May 20, 1989, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq., as amended by Pub. L. 100-707), as follows:

I have determined that the damage in certain areas of the State of Louisiana resulting from severe storms and flooding beginning on May 5, 1989, is of sufficient severity and magnitude to warrant a major disaster declaration under Pub. L. 93-288, as amended by Pub. L. 100-707, I, therefore, declare that such a major disaster exists in the State of Louisiana.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses. You are authorized to provide Individual Assistance in the designated areas. Public Assistance may be provided at a later time, if needed. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under Pub. L. 93-288, as amended by Pub. L. 100-707, for Public Assistance will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I...
ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of North Dakota (FEMA-825-DR), dated May 8, 1989, and related determinations.


Notice: The notice of a major disaster for the State of North Dakota, dated May 9, 1989, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of May 8, 1989:

- Pembina County for Individual Assistance and Public Assistance.

AGENCY: Federal Emergency Management Agency.

[FR Doc. 89-12734 Filed 5-26-89; 8:45 am]
BILLING CODE 6710-02-M

FEMA-827-DR

Amendment to Notice of a Major Disaster Declaration; North Carolina

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of North Carolina (FEMA-827-DR), dated May 17, 1989, and related determinations.

DATED: May 21, 1989.


NOTICE: The notice of a major disaster for the State of North Carolina, dated May 17, 1989, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of May 17, 1989:

- The counties of Anson and Rutherford for Individual Assistance.
- Guilford County for Public Assistance.

AGENCY: Federal Emergency Management Agency.

[FR Doc. 89-12738 Filed 5-26-89; 8:45 am]
BILLING CODE 6718-02-M

FEMA-828-DR

Major Disaster and Related Determinations; Texas

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Texas (FEMA-828-DR), dated May 19, 1989, and related determinations.

DATED: May 19, 1989.


Notice: Notice is hereby given that, in a letter dated May 18, 1989, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq., Public Law 93-288, as amended by Pub. L. 100-707), as follows:

I have determined that the damage in certain areas of the State of Texas, resulting from severe storms, tornadoes, and flooding beginning on May 4, 1989, is of sufficient severity and magnitude to warrant a major disaster declaration under Public Law 93-288, as amended by Pub. L. 100-707. Therefore, declare that such a major disaster exists in the State of Texas.

In order to provide Federal assistance, you are hereby authorized to allocate funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas. Public Assistance may be provided at a later date, if needed. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under Pub. L. 93-288, as amended by Pub. L. 100-707, for Public Assistance will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a). Priority to Certain Applications for Public Facility and Public Housing Assistance, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Robert D. Broussard of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Texas to have been affected adversely by this declared major disaster:

The counties of Dallas, Hood, Palo Pinto, and Tarrant for Individual Assistance.

AGENCY: Federal Emergency Management Agency.

[FR Doc. 89-12737 Filed 5-26-89; 8:45 am]
BILLING CODE 6710-02-M

Board of Visitors for the National Fire Academy; Open Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following committee meeting:

Name: Board of Visitors for the National Fire Academy

Dates of Meeting: July 9—10, 1989.

Place: Sheraton-Kensington Hotel, 1902 East 71st Street South, Tulsa, Oklahoma

Time:

July 9—10:00 a.m.—12:00 p.m. (Quarterly Meeting)

—1:30 p.m. to completion (Field Survey Meeting)

July 10—10:00 a.m. to completion (Quarterly Meeting Continued)

The meeting will be open to the public with seating available on a first-come, first-serve basis. Members of the general public who plan to attend the meeting should contact the Office of the Superintendent, National Fire Academy, Office of Training, 16623 South Seton Avenue, Emmitsburg, Maryland, 21727 (telephone number, 301-447-1129) on or before June 30, 1989.

Minutes of the meeting will be prepared by the Board and will be available for public viewing in the Director's Office, Office of Training, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472. Copies of the minutes will be available upon request 30 days after the meeting.

Dated: May 18, 1989.

Dave McLoughlin,
Director, Office of Training.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Program Announcement Number 942]

Agency for Toxic Substances and Disease Registry; for State Health Departments To Conduct Health Assessments

Introduction

The Agency for Toxic Substances and Disease Registry (ATSDR) announces the availability of FY 1989 funds for cooperative agreements with State health agencies to perform health assessments and to provide health consultations on sites listed or proposed for listing on the National Priorities List (NPL) excluding all Federal facilities.

Authority


Eligible Applicants

Eligible applicants are the official health agencies of States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Federated State of Micronesia, the Republic of the Marshall Islands, the Republic of Palau, the Northern Mariana Islands, and American Samoa.

Availability of Funds

ATSDR announces the availability of funds for FY 1989 in the amount of $1.5 million to fund approximately 4 new cooperative agreements with States to perform health assessments and health consultations. Additionally, approximately $3.5 million is available to support continuation applications to perform health assessments in the 16 States currently funded under a previous announcement. While these 16 States will still have 1 to 2 years remaining on their current project periods, ATSDR would like a common expiration date for all awards under this program. Therefore, these States are requested to submit competitive continuation applications in order to have an August or September 1992 expiration date. Should a State choose not to apply for competitive continuation and, provided it is making satisfactory progress, ATSDR will honor the current awards through the expiration of the project period, subject to availability of funds.

It is anticipated that the cooperative agreements will begin on or about September 1, 1989, with a 12-month budget period and a 3-year project period.

ATSDR anticipates that funds will be available in Fiscal Years 1990 and 1991 to continue approved projects. Funding estimates may vary and are subject to change. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Individual project awards are expected to average $250,000 to $325,000 for FY 1990 and $300,000 to $375,000 for FY 1991. ATSDR anticipates that funds will be available in Fiscal Years 1990 and 1991 to continue approved projects. Funding estimates may vary and are subject to change.

It is anticipated that the cooperative agreements will begin on or about September 1, 1989, with a 12-month budget period and a 3-year project period.

ATSDR anticipates that funds will be available in Fiscal Years 1990 and 1991 to continue approved projects. Funding estimates may vary and are subject to change.

Program Requirements

Recipient Activities

1. Conduct health assessments or preliminary health assessments at all NPL sites within the respective State in accordance with a schedule, to be mutually agreed upon by ATSDR and recipient, that complies with requirements of applicable sections of
CERCLA, as amended. All health assessments and preliminary health assessments will be performed in accordance with the methodology provided in the ATSDR Health Assessment Guidance Manual. The health assessment process will generally consist of the following activities:

1. Acquire appropriate data from relevant State agencies, EPA regional offices, independently or in conjunction with ATSDR staff. Visit each site prior to writing the health assessment report.
2. Conduct a comprehensive, multidisciplinary review and analysis of appropriate extant data in accordance with the ATSDR Health Assessment Guidance Manual. Such review and analysis will include:
   (1) Assessment of contaminants identified and their toxicity.
   (2) Evaluation of actual or potential on-site and off-site environmental pathways.
   (3) Evaluation of actual or potential on-site and off-site human exposure pathways.
   (4) Assurance that the analytical data being reviewed meets all applicable quality assurance and quality control standards.
   (5) Identification of significant data gaps, inconsistencies, and environmental sampling needs.
   (6) Where data are available, comparison of rates or indices of relevant morbidity and mortality data on diseases that may be associated with measured, suspected, or potential levels of exposure related to the site.
   (7) Prepare draft health assessments or preliminary health assessments for review and comment by ATSDR and the relevant EPA regional office. Such draft documents should conform to the ATSDR Health Assessment Guidance Manual, and timing, routing, and handling of the draft review process should conform to the ATSDR Health Assessment Communication Procedures. The draft documents should address the following major areas of concern:
      (1) Identification of potentially hazardous substances.
      (2) Concentrations of concern by chemical and environmental media.
      (3) Environmental and human exposure pathways.
   (4) The judgment of the recipient as to whether the pathways constitute a public health problem and the basis for such judgments.
   (5) The overall public health implications of the site.
   (6) Recommendations related to mitigating the potential human exposure and the need for follow-up actions, as necessary, including epidemiologically-based health studies.

2. Make available draft health assessments and preliminary health assessment reports to the general public for comment in accordance with the ATSDR Health Assessment Communications Procedures. In conjunction with this process and/or as needed, participate in State health, environmental, and/or EPA public workshops and community meetings to discuss and/or respond to questions concerning the site's impact on public health.

3. Develop a final report in collaboration with ATSDR that reasonably and responsibly incorporates comments and concerns elicited in the draft review process, such that the final product represents, insofar as possible, the consensus of the Recipient and ATSDR.

4. On own initiative or upon request from ATSDR if appropriate, perform addenda to health assessments of NPL sites previously performed by the recipient or ATSDR.

5. Provide technical assistance and support in the performance of health assessments; assist recipients in establishing and maintaining appropriate and timely schedules of the health assessment process.

6. Assist the recipients in assessing and maintaining appropriate and timely schedules of the health assessment process.

7. Collaborate with recipients in acquiring appropriate data for performance of health assessments; assist recipient in evaluating completeness and quality of relevant data.

ATSDR Activities

1. Collaborate with recipients in acquiring appropriate data for performance of health assessments; assist recipient in evaluating completeness and quality of relevant data.
2. Assist the recipients in establishing and maintaining appropriate and timely schedules of the health assessment process.
3. Assist recipients in assuring appropriate training for and use of personal protective equipment by their personnel.
4. Analyze environmental and/or biological results or specific situations in which ATSDR has unique capabilities.
5. Provide technical assistance and guidance in preparing health assessments, as needed, including participation in site visits.
6. Through close technical review and comment on draft documents, collaborate with the recipients in the development of the final reports.
7. Evaluate the overall performance of recipients' adherence to technical and policy guidelines set forth in the ATSDR Health Assessment Guidance Manual as embodied in the recipients' completed health assessments and preliminary health assessments.

Evaluation Criteria

1. Review Procedures
   Applications will be reviewed by the Grants Management Officer, Centers for Disease Control and the review of applications will be conducted in accordance with Public Health Service Grants Administrative Manual, Part 134. All applications (new and renewal or continuation) shall be reviewed in accordance with the criteria established in this announcement. Each application approved will be numerically ranked for funding. The applications will be funded from the highest ranked to the lowest ranked until available funds are exhausted. If a currently funded State applies for a competitive continuation and does not receive a sufficiently high score to receive an extension in its project period, ATSDR will continue to honor the existing award, subject to satisfactory progress and availability of funds.

2. Scientific and Technical Merit Review Criteria
   The review for scientific and technical merit will be based on the following criteria:
   a. Relevance of the proposal to the activities and objectives identified in the Purpose and Program Requirements.
   b. Demonstrated experience in evaluating human exposures to hazardous substances in the environment through multi-media exposure pathways.
   c. Training and experience of staff to be assigned to and/or hired for this project.
   d. Suitability of facilities and equipment available or to be purchased for this project.
   e. Appropriateness of the requested budget relative to the work proposed.
   f. Capability of the applicant and its consultants/contractors to carry out the tasks involved in the health assessment process.
   g. Soundness and innovation of the proposed approach to the range of activities presented in the health assessment program contained in this announcement.
   h. Capability of applicant's administrative structure to foster successful scientific and administrative management and to use this cooperative agreement to complement and to increase other environmental health capabilities of the State.
   i. Suitability of any proposed contractors/consultants (such as local universities, medical schools, or schools of public health).
   j. Adequacy of the proposed time frame to meet and complete health assessments and preliminary health assessments at all NPL sites within the State in a timely fashion.
   k. Number and diversity of NPL or other hazardous sites in the State to be served.
1. Absence of real or potential conflicts of interest.

**Funding Priorities**

As stated in the Availability of Funds, up to 4 new projects will be funded, and the 16 currently funded projects may be refunded, depending on the extent to which they satisfy evaluation criteria. Additionally, the priority order for funding the new cooperative agreements is as follows:

1. States with 50 or more sites listed or proposed for listing on the NPL, excluding Federal facilities.
2. States with 30 to 49 sites listed or proposed for listing on the NPL, excluding Federal facilities.
3. States with fewer than 30 sites listed or proposed for listing on the NPL, excluding Federal facilities.

**Executive Order 12372 Review**

Applications are subject to review as governed by Executive Order 12372, entitled Intergovernmental Review of Federal Programs.

**Catalog of Federal Domestic Assistance Number**

The Catalog of Federal Domestic Assistance number is 13.161, Health Programs for Toxic Substances and Disease Registry.

**Application and Submission Deadline**

The original and two copies of the application (Form PHS 5161–1 Rev. 3/89) must be submitted to Henry S. Cassell III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., Room 300, Mail Stop E–14, Atlanta, Georgia 30305, (404) 482-6797 or FTS 236-6797.

**Where to Obtain Additional Information**

A complete program description, information on application procedures, and an application package may be obtained from Harvey Rowe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., Room 300, Mail Stop E–14, Atlanta, Georgia, 30305, (404) 842-6797 or FTS 236-6797.

Please refer to announcement number 942 when requesting information and submitting an application under this Request for Assistance. Technical assistance may be obtained from Luther E. DeWeese, Deputy Director, Office of Health Assessment, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mail Stop F1-20, Atlanta, Georgia 30333, (404) 488-4810 or FTS 236-4810.

**Dated:** May 3, 1989.

**Mary E. Guinan,**

**Acting Administrator, Agency for Toxic Substances and Disease Registry.**

[FR Doc. 89–12711 Filed 5–26–89; 8:45 am]

**BILLING CODE 4160-70-M**

### Alcohol, Drug Abuse, and Mental Health Administration

**Methodologic Research for Multi-Site Epidemiologic Surveys of Mental Disorders in Child and Adolescent Populations**

**AGENCY:** National Institute of Mental Health.

**ACTION:** Notice of restricted eligibility.

**SUMMARY:** The National Institute of Mental Health (NIMH) announces the availability of cooperative agreements to plan and conduct methodologic research designed to lead to a second phase, multisite epidemiologic and services research study of mental disorders of U.S. children and adolescents, ages 9–17. These cooperative agreements will be made under the authority of Section 301 of the Public Health Service Act, as amended, 42 U.S.C. 241. The Catalog of Federal Domestic Assistance Number for this program is 13.242.

The purpose of this project is to complete development, field testing, and validation of assessment instruments and survey procedures which may be used in the full-scale, multi-site epidemiologic survey. The cooperative agreement mechanism is being used to support this program because it offers the opportunity for collaborative activity among the grantees and NIMH. A coordinated approach is the most effective way to resolve several complex methodologic issues involved in conducting epidemiologic research on mental disorders of children. Although the awardees are primarily responsible for the conduct of the study, there will be collaboration among the participating sites and NIMH staff will have substantial programmatic involvement above and beyond the levels regularly required for traditional program management of grants. The NIMH is not specifying or mandating the use of particular assessment instruments in this research program.

Up to six cooperative agreements will be funded for three years. It is anticipated that up to $3 million will be available to support this program in Fiscal Year 1989. Eligibility for funding under this program is limited to applications from domestic institutions.

Research cooperative agreement applications may be submitted by any public or private or profit-making organization such as universities, colleges, hospitals, units of State or local government, and authorized units of the Federal Government. For a copy of the Request for Applications (MH–89–22), potential applicants should contact: Ben Z. Locke, Chief, Epidemiology and Psychopathology, Research Branch, Division of Clinical Research, National Institute of Mental Health, Room 10C–05, 5600 Fishers Lane, Rockville, MD 20857, (Telephone: 301:443–3774).

**Joseph R. Leone,**

**Associate Administrator for Management, Alcohol, Drug Abuse, and Mental Health Administration.**

[FR Doc. 89–12719 Filed 5–26–89; 8:45 am]

**BILLING CODE 4160-20-M**

### Food and Drug Administration

**Animal Drug Export; Enrofloxacin Injectable Solution**

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Mobay Corp. has filed an application requesting approval for the export of the animal drug enrofloxacin injectable solution to Canada.

**ADDRESS:** Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs...
under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT:
Beverly E. Bartolomeo, Center for Veterinary Medicine (HFV-142), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2855.

SUPPLEMENTARY INFORMATION: The Drug Export Amendments Act of 1986 (Pub. L. 99-660) (section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382)) provides that FDA may approve applications for the export of drugs that are not currently approved in the United States. The approval process is governed by section 802(b) of the act. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Mobay Corp., Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, has filed an application requesting approval for the export of the animal drug enrofloxacin solution (turkey egg dip concentrate) to Canada. The application was received and filed in the Center for Veterinary Medicine on May 16, 1989, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Documents Management Branch (address above) in two copies (except that individuals may submit single copies) and identify with the docket number found in brackets in the heading of this document. These submissions may be seen in the Documents Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by June 9, 1989, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (Sec. 802, Pub. L. 99-660 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.44).

Dated: May 19, 1989.
Robert C. Livingston,
Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 89-12722 Filed 5-26-89; 8:45 am]
BILLING CODE 4160-01-M

[Docket No. 89N-0183]
Animal Drug Export; Enrofloxacin Solution

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Mobay Corp. has filed an application requesting approval for the export of the animal drug enrofloxacin solution (turkey egg dip concentrate) to Canada.

ADDRESS: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-02, 5600 Fishers Lane, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT:
Beverly E. Bartolomeo, Center for Veterinary Medicine (HFV-142), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2855.

SUPPLEMENTARY INFORMATION: The Drug Export Amendments Act of 1986 (Pub. L. 99-660) (section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382)) provides that FDA may approve applications for the export of drugs that are not currently approved in the United States. The approval process is governed by section 802(b) of the act. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Mobay Corp., Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, has filed an application requesting approval for the export of its animal drug enrofloxacin solution, to Canada. The drug is intended for the control of _Arizona hinshawii_ (paracolon) infections in turkey hatchery eggs. The application was received and filed in the Center for Veterinary Medicine on May 16, 1989, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Documents Management Branch (address above) in two copies (except that individuals may submit single copies) and identify with the docket number found in brackets in the heading of this document. These submissions may be seen in the Documents Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by June 9, 1989, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (Sec. 802, Pub. L. 99-660 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.44).

Dated: May 19, 1989.
Robert C. Livingston,
Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 89-12723 Filed 5-26-89; 8:45 am]
BILLING CODE 4160-01-M

[Docket No. 89E-0150]
Determination of Regulatory Review Period for Purposes of Patent Extension; Paraplatin®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Paraplatin® (Carboplatin) 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.
from the Bristol-Myers Co. and requested FDA's assistance in determining the patent's eligibility for patent term restoration. FDA, in a letter dated May 4, 1989, advised the Patent and Trademark Office that the human drug product had undergone a regulatory review period. The letter also stated that the active ingredient, carboplatin, represented the first permitted commercial marketing or use. 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 Paraplatin® is 1,585 days. Of this time, 1,338 days occurred during the testing phase of the regulatory review period, while 247 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 became effective: November 1, 1984. FDA has verified the applicant's claim that the date the investigational new drug application became effective was November 1, 1984.

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 30, 1988. FDA has verified the applicant's claim that the new drug application (NDA 19-880) was initially submitted on June 30, 1988.

3. The date the application was approved: March 3, 1989. FDA has verified the applicant's claim that NDA 19-880 was approved on March 3, 1989.

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 915 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 31, 1989, 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 November 27, 1989, 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, 96th 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.


Stuart L. Nightingale, Associate Commissioner for Health Affairs.

Associate Commissioner for Health Affairs.

FOR FURTHER INFORMATION CONTACT: Nancy E. Pirt, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.
Health Resources and Services Administration

Program Announcement for Grants for the Establishment of Departments of Family Medicine

The Health Resources and Services Administration announces that applications for Fiscal Year 1990 Grants for Establishment of Departments of Family Medicine are being accepted under the authority of section 780 of the Public Health Service Act, as amended by Pub. L. 100-607.

Section 780 authorizes awards to health departments to meet the costs of projects to establish, maintain, or improve family medicine academic units (which may be departments, divisions, or other units) to provide clinical instruction in family medicine. Funds awarded will be used to (1) plan and develop model educational predoctoral, faculty development and graduate medical education programs in family medicine which will meet the requirements of section 786(a), Title VII of the Act, as amended by the Health Professions Reauthorization Act of 1988. Title VI of Pub. L. 100-607, by the end of the project period of section 780 support, and (2) support academic and clinical activities relevant to the field of family medicine.

The program may also assist schools to strengthen the administrative base and structure that is responsible for the planning, direction, organization, coordination, and evaluation of all undergraduate and graduate family medicine activities. Funds are to complement rather than duplicate programmatic activities for actual operation of family medicine training programs under section 786(a), as amended by the Health Professions Reauthorization Act of 1988. Title VI of Pub. L. 100-607.

The Administration's budget request for Fiscal Year 1990 does not include funding for this program. Applicants should be advised that this program announcement is a contingency action being taken to ensure that should funds become available for this purpose, they can be awarded in an timely fashion consistent with the needs of the program as well as provide for even distribution of funds throughout the fiscal year. This notice regarding applications does not reflect any change in this policy.

To be eligible to receive support for this grant program, the applicant must be a public or nonprofit private accredited school of medicine or osteopathy.

To receive support, programs must meet the requirements of final regulations as set forth in 42 CFR Part 57, Subpart R.

Review Criteria

The review of applications will take into consideration the following criteria:

1. The degree to which the proposed project adequately provides for the project requirements in § 57.1704; 2. The administrative and management capability of the applicant to carry out the proposed project in a cost effective manner;

3. The qualifications of the proposed staff and faculty of the unit; and 4. The potential of the project to continue on a self-sustaining basis.

In addition, the following mechanisms may be applied in determining the funding of approved applications:

1. Funding preferences—funding of a specific category or group of approved applications ahead of other categories or groups of applications, such as competing continuations ahead of new projects.

2. Funding priorities—favorable adjustment of review scores when applications meet specified objective criteria.

3. Special considerations—enhancement of priority scores by merit reviewers based on the extent to which applications address special areas of concern.

Section 780, as amended by Pub. L. 99-129, requires that the Secretary shall give priority to applicants that demonstrate to the satisfaction of the Secretary a commitment to family medicine in their medical education training programs.

Funding Priority

A funding priority will be given to applications which show a representation of underrepresented minority faculty in a family medicine administrative unit which is at least twice the National average of 2.8 percent in U.S. medical schools or can document an increase in the number of underrepresented minority faculty in the unit (i.e., Black, Hispanic and American Indian/Alaskan Native), over average of the past three years.

Special Consideration

Special considerations will be given to:

• Applicants that demonstrate the potential to continue the project on a self-sustaining basis.

• Applicants that demonstrate to the satisfaction of the Secretary a commitment to family medicine in their medical education training programs, as required by section 780, as amended by Pub. L. 100-607.

This funding priority and special considerations were implemented in Fiscal Year 1989 and the Department is extending this priority and special considerations in Fiscal Year 1990.

Requests for application materials and questions regarding grants policy should be directed to: Grants Management Officer (D32), Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 8C-22, Rockville, Maryland 20857, Telephone: (301) 443-6960.

Application materials should be mailed to the Grants Management Officer at the above address.

Questions regarding programmatic information should be directed to: Division of Medicine, Primary Care
four projects, which will focus on vocational assessment, rehabilitation and placement into competitive employment, will be funded under this section of the law. Eighteen demonstration projects require that section 222(a) of the Social Security Act (the Act) be waived, permitting direct referral of Social Security disability insurance (SSDI) beneficiaries from the Social Security Administration (SSA) or the State agencies that make disability determinations for SSA, to the organizations (vocational rehabilitation (VR) referral waiver). Additionally, 1 of these 18 projects "Try Work," also requires that section 222(c)(4)(A) of the Act be waived, permitting deferral of the trial work period (TWP) for up to 6 consecutive months of employment. The six remaining demonstrations do not require any waiver and notice is given for informational purposes only. We are publishing this notice to comply with 2 CFR 404.156(d), which requires publication of a notice in the Federal Register before starting certain demonstration projects.

A number of demonstration projects will involve individuals who are receiving concurrent SSDI and Supplemental Security Income (SSI) payments. Section 1110(b) of the Act authorizes the Secretary of Health and Human Services (the Secretary) to undertake demonstration projects designed to help SSI recipients return to work. Section 1615 of the Act will be waived, in appropriate cases, to permit referral of SSI recipients to an organization other than the State VR agency for employment service. We are publishing this notice to comply with 2 CFR 416.250(e), which requires such notification.

FOR FURTHER INFORMATION CONTACT:
Malcolm H. Morrison, Social Security Administration, Office of Disability, 2223 Annex, 6401 Security Boulevard, Baltimore, Maryland 21235, Phone (301) 965-0091.

Background Information: The Social Security Disability Amendments of 1980, Pub. L. 96-265, section 505(a), as amended by Pub. L. 99-272, section 12101, directs the Secretary to develop and carry out experiments and demonstration projects designed to: 1) Encourage disabled beneficiaries to return to work, and 2) accrue trust fund savings or otherwise promote the objectives or facilitate the administration of title II of the Act. Section 505 of Pub. L. 96-265, as amended by Pub. L. 99-272, section 12101, also authorizes the Secretary to waive certain provisions of the Act as is necessary to conduct these experiments and demonstration projects. This includes waiver of section 222(a) which requires SSA to refer disability beneficiaries to State VR agencies. This also includes waiver of section 222(c)(4)(A) which provides that any month an individual provides services must be counted in the TWP.

Overall Objectives: SSA wishes to assist its disabled beneficiaries in returning to competitive employment. SSA's focus is on significantly improved integration and use of VR and other employment program resources providing for more employment opportunities, better mechanisms for identifying and referring candidates for rehabilitation and other employment services, more effective incentives for rehabilitation and employment, increased access to employment service systems and networks, and more effective and efficient employment intervention for beneficiaries.

Description of Demonstration Projects

(1) Alabama State Department of Education: Montgomery, Alabama: "Early Rehabilitation Intervention for Disability Recipients." The project will involve sites in Montgomery, Birmingham and Decatur (no waiver required). It will focus on early intervention by referring individuals for VR services as early as possible in the disability process. VR counselors will direct a coordinated case management approach in assisting return to employment including use of private sector job placement firms.

(2) American Institute of Rehabilitation, Education and Employment: Sterling, Virginia; "Early Intervention In Private Job Placement of SSDI Beneficiaries" (VR referral waiver required). This project will have three sites, still to be determined. It will focus on early intervention with referrals from SSA field offices before the disability determination is made. Projects with industry sites will be used to provide a full range of VR services. This project represents an alliance of business, labor unions, private rehabilitation agencies and public rehabilitation agencies directing a coordinated return to work effort.

(3) Baltimore County Economic Development and Rehabilitation Alliances, Incorporated: Baltimore, Maryland; "Accessing Rehabilitation Engineering" (VR referral waiver required). Direct marketing will be used to contact physically disabled beneficiaries who are likely to benefit from rehabilitation engineering techniques. They will be enrolled in job
placement programs emphasizing rehabilitation engineering services.

(4) C.A.R.E., Incorporated: Orange County, California; "Computer Assisted Vocational Assessment and Intensive Job Placement" (VR referral waiver required). This project will provide vocational assessment and intensive job placement services where SSDI benefits have been terminated because of medical improvement. Computer-assisted assessment and job matching will be used to assure prompt intervention. It will examine the effects of early post termination intervention on the recidivism' rate and appeals of disability cessation.

(5) Custom Manufacturing Services, Incorporated: Louisville, Kentucky; "Metal Working Occupations for Persons with Mental Retardation" (no waiver required). Seeks to demonstrate the capability of mentally retarded individuals to become a spot welder or press brake machine operator to produce at the same level as non-impaired individuals. Will provide training and supervision in the areas of machine setup, equipment maintenance and quality control.

(6) Fountain House, Incorporated: New York, New York; "The Development, Analysis and Cost-Effectiveness of an Employment System" (VR referral waiver required). This project will design, develop and analyze the effects of a comprehensive employment system for the chronically mentally ill. It will emphasize supportive case management and entry level employment for individuals who have not benefitted from past employment opportunities. The use of vocational services will be used to document specific patterns of community adjustment.

(7) Goodwill Industries of Dayton, Incorporated: Dayton, Ohio; "Case Management/Placement Program for the Severely Disabled" (VR referral waiver required). This project will provide individual rehabilitation planning for selected SSDI beneficiaries. It will expedite the process by using case managers and the integration of vocational resources, including in-house assessment, evaluation, job coaching, rehabilitation engineering and job placement. Cost-benefits will be monitored by a management information system already in place.

(8) International Center for the Disabled: New York, New York; "How and When to Invest in Case Management Employment Services" (VR referral waiver required). This project will test the effectiveness of VR intervention by improving employment outcomes for new referrals versus those receiving disability benefits for at least 1 year. Employment services will be provided by the State VR agency. Final results will include a cost-benefit analysis.

(9) Jordan Rehabilitation Services, Incorporated: Rural and urban areas, New Jersey; "Case Management Project" (VR referral waiver required). This project will provide comprehensive and systematic VR and employment services to beneficiaries who have been disabled no more than 1 year. They will provide goal directed services, including medical/vocational case management, motivational counseling and other support techniques. Provisions are made for a copayment of rehabilitation costs by third party insurers.

(10) Kingsbrook Jewish Medical Center: Brooklyn, New York; "Computerized Evaluation of Functional Capacity for Work Performance" (VR referral waiver required). This project seeks to measure the dynamic residual functional capacity of beneficiaries with musculoskeletal and/or neurological impairments using state-of-the-art technology. It will establish functional requirements for various standard occupations and match project participants with those jobs. Project participants will then be referred to the State VR for job placement.

(11) Medical College of Wisconsin: Milwaukee, Wisconsin; "Cardiac Work Evaluation and Training Center" (VR referral waiver required). This project will develop a model state-of-the-art evaluation and training center for SSDI beneficiaries with cardiac impairments, emphasizing early intervention and return to work. The center will provide individualized residual functional capacity assessment, conditioning, stress management training and work tolerance training.

(12) National Rehabilitation Hospital: Washington, DC; "A Composite Model for Worksite Evaluation and Accommodation" (no waiver required). This project seeks to develop an effective team approach for worksite evaluation and accommodations to assist return to work efforts of beneficiaries. This multidisciplinary approach will combine rehabilitation engineering, occupational therapy and VR counselors. They will conduct approximately 50 worksite evaluations and 10 worksite accommodations in order to link beneficiaries needing technological intervention to return to work.

(13) State of Oklahoma Department of Human Services: Oklahoma City, Oklahoma; "Job Development/VR Special Project" (no waiver required). This project will have sites in Tulsa, Osage and Creek Counties, Oklahoma. It seeks to supplement the services provided by State VR counselors by using counselor aids who are retired senior citizens to provide referrals, support and tracking services to beneficiaries. The expectation is that the special services provided by the counselor aides will significantly increase the number of beneficiaries who successfully complete VR and obtain employment.

(14) Pennsylvania Department of Public Welfare, Office of Mental Health: Philadelphia, Pennsylvania; "Vocational Improvement Program (VIP) Jobs for Mentally Ill Black Men" (VR referral waiver required). Through outreach by case managers this project will provide an intensive 2-year program of vocational services to 46 young black male disabled beneficiaries. These services will include skill enhancement, transportation, job matching, job coaching and 24-hour support services. Success will be measured by retention in the program, involvement with prevocational services and attaining of part-time and full-time employment.

(15) Projects With Industry, Stout Vocational Rehabilitation Institute: Menomonie, Wisconsin; "Cooperative Occupational Options Project for DI Beneficiaries" (VR referral waiver required). This project seeks to develop a service model emphasizing early intervention, comprehensive needs assessment, coordinated referral, placement and follow-up services. To maximize available resources, formal cooperative service agreements will be established with both public and private agencies, including Private Industry Councils (PIC).

(16) REGAIN: San Diego, California; "REGAIN Demonstration Program for Orthopedically Disabled" (VR referral waiver required). This project will have sites in San Diego and Tustin, California. It will focus on orthopedically disabled beneficiaries and provide assessment, development of individual rehabilitation plans, job seeking skills training, placement and follow-up. A system approach that has been successful in the rehabilitation of Workers' Compensation beneficiaries will be used.

(17) Research Foundation of the City University of New York Graduate School and University Center: New York, New York; "Collaborative Employment Program for SSI Youth" (no waiver required). This project will focus on providing disabled high school youth with work experience. It will coordinate placement activity with the PIC and develop a written cooperative agreement between the school.
rehabilitation agencies and employers. It is expected that after completion of high school those individuals will make a smooth transition to full-time employment.

(18) Sharp Rehabilitation Center: San Diego, California; "Enhancing Employment Success for Individuals with Traumatic Brain Injury (TBI)" (VR referral waiver required). This project will provide comprehensive rehabilitation services to individuals who are disabled because of mild to moderate traumatic brain injuries and are currently receiving treatment on an outpatient basis. It will identify key variables which can be used to predict which TBI individuals are likely to benefit from rehabilitation intervention.

(19) Small and Associates, Incorporated: New York, New York; "Hospitality Industry Employment Program" (VR referral waiver required). This project will establish a collaborative employment program between SSA, hospitality industry employers led by the Marriott Corporation and the Job Training Partnership Act (JTPA) employment system. This joint venture will offer enhanced recruitment and competitive employment opportunities for SSA’s disabled beneficiaries.

(20) Southwest Business, Industry and Rehabilitation Association (SWBIRA): Scottsdale, Arizona; "Try Work" (State VR referral waiver and trial work period excluded for up to 6 consecutive months required). The project site will be in the Phoenix, Arizona area and will determine the effectiveness of short term work (6 consecutive months or less) enhanced by preplacement and work adjustment assistance in leading to eventual full-time competitive employment. Participants in this project will be able to work for up to 6 consecutive months and not have this employment count as part of their trial work period (TWP).

(21) The Navajo Nation: Window Rock, Arizona; "Project VALUE (Vocational Avenues Lead to Useful Employment)" (no waiver required). This project will implement a collaborative effort between SSA and the Navajo Vocational Rehabilitation Program (NVRP) in supporting a comprehensive and systematic approach to employment assistance for SSA’s disabled beneficiaries. It will provide counseling, career guidance and job placement services, to eligible beneficiaries who are also native American Indians and members of the Navajo Nation. An automated case status reporting system will be maintained.

(22) The Menninger Clinic, Inc.: Topeka, Kansas; "Profile of DI Beneficiaries Who Return to Work" (VR referral waiver required). This project will identify key beneficiary variables which will predict who would benefit from vocational rehabilitation services and return to work. It will develop matching computer software and demonstrate the use of this information by referring individuals for vocational rehabilitation and employment services.

(23) Vanderbilt University: Nashville, Tennessee; "Early Intervention with Mentally Impaired SSI/SSDI Applicants" (VR referral waiver required). This project will demonstrate that early intervention and comprehensive job placement and counseling services will significantly increase the rate of work for SSDI/Supplemental Security Income applicants. It will emphasize a team case management approach and examine the extent to which disincentives affect the return to work rate.

(24) Virginia Commonwealth University: Richmond, Virginia; "Competitive Employment for Persons with Traumatic Brain Injury (TBI)" (VR referral waiver required). This project will involve sites in Richmond and Norfolk, Virginia. This project will provide comprehensive and innovative vocational services to SSDI beneficiaries with traumatic brain injuries. It will use cognitive strategies such as visual cues and physical adaptations including lapboards and/or adaptive switches. Job coaches will assist individuals at the actual job site.

Statutory Provisions to be Waived:

Sections 222(a) and 1615 of the Act are being waived for the purpose of determining his or her TWP.

The Notices list the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total numbers of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the
The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35) and also solicited a public comment on the subject proposal. Additional persons interested in commenting should be sent to the Department's Office of Management and Budget, New Executive Office Building, Washington, D.C. 20503.

For further information contact: David S. Cristy, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street Southwest, Washington, D.C. 20410, telephone (202) 755-6309. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Cristy.

Supplementary Information: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). It is also requested that OMB complete its review within seven days.

The notice lists the following: (1) the title of the information collection proposal; (2) the Office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) agency form number; (5) what members of the public will be affected by the proposal; (6) how frequent the information will be required; (7) an estimate of the total number of hours.
needed to prepare the information submission including the number of respondents; (8) whether the proposal is new or a revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Sec. 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; sec. 7(d) of the Department of Housing and Development Act, 42 U.S.C. 3535(d).

#### Notice of Submission of Proposed Information Collection to OMB

**Proposal: Nehemiah Housing Opportunity Grant Program—24 CFR Part 280.**

**Office:** Housing.

**Description of the Need for the Information and Its Proposed Use:**

Under the Nehemiah Housing Opportunity Program, the Department is authorized to make grants to non-profit organizations to enable them to provide loans to families purchasing homes that are constructed or substantially rehabilitated in accordance with HUD approved programs.

**Form Number:** HUD-91102.

**Respondents:** Individuals or Households, State or Local Governments, and Non-Profit Organizations.

**Frequency of Submission:** On Occasion.

**Reporting Burden:**

<table>
<thead>
<tr>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Hours per response</th>
<th>Burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>150</td>
<td>1</td>
<td>8</td>
<td>1,200</td>
</tr>
<tr>
<td>10</td>
<td>1</td>
<td>306.7</td>
<td>3,066.5</td>
</tr>
</tbody>
</table>

**Total Estimated Burden Hours:** 4,266.5.

**Status:** New.

**Contact:**

Howard D. Mayfield, HUD, (202) 755-0723

John Allison, OMB, (202) 395-6880

**Date:** May 17, 1989.

**Supporting Statement for Final Rule for Nehemiah Housing Opportunity Grant Program**


The purpose of the program is to provide an opportunity for those families who otherwise would not be financially able to realize their dream of owning a home, to increase the employment opportunities of the residents in neighborhoods where the housing is proposed and to create sound and attractive neighborhoods.

The maximum loan is $15,000 per family. Only owner occupied, first time homebuyers or families who have not owned a home for the past three years are eligible. The family's income shall not be more than the median income of a family of four persons in the metropolitan statistical area where the project will be located. Fifteen percent of the families may have incomes as high as 115 percent of the median income of the area if the unit of local government determines that the increase necessary to achieve or maintain neighborhood stability. To obtain the fifteen percent modification, the recipient must submit a request by the unit of government to the Department of Housing and Urban Development (HUD) for approval. The Department of Housing and Urban Development (HUD) will select Nonprofit Corporations through a competitive process to administer loans to the applicable families. The Nonprofit Corporations (respondents) will submit applications with the documentation regarding their projects. The application will include the number of units, grant requested, location of the proposed project and statistical data regarding the neighborhood. The respondents are also required to submit information and/or documents concerning the following:

- a. Site plans/floor plans;
- b. Description of construction/renovation;
- c. Compliance with Home Quality Standards;
- d. Site control and zoning;
- e. Market analysis;
- f. Description of sales program;
- g. Local resident participation;
- h. Local government approval; and
- i. Program schedule and projected annual program budget.

It will take approximately eight hours for the respondents to prepare the applications. The HUD Field Offices will review the applications submitted in their jurisdictions and send their recommendations to Headquarters for final review and selection.

The following information will also be collected by the respondents:

1. Frequency of recordkeeping or reporting, Subpart D, Application and Selection Procedures, Section 280.207 (vii).

- The recipients will be required to include (attach) a copy of the lead-based paint inspection report with the recorded 2nd mortgage (securing the Nehemiah loan) of all homebuyers. In addition, the case binders of all insured loans will include a copy of the inspection report.

2. Income Limitations (request for modification and supporting documentation), Subpart E, Eligible Purchasers, Section 280.315 (f).

- The modification request shall be submitted within 15 days after the execution. Each request must include the supporting documentation so that action is necessary to achieve or maintain neighborhood stability.

3. The applications are submitted by the sponsor on a case by case basis, and there is no available technology to reduce the burden.

4. No applicable.

5. The method of collecting this information is similar to the process used under 24 CFR Part 885—Elderly Housing and 24 CFR Part 850, Housing Development Grant Program. A draft of the application form for the Nehemiah Housing Opportunity Program is attached. We are still in the process of making appropriate changes.

6. The information included in the applications for selection consist of material available to respondents through consultation with related companies in the housing industry. The information is compiled and forwarded to the Secretary for review and final selection.

7. The information is collected only once during the fiscal year appropriations are made. The
information is adjusted as much as possible to reduce the burden.

8. Not applicable. The collection of information is not inconsistent with the guidelines in 5 CFR 1320.6.

9. Not applicable. No outside consultation from prospective applicants.

10. No assurances of confidentiality are provided to respondents.

11. There are no questions of a sensitive nature included in the applications.

12. The estimate of annualized cost to respondent will vary depending on their respective capabilities. However, we estimate the annual cost to be $12.00 per hour × 4,266.5 burden hours or $51,198.

The annualized cost to the Federal government will be $20.00 per staff hour × 750 staff hours or $15,000.

13. Item No. 17 (SF-83).

| No. of respondents | 150 |
| No. of responses per respondent | 1 |
| Total responses | 150 |
| No. of hours per response | 8 |
| Total burden hours | 1,200 |

There are 10 recordkeepers × the total annual staff hour per recordkeepers which is 306.7 or 3,066.5 hours.

The recordkeeping hours for the lead-based paint and modification request are included in the burden hours as outlined on attachment 2, Tabulation of Annual Reporting Burden, items #4 and #6.

14. The information collection is the result of implementing new statutory requirements and subsequent appropriations.

15. Not applicable. This information is not being collected for statistical use and will not be published.

### Tabulation of Annual Reporting Burden

**Final Rule—Nehemiah Housing Opportunity Grants Program**

<table>
<thead>
<tr>
<th>Information collection requirement</th>
<th>Section of CFR affected</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual response</th>
<th>Hours per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application Submission Requirements</strong></td>
<td>§ 280.105(b) &amp; (c); § 280.110(a) &amp; (b); § 280.125; § 280.215(b)(2)(i); (b)(2)(iv); (b)(7); &amp; § 280.270(a)(6).</td>
<td>150</td>
<td>1</td>
<td>150</td>
<td>6.00</td>
<td>1,200.0</td>
</tr>
<tr>
<td><strong>Affirmative Fair Housing Marketing Requirements</strong></td>
<td>§ 280.307(a)(6).</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>3 minutes</td>
<td>.5</td>
</tr>
<tr>
<td><strong>Racial and Ethnic Data Collection Requirements</strong></td>
<td>§ 280.307(a)(7).</td>
<td>10</td>
<td>145</td>
<td>1,450</td>
<td>3 minutes</td>
<td>43.5</td>
</tr>
<tr>
<td><strong>Lead-Based Paint Reporting and Recordkeeping Requirements</strong></td>
<td>§ 280.307(d).</td>
<td>2</td>
<td>145</td>
<td>290</td>
<td>.50</td>
<td>145.0</td>
</tr>
<tr>
<td><strong>Grant Agreement</strong></td>
<td>§ 280.303(a).</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>2.00</td>
<td>20.0</td>
</tr>
<tr>
<td><strong>Request for Modification of Requirement for Eligible Buyers</strong></td>
<td>§ 280.315(a).</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>1.50</td>
<td>7.5</td>
</tr>
<tr>
<td><strong>Sales Contract Requirement</strong></td>
<td>§ 280.322(b).</td>
<td>10</td>
<td>145</td>
<td>1,450</td>
<td>.50</td>
<td>725.0</td>
</tr>
<tr>
<td><strong>Loan and Second Mortgage Requirement</strong></td>
<td>§ 280.322(a).</td>
<td>10</td>
<td>145</td>
<td>1,450</td>
<td>.50</td>
<td>725.0</td>
</tr>
<tr>
<td><strong>Request for Reimbursement</strong></td>
<td>§ 280.330(b).</td>
<td>10</td>
<td>45</td>
<td>450</td>
<td>1.50</td>
<td>675.0</td>
</tr>
<tr>
<td><strong>Total Burden Hours</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4,266.5</td>
</tr>
</tbody>
</table>
Application for Nehemiah Housing Opportunity Grant Program

U.S. Department of Housing and Urban Development
Office of Housing
Federal Housing Commissioner

Application Number: ______________________

OMB Approval No. 2502-0385 (exp. 12/31/89)

Public Reporting Burden for this collection of information is estimated to average 8 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Reports Management Officer, Office of Information Policies and Systems, U.S. Department of Housing and Urban Development, Washington, D.C. 20410-3600; and to the Office of Management and Budget, Paperwork Reduction Project (2502-0385), Washington, D.C. 20503.

Privacy Act Notice: The information requested in this form is to be used by the Department of Housing and Urban Development (HUD). It will not be disclosed or released outside of HUD, except as required and permitted by law. You do not have to give us this information. The Department of HUD is authorized to ask for this information by the National Housing Act (42 U.S.C. 1701 et seq.).

Section A. Project Identification and Location

1. Name of Project: ____________________________
2. Location (City, State & Zip Code):
   County: ____________________________
3. Median Family Income $ ____________________________

4. Applicant(s):
5. Address of Applicant ____________________________

6. Grant Amount Requested ____________________________
7. Number of Homes to be Constructed or Rehabilitated ____________________________
8a. Unit of Local Government ____________________________
8b. Number of Dwelling Units ____________________________

9. Neighborhood No. 1 Name ____________________________
   Physical and Economic Conditions (Blight):
   Located in an Enterprise Zone? [ ] Yes [ ] No ____________________________

10. Neighborhood No. 2 Name ____________________________
    Physical and Economic Conditions (Blight):
    Located in an Enterprise Zone? [ ] Yes [ ] No ____________________________

11. Neighborhood No. 3 Name ____________________________
    Physical and Economic Conditions (Blight):
    Located in an Enterprise Zone? [ ] Yes [ ] No ____________________________

12. Neighborhood No. 4 Name ____________________________
    Physical and Economic Conditions (Blight):
    Located in an Enterprise Zone? [ ] Yes [ ] No ____________________________

form HUD-91102 (5/89)
ref. handbook XXXXXX

page 1 of 2
Section B. Sites & Construction Exhibits / Local Government Approval & Consultation Exhibits / Sales & Marketing Exhibits

<table>
<thead>
<tr>
<th>Exhibit Type</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Site Plans / Floor Plans</td>
<td>Description of Site Plans</td>
</tr>
<tr>
<td>b. Description of Construction/Rehabilitation</td>
<td>Local Government Approval</td>
</tr>
<tr>
<td>c. Compliance with Home Quality Standards</td>
<td>Local Resident Participation</td>
</tr>
<tr>
<td>d. Site Control &amp; Zoning</td>
<td>Program Schedule &amp; Projected Annual Program Budget</td>
</tr>
<tr>
<td>e. Market Analysis</td>
<td></td>
</tr>
</tbody>
</table>

Section C. Program Financial Data

<table>
<thead>
<tr>
<th>Financial Information</th>
<th>Amount/Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Total Cost of Development</td>
<td>$150,000</td>
</tr>
<tr>
<td>b. Average Cost per Home</td>
<td>$50,000</td>
</tr>
<tr>
<td>c. Source of Program Funds</td>
<td></td>
</tr>
<tr>
<td>(1) Financial Contributions by Public &amp; Private Entities</td>
<td>$100,000</td>
</tr>
<tr>
<td>(2) Contributions of Land</td>
<td></td>
</tr>
<tr>
<td>(3) Other &quot;in kind&quot; Contributions</td>
<td></td>
</tr>
<tr>
<td>d. Other Applicant’s Contributions</td>
<td></td>
</tr>
<tr>
<td>(1)</td>
<td></td>
</tr>
<tr>
<td>(2)</td>
<td></td>
</tr>
<tr>
<td>(3)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
</tr>
</tbody>
</table>

Section D. Local Resident Involvement

<table>
<thead>
<tr>
<th>Residency Involvement</th>
<th>Number &amp; Types of Jobs Projected for Neighborhood Residents</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Local Resident Participation</td>
<td>100</td>
</tr>
<tr>
<td>b. Program Contact Person</td>
<td>X</td>
</tr>
<tr>
<td>c. Racial / Ethnic Composition of the Principals</td>
<td>White</td>
</tr>
<tr>
<td>d. Signature and Date</td>
<td>X</td>
</tr>
</tbody>
</table>

Warning - U.S. Criminal Code, Section 1010, Title 18, U.S.C., "Federal Housing Administration transactions", provides in part: "Whoever, for the purpose of ... the action of such Administration ... makes, passes, utters, or publishes any statement, knowing the same to be false, ... shall be fined not more than $5,000 or imprisoned not more than two years, or both."

DRAFT
The Department was unable to maintain
these efforts because the
program had floundered, in part, because the
Department was not able to produce
regulatory requirements, conduct
important to the Department's efforts to
monitor compliance with statutory and
HUD's statistical reports.
In addition, the data is
multifamily data, which is essential to
the Multifamily Tenant Characteristics
System. This new information collection is needed to support the processing of public and
Indian housing tenant data for the
Multifamily Tenant Characteristics System.

Form HUD-50060, Transmittal of Form HUD-50058 (Tenant Data Summary).
Office: Public and Indian Housing.
Description of the need for the
information and its proposed use: This
new information collection is needed to support the processing of public and
Indian housing tenant data for the
Multifamily Tenant Characteristics System.

Form HUD-50060, transmittal of Form HUD-50058 (Tenant Data Summary),
will be used to transmit Forms HUD-
50058 from the respondent to HUD's
data capture contractor. Public housing
agencies and Indian housing authorities
will submit one transmittal form each
month for each project.

Form Number: HUD-50060.
Respondents: State or Local
Governments.
Frequency of submission: Monthly
Reporting Burden:

<table>
<thead>
<tr>
<th>No. of respondents</th>
<th>Frequency of response</th>
<th>Hours per response</th>
<th>Total Burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>3253</td>
<td>50</td>
<td>3 mins.</td>
<td>8,133</td>
</tr>
</tbody>
</table>

Total Estimated burden hours: 8,133.
Status: New.
Date: May 19, 1989.

Supporting Statement—Form HUD-50060, Transmittal of Form HUD-50058 (Tenant Data Summary)

1. HUD has been trying to establish
the Multifamily Tenant Characteristics System (MTCS) for several years. Information about the characteristics of
HUD-assisted tenants is essential to
HUD's policy development and
evaluation, budget development, and the
estimation of the impact of legislative changes. In addition, the data is
important to the Department's efforts to
monitor compliance with statutory and
regulatory requirements, conduct
program evaluations, and produce
statistical reports.
Past efforts at collecting tenant data
have floundered, in part, because the
Department was unable to maintain
adequate controls over incoming
documents. Form HUD-50060,
Transmittal of Form HUD-50058, will
allow the Department to establish
appropriate management control
procedures to assure complete and
accurate reporting of tenant data. [Form
HUD-50058, Tenant Data Summary
(OMB Approval Number 2577-0083), is
the data entry vehicle for MTCS for the
collection of information on public and
Indian housing tenants.]

The information collections
associated with MTCS are required by
the following statutory provisions:
Section 108 of the Housing and
Community Development Act of 1987.
Title VI of the Civil Rights Act of 1964.
Title VIII of the Civil Rights Act of 1968.
Executive Order 11066—Equal
Opportunity in Housing.

The information collections
associated with MTCS are required by
the following regulatory provisions:
24 CFR 913.104(b)
24 CFR 913.105(d)
24 CFR 913.109(b)

2. The respondents (PHAs) must
submit Form HUD-50060 with Forms
50058 for each project each month. In
the first year, data will be requested
from large and medium-sized PHAs [500
to 4,999 units], the second year from small and extra large PHAs [100 to 499
units and 5,000 and over], and the third
year from the extra small PHAs [1 to 99
units].

Form HUD-50060 will allow the data
capture contractor to determine if the
shipment of HUD-50058s is complete, to
check for errors in reporting project
numbers, and to anticipate future
submissions of HUD-50058s. The
contractor will also be able to know
whether a month of no HUD-50058s
being submitted for a project was
intentional and not due to oversight. The
Form also will give the name of a contact person at the PHA for problem-
solving and follow-up questions.

3. The Department does not have a
mechanism for getting this information
through improved information
technology.
4. There is no duplication.  
5. There is not similar information available. The information requested on Form HUD-50060 serves the submission of Form HUD-50058 data.  
6. The only way to minimize the burden is to eliminate the Form.  
7. The collection cannot be conducted any less frequently if it is to serve the functions for which it is needed.  
8. The collection will be conducted in a manner consistent with 5 CFR 1320.6.  
9. There has been no effort to consult with persons outside the agency other than the MTCS data collection contractor.  
10. No assurance of confidentiality is necessary.  
11. There are no questions of a sensitive nature on this Form.  
12. There is no cost to the Federal Government or the PHAs. The contractor will send Form HUD-50060s to the PHAs chosen to submit Form HUD-50058s. The cost will be absorbed in the MTCS data-processing contract.  
13. We estimate the information collection burden to be 920 hours the first year, 4,233 hours the second year, and 8,133 hours the third year.  

<table>
<thead>
<tr>
<th>Year</th>
<th>No. PHAs</th>
<th>Av. No. projects per PHA</th>
<th>Forms per project</th>
<th>Annual No. TFs</th>
<th>Mins. per TF</th>
<th>Burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td>368</td>
<td>4.17</td>
<td>12</td>
<td>18,400</td>
<td>3</td>
<td>920</td>
</tr>
<tr>
<td>Second</td>
<td>1,693</td>
<td>4.17</td>
<td>12</td>
<td>84,650</td>
<td>3</td>
<td>4,233</td>
</tr>
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<td>Third</td>
<td>3,253</td>
<td>4.17</td>
<td>12</td>
<td>162,650</td>
<td>3</td>
<td>8,133</td>
</tr>
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</table>

14. This is a new information collection.  
15. There are no plans to publish this information collection.  
BILLING CODE 4210-33-M
Transmittal of form HUD-50058
(Tenant Data Summaries)

Federal Register
Vol. 54, No. 102 / Tuesday, May 30, 1989 / Notices

U.S. Department of Housing
and Urban Development
Office of Public and Indian Housing

Public reporting burden for this collection of information is estimated to average 3 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Reports Management Officer, Office of Information Policies and Systems, U.S. Department of Housing and Urban Development, Washington, D.C. 20410-3600 and to the Office of Management and Budget, Paperwork Reduction Project (2577-XXXX), Washington, D.C. 20503.

1. Reporting Month Ending Date (mm/yy) 2. Date of Transmittal (mm/dd/yy)

3. Public Housing Agency (name & address)

4. Name of Contact Person (please print) 4a. Phone Number (include area code)

5. Project Number 5a. Project Name

6. Number of Expected Initial Submissions for this Fiscal Year
   1st Quarter 2nd Quarter 3rd Quarter 4th Quarter

7. Number of Attached Submissions
   7a. Mark this block for No Submissions this month.
   7b. Number of form HUD-50058s (Do not include those in 7d).
   7c. Number of corrected error reports.
   7d. Number of resubmissions of form HUD-50058.

8. Proposed Change in Media for HUD-50058 Data Submission
   8a. Proposed Media
       □ Magnetic Tape □ Diskette □ Paper
   8b. Month media change will occur (MM/YY)

Return this form to: MTCS Processing Center
PO Box 4196
Iowa City, IA 52244-4196

DRAFT

For HUD use only
Date this form was Received (mm/dd/yy) Date of Entry into Log File (mm/dd/yy) Signature of Logger

form HUD-50060 (5/89)
ref. Handbook 7465.3
DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service

Receipt of Applications for Permits

The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, et seq.):

PRT-736470
Applicant: Driscoll Properties, Inc., Key Largo, FL

The applicant requests a permit for incidental take of the Key Largo woodrat (Neotoma floridana smallii), the Key Largo cottonmouse (Peromyscus gossypinus allapaticola), and the Schaus swallowtail butterfly (Heraclides =Papilio aristodemus Schaus) which may occur during the completion of a residential subdivision and related harbor. The applicant has submitted conservation and revegetation plans.

Interested persons may comment on this application by submitting written data, views or arguments to the U.S. Fish and Wildlife Service, Russell Federal Building, 75 Spring Street, SW., Suite 1276, Atlanta, GA, 30303, Attention Mary Anne Young. Please refer to the Driscoll Properties, Inc. Key Largo Incidental Take Permit PRT-736470 when submitting comments.

PRT-736990
Applicant: William Karesh, DVM, Center for Wildlife Conservation, Seattle, WA

The applicant requests a permit to import 100 skin biopsy samples from captive and wild orang-utans (Pongo pygmaeus) in Indonesia for the purpose of genetic analysis.

PRT-736813
Applicant: Museum of Zoology, Univ. of Michigan, Ann Arbor, MI

The applicant requests a permit to import the following reptiles that died while in captivity at the Reptile Breeding Foundation, Pictou, Ontario Canada, for the purpose of scientific research: 1 Casarea dussemieri, 1 Epicrates subflavus, 1 E. inornatus and 3 Phelsuma guentheri.

PRT-697823
Applicant: U.S. Fish & Wildlife Service, Region 5, Newton Corner, MA

The applicant requests permits to purchase in interstate commerce captive-born specimens of the following endangered species from Herpetofauna, Inc., Ft. Myers, Florida, for the purpose of enhancement of propagation:

- 2 pairs of Yacare caiman (Caiman crocodilus yacare) PRT 737569
- 1 pair of saltwater crocodiles (Crocodilus porosus) PRT 737570
- 1 pair of Siamese crocodiles (Crocodilus siamensis) PRT 737571
- 1 pair of Nile crocodiles (Crocodylus niloticus) PRT 737572
- 1 pair of American crocodiles (Crocodylus acutus) PRT 737573

Applicant: University of Georgia, Athens, GA

The applicant requests a permit to import the following reptiles that died while in captivity at the Reptile Breeding Foundation, Pictou, Ontario Canada, for the purpose of scientific research: the eggs will be imported from the Saskatchewan Cooperative Falcon Project, Saskatoon, Saskatchewan, Canada.

PRT-706831
Applicant: U.S. Fish & Wildlife Service, Region 1, Portland, OR

The applicant requests an amendment to their current permit to allow take of the American burying beetle (Nicophorus americanus) for scientific purposes and the enhancement of propagation or survival of the species in accordance with Recovery Plans, listing, or other Service work for that species.

The applicant requests permits to import 6 to.10 infertile peregrine falcon (Falco pereginus anatum) in Indonesia for the purpose of enhancement of propagation or survival of the species in accordance with Recovery Plans, listing, or other Service work for that species.

Applicant: University of Georgia, Athens, GA

The applicant requests a permit to import 4 female Bengal tigers (Panthera tigris) captive-bred in the United States to Canada for enhancement of survival through conservation education. The applicant may reexport the animals to additional countries in the future.

Applicant: John Mellyn, Wauconda, IL

The applicant requests permits to purchase in interstate commerce captive-born specimens of the following endangered species from Herpetofauna, Inc., Ft. Myers, Florida, for the purpose of enhancement of propagation:

- 2 pairs of Yacare caiman (Caiman crocodilus yacare) PRT 737569
- 1 pair of saltwater crocodiles (Crocodilus porosus) PRT 737570

Applicant: Museum of Zoology, Univ. of Michigan, Ann Arbor, MI

The applicant requests permits to import 1 pair of saltwater crocodiles (Crocodilus porosus) PRT 737570

Applicant: University of Georgia, Athens, GA

The applicant requests permits to import 6 to.10 infertile peregrine falcon (Falco pereginus anatum) in Indonesia for the purpose of enhancement of propagation or survival of the species in accordance with Recovery Plans, listing, or other Service work for that species.

PRT number when submitting comments.

R.K. Robinson,
Chief, Branch of Permits, U.S. Office of Management Authority.

BILLING CODE 4310-55-M

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY
Agency for International Development
Housing Guaranty Program; Investment Opportunity

The Agency for International Development (A.I.D.) has authorized the guaranty of a loan for the Republic of Indonesia as part of A.I.D.'s development assistance program. The proceeds will be used to finance infrastructure and shelter projects for low-income families in Indonesia. At this time, the Government of Indonesia has authorized A.I.D. to request proposals from eligible lenders for a loan under this program of Twenty Five Million U.S. Dollars ($25,000,000). The name and address of the representatives of the Borrower to be contacted by interested U.S. lenders of investment bankers, the amount of the loan and project number are indicated below:

Government of Indonesia
Project No: 497-HG-001—$25,000,000.

(1) Attention: Mr. Benjamin Parwoto, Director General of Budget, Ministry of Finance, Jalan Lampangan Banteng Timur No. 2, Jakarta, Indonesia, Telex No.: 45790 DJMLNIA, Telefax No.: 62/21/365363, Telephone No.: 62/21/358289, 357258 or 342234.

(2) Attention: Mr. Syahril Sabirin, Bank of Indonesia, J.L. M.H. Thumrin No. 2, Jakarta, Indonesia, Telex No.: 45712 BITMR or 46671 BISIR, Telefax Nos.: 62/21/362869, Telephone No.: 62/21/362938.

(3) Attention: Mr. Djmalius Luddin, Bank of Indonesia, One World Financial Center, 200 Liberty Street, Sixth Floor, New York, NY 10281, Telexfax No.: 212/945-1316, Telephone No.: 212/945-1310.

Interested lenders should contact the Borrower as soon as possible and indicate their interest in providing financing for the Housing Guaranty Program. Interested lenders should deliver their bids to all of the Borrower’s representatives by June 7, 1989, 12:00 noon Easter Standard time. Bids should be open at least 48 hours. Copies of all bids should be simultaneously sent to the following:

World Bank,
Department of the Interior, Fish and Wildlife Service, Department of the Interior, Washington, D.C., 20240, Attention: Mr. Djamaluddin, Mr. Parwoto, Mr. Sabirin, Mr. Luddin.

DEPARTMENT OF THE INTERIOR
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To be eligible for an A.I.D. guaranty, the loans must be repayable in full no later than the thirtieth anniversary of the disbursement of the principal amount thereof and the interest rates may not be higher than the maximum rate established from time to time by A.I.D.

Information as to the eligibility of lenders and other aspects of the A.I.D. Housing Guaranty Program can be obtained from: Peter M. Kimm, Director, Office of Housing and Urban Programs, Agency for International Development, Room 401, SA-2, Washington, DC 20523-0214. Telephone: 202/633-2530.

Date: May 24, 1989.
Housing Guaranty Program can be obtained from:

Date: May 27, 1989.

Michael G. Kitay,
Assistant General Counsel, Bureau for Private Enterprise, Agency for International Development.

[FR Doc. 89–12927 Filed 5–26–89; 8:45 am]

BILLING CODE 6116–01–M

COMMISSION

[FR Doc. 89–12741 Filed 5–28–89; 8:45 am]

BILLING CODE 7035–01–M

INTERSTATE COMMERCE COMMISSION

[EX Parte No. 274; Sub 13]

Rail Abandonments—Use of Rights–of–Way as Trails; Supplemental Trails Act Procedures

AGENCY: Interstate Commerce Commission.

ACTION: Notice.

SUMMARY: The Commission has considered a request to amend its rules implementing section 1246(d) of the National System Trails Act, 16 U.S.C. 1247(d), adopted in Rail Abandonments—Use of Rights–of–Way as Trails, 2 I.C.C.2d 591 (1988), and Rail Abandonments—Use of Rights–of–Way as Trails—Supplemental Trails Act Procedures, 4 I.C.C.2d 152 (1987), codified at 49 CFR 1152.29. The requested changes would require reports on the outcome of Trails Act negotiations and, if an interim trail use agreement is reached: (1) Reports on such matters as payment of taxes, maintenance, trail groups’ interests in rights–of–way, and termination of trail use; and (2) the identification of trail operators to persons holding reversionary interests in rights–of–way. After considering the proposal of the National Association of Reversionary Property Owners (NARPO), and the comments received in response to our May 1988 decision and notice, we find that no changes to our current Trails Act procedures are necessary or appropriate.

DATES: This action is effective on June 29, 1989.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 275–7245 (TDD for hearing impaired) (202) 275–7211

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission’s decision. To purchase a copy of the full decision write to, call, or pick up in person from: Dynamic Concepts, Inc., Room 2229, Interstate Commerce Commission Building; Washington, DC 20423. Telephone: (202) 229–4357/4359. [Assistance for the hearing impaired is available through TDD Services (202) 275–1721.]

Decided: May 18, 1989.

By the Commission, Chairman Gradison, Vice Chairman Simmons, Commissioners Andre, Lamboley, and Phillips. Commissioner Andre dissented in part with a separate expression.

Noreta R. McGee,
Secretary.

[FR Doc. 89–12741 Filed 5–28–89; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF JUSTICE

Joint Newspaper Operating Agreement

Notice is hereby given that the Attorney General has extended the date for submitting written comments and requests for a hearing concerning the application by two Pennsylvania newspapers, the York Daily Record and the York Dispatch/York Sunday News, for a joint operating arrangement (JOA) under the Newspaper Preservation Act, 15 U.S.C. 1801 et seq.

The Antitrust Division of the Department of Justice filed a motion for an extension of time with respect to submitting its report on the proposed JOA. The Attorney General granted the motion in an order signed on May 5, 1989. The original notice concerning the application by the two newspapers appeared in 54 FR 11579 on March 21, 1989.

Interested parties may now file their comments or requests for a hearing by mailing or delivering five copies to the Assistant Attorney General for Administration, Justice Management Division, Department of Justice, Washington, DC 20530, by June 5.

FOR INFORMATION CONTACT: Janis A. Sposato, General Counsel, Justice Management Division, 202–833–3452.

Harry H. Flickinger,
Assistant Attorney General for Administration.

[FR Doc. 89–12745 Filed 5–26–89; 8:45 am]

BILLING CODE 4410–01–M

Logging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act and Other Statutes

In accordance with Department policy, 28 CFR 50.7, notice is hereby given that a proposed partial consent decree in United States of America v. A & F Materials Company, Civil Action No. 83–3123 was lodged with the United States District Court for the Southern District of Illinois. The first amended complaint filed by the United States in this action alleged that numerous persons, including each of the parties to the pending proposed consent decree, are jointly and severally liable to take conditions present across the river from the Greenup site, which would not present an endangerment, and that any migration of contaminants will not produce a measurable adverse impact on the nearby Embarras River.

The proposed consent decree also establishes requirements for development and implementation of a Supplemental Response Action if contaminants should subsequently be detected in concentrations exceeding specified action levels in the Embarras River or in monitoring wells across the river from the Greenup site. Finally, the attached decree includes provisions for implementation of "Institutional Controls" that would limit the potential for use of groundwater in a small area situated between the Greenup site and the Embarras River.

The Department of Justice will receive comments relating to the proposed consent decree for a period of thirty (30) days from the date of this publication. Comments should be addressed to the Assistant Attorney General of the Land and Natural Resources Division, Department of Justice, Washington, DC and should refer to United States v. A & F Materials Company, Inc., D.J. Ref. No. 89–7–1–140.

The proposed Consent Decree may be examined at the office of the United States Attorney, 750 Missouri Avenue, East St. Louis, Illinois 62203 and at the Office of Regional Counsel, United States Attorney, 750 Missouri Avenue.
States Environmental Protection Agency, Region V, 111 West Jackson Street, Third Floor, Chicago, Illinois 60604. Copies of the proposed consent decree may be examined at the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice, Room 1915, Ninth Street and Pennsylvania Avenue, NW., Washington, DC 20530. A copy of the proposed consent decree may be obtained in person or by mail from the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice. In requesting a copy, please enclose a check in the amount of $23.40 (ten cents per page reproduction cost) payable to the Treasurer of the United States.

Donald A. Carr,
Acting Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 89-12748 Filed 5-26-89; 8:45 am]
BILLING CODE 4410-01-M

Lodging of Consent Decree Pursuant to the Resource and Conservation Recovery Act

In accordance with Department policy, 28 CFR 50.7, notice is hereby given that on May 12, 1989, a proposed consent decree in United States v. Allegan Metal Finishing Company, Civil Action No. K 88-441-C, was lodged with the United States District Court for the Western District of Michigan. The proposed consent decree resolves a judicial enforcement action brought by the United States against Allegan Metal Finishing Company for violations of the Resource Conservation and Recovery Act (“RCRA”).

The proposed consent decree provides that, except in full compliance with all Federal and State laws and regulations, Allegan shall not treat, store or dispose of any hazardous waste into or on any land treatment or land disposal unit at the Allegan facility. The proposed consent decree also requires Allegan to close its two surface impoundments as required by RCRA. The proposed decree also requires Allegan, within 30 days of the entry of the consent decree, to satisfy the liability insurance requirement for sudden and non-sudden accidental occurrences from the two surface impoundments. If Allegan does not satisfy these requirements despite its good faith efforts, it shall periodically provide documentation of its good faith efforts to satisfy these requirements. Finally, the consent decree requires Allegan to pay a civil penalty of $43,000.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General of the Land and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to United States v. Allegan Metal Finishing Company, D.J. 90-7-1-343.

The proposed consent decree may be examined at the office of United States Attorney, 399 Federal Building, Grand Rapids, Michigan and at the office of Regional Counsel, Environmental Protection Agency, 230 South Dearborn Street, Chicago, Illinois.

Copies of the consent decree may be examined at the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice. In requesting a copy, please enclose a check in the amount of $1.00 (10 cents per page reproduction cost) payable to the Treasurer of the United States.

Donald A. Carr,
Acting Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 89-12704 Filed 5-26-89; 8:45 am]
BILLING CODE 4410-01-M

Lodging of Consent Order Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with 42 U.S.C. 9622(f) and with Departmental policy, 28 CFR 50.7, notice is hereby given that a proposed consent order in United States v. Velsicol Chemical Corporation, Civil Action No. 89-4128, has been lodged with the United States District Court for the Southern District of Illinois on May 18, 1989. The proposed consent order concerns cleanup of a hazardous waste site at a Velsicol Chemical Corporation plant which is located in Marshall, Clark County, Illinois. The proposed consent order requires defendant to perform a cleanup at the Site, and pay certain United States Environmental Protection Agency costs.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed consent order. Comments should be addressed to the Assistant Attorney General of the Land and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to United States v. Velsicol Chemical Corporation, D.J. Ref. 90-11-2-361.

The proposed consent order may be examined at the office of the United States Attorney for the Southern District of Illinois, Room 330, 750 Missouri Avenue, East St. Louis, Illinois 62201, and at the Office of Regional Counsel, United States Environmental Protection Agency, Region V, 111 West Jackson Street, Chicago, Illinois 60604. Copies of the consent order may be examined at the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice, Room 1517, Ninth Street and Pennsylvania Avenue, Washington, DC 20530. A copy of the proposed consent order may be obtained in person or by mail from the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice. In requesting a copy, please enclose a check in the amount of $7.10 (10 cents per page reproduction cost) payable to the Treasurer of the United States.

Donald A. Carr,
Acting Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 89-12705 Filed 5-26-89; 8:45 am]
BILLING CODE 4410-01-M

Antitrust Division

Notice Pursuant to the National Cooperative Research Act of 1984; National Center for Advanced Technologies, Inc.

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 et seq. (“the Act”), the National Center for Advanced Technologies, Inc. on April 18, 1989, filed a written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notification was filed for the purpose of invoking the Act’s provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties to the venture and its general areas of planned activities, are given below.

The participants in the National Center for Advanced Technologies, Inc. are:

National Center for Advanced Technologies, Inc.
Aerospace Industries Association of America, Inc.
Aerojet General
Aeronca, Inc.
Allied-Signal Aerospace Company
Aluminum Company of America
Agro-Tech Corporation
B. H. Aircraft Company, Inc.
The Boeing Company
Celion Carbon Fibers
Chrysler Technologies Corporation
Colt Industries, Inc.
E-Systems, Inc.
Fairchild Industries
FMC Corporation
General Dynamics Corporation
General Electric Company
General Motors Corporation
General Electric Company
Honeywell, Inc.
Hexcel Corporation
IBM Corporation, Systems Integration Division
The Interlake Corporation
ISC Defense & Space Group, Inc.
ITT Defense Technology Corporation
Kaman Aerospace Corporation
Lear Astronics Corporation
Lockheed Corporation
The LTV Corporation
Lucas Western, Inc.
Martin Marietta Corporation
McDonnell Douglas Corporation
Morton Thiokol, Inc.
Northrop Corporation
Parker Hannifin Corporation
Pneumo Abex Corporation
Precision Castparts Corporation
Raytheon Company
Rockwell International Corporation
Rohr Industries, Inc.
SII Avionics Corporation-Smiths Industries Sundstrand Corporation
Teledyne CAT
Textron, Inc.
TRW, Inc.
United Technologies Corporation
Westinghouse Electric Corporation
Wyman-Gordon Company

The National Center for Advanced Technologies, Inc. plans to coordinate research and development, conduct research and development, and collect and disseminate information concerning research and development in the areas of composite materials, very large scale integrated circuits, software development, propulsion systems, advanced sensors, optical information processing, artificial intelligence and ultrareliable electronics.

Joseph H. Widmar,
Director of Operations, Antitrust Division.

[AA/G/A Order No. 33-89]
Privacy Act of 1974; New System of Records

Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), notice is hereby given that the Department of Justice proposes to establish a new system of records to be maintained by the Immigration and Naturalization Service (INS).

The Fees and Application Receipt and Entry System (FARES) JUSTICE/INS-013 is a new system of records for which no public notice consistent with the provisions of 5 U.S.C. 552a(e)(4) has been published in the Federal Register. The new system will enable INS to determine the status of pending applications and petitions for benefits; to account for and control the receipt and disposition of any fees or refunds collected, including those which accompany applications, petitions, posted bonds, and Freedom of Information/Privacy Act (FOIA/PA) requests; and to locate related files and respond to inquiries about these records.

This system, which is broader in scope, will replace the Application/Petition Tracking System (APTS), Justice/INS-002, last published on December 11, 1987. A notice to remove the APTS system will be published in the near future.

5 U.S.C. 552a(e)(4) and (11) provide that the public be given a 30-day period in which to comment on the new routine use; the Office of Management and Budget (OMB), which has oversight responsibility under the Act, requires a 60-day period in which to conclude its review of the system. Therefore, please submit any comments by (30 days from the publication date of this notice). The public, OMB, and the Congress are invited to submit comments to Patricia E. Neely, Staff Assistant, Facilities and Management Division, Department of Justice, Room 539, 633 Indiana Avenue NW., Washington, DC 20530.

In accordance with 5 U.S.C. 552a(o), the Department has provided a report on this system to OMB and the Congress.

Date: May 12, 1989.

Harry H. Flickinger,
Assistant Attorney General for Administration.

JUSTICE/INS-013
System Name: Fees and Application Receipt and Entry System (FARES)
System Location: Immigration and Naturalization Service (INS) Central Office, Regional Service Centers, District Offices and sub-offices as detailed in Justice/INS-999.

Categories of Individuals Covered by the System:

Individuals who have filed applications or petitions for benefits under the Immigration and Nationality Act, as amended, and/or who have submitted fee payments with such applications or petitions; individuals who have paid fees for access to records under the Freedom of Information/Privacy Acts (FOIA/PA); individuals who have posted a bond and related fees with INS; and individuals who have refunded money to INS.

Categories of Records in the System:

Information which identifies individuals named above, e.g., name and address, date of birth, and alien registration number. Records in the system may also include such information as date documents were filed or received in INS, status, location of record, FOIA/PA or other control number where applicable, fee receipt data, and posted bond data.

Authority For Maintenance of The System:


Purpose of the System:

This system will enable INS to determine the status of pending applications and petitions for benefits; to account for and control the receipt and disposition of any fees or refunds collected, including those which accompany applications, petitions, posted bonds, and FOIA/PA requests; and to locate related files and respond to inquiries about these records.

Routine Uses of Records Maintained in the System, Including Categories of Users and the Purposes of Such Uses:

No external disclosure will be made from this system. The system will be used by employees as indicated under “Purpose of the System.”

Policies and Practices for Storing, Retrieving, Accessing, Retaining, and Disposing of Records in the System:

Storage:

Information is stored on magnetic disks and tape.

Retrievability:

Records may be retrieved by name of the individuals covered by the system; and by fee receipt number.

Safeguards:

Records are safeguarded in accordance with Department of Justice rules and procedures. INS offices are located in buildings under security guard, and access to premises is by official identification. Offices are locked...
during non-duty hours. Access to this system is obtained through remote terminals which require the use of restricted passwords and a user ID.

Retention and Disposal:
Records are archived off-line for an indefinite period one year after the final action. A disposition schedule for archived records is pending.

System Manager:
Assistant Commissioner, Records Systems Division, Immigration and Naturalization Service, 425 I Street NW., Washington, DC 20536.

Notification Procedure:
Inquiries should be addressed to the system manager.

Record Access Procedure:
Make all requests for access in writing to the FOIA/PA Officer at any INS office. Clearly mark the envelope and letter "Privacy Act Request." Depending on the type of record, provide the name and date of birth of the applicant, name of petitioner or FOIA/PA requester, alien registration number of beneficiary and receipt number to assist in locating and/or verifying the identity of the record. For your convenience, INS Form G-639, Freedom of Information Act Privacy Act Request, may be obtained from the nearest INS office and used to submit a request.

Contesting Records Procedure:
Direct all requests to contest or amend information to the FOIA/PA Officer at any INS office. State clearly and concisely the information being contested, the reason for contesting it, and the proposed amendment thereof. Clearly mark the envelope "Privacy Act Amendment Request." The record must be identified in the same manner as described for making a request for access.

Record Source Categories:
Information contained in this system of records is obtained from the individuals covered by the system.

Systems Exempted From Certain Provisions of the Act:
None.

Drug Enforcement Administration

Aggregate Production Quota for Methaqualone: Correction

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTIONS: Notice of an established 1989 aggregate production quota: Correction.

SUMMARY: This notice corrects the date (year) for the aggregate production quota for methaqualone which was previously published in the Federal Register, April 24, 1989 (54 FR 16419). The date is corrected to read 1989 Aggregate Production Quota (Grams).

John C. Lawn,
Administrator; Drug Enforcement Administration.

Date: May 18, 1989.

DEPARTMENT OF LABOR

Employment and Training Administration

Federal-State Unemployment Compensation Program;
Unemployment Insurance Program
Letter Interpreting Federal Unemployment Insurance Law

The Employment and Training Administration interprets Federal law pertaining to unemployment insurance as part of the fulfillment of its role in administration of the Federal-State unemployment insurance system. These interpretations are issued in Unemployment Insurance Program Letters (UIPLs) to State Employment Security Agencies (SESAs). The UIPL described below is published in the Federal Register in order to inform the public.

Unemployment Insurance Program Letter No. 25-89

This directive transmits to SESAs the Secretary of Labor's decision in the 1988 conformity proceedings concerning the State of Minnesota. At issue was a provision of Minnesota's unemployment compensation law which permitted the withholding of up to 50 percent of the unemployment compensation otherwise payable to an individual "for unpaid contributions, interest, penalties, and costs which the individual has been determined liable to pay." The Secretary upheld the Department's position that this provision conflicted with certain Federal law requirements.


Robert T. Jones,
Assistant Secretary of Labor.
UNEMPLOYMENT INSURANCE PROGRAM LETTER NO. 25-89

TO: ALL STATE EMPLOYMENT SECURITY AGENCIES

FROM: DONALD J. KULICK
Administrator
for Regional Management

SUBJECT: Secretary's Decision in the 1988 State of Minnesota Conformity Proceedings

1. Purpose. To announce the Secretary of Labor's decision in the 1988 conformity proceedings concerning the State of Minnesota.

2. References. Sections 303(a)(1) and (5) of the Social Security Act (SSA); Sections 3304(a)(4) and 3306(h) of the Federal Unemployment Tax Act (FUTA); Secretary's Decision in Case No. 88-UIA-9, dated December 16, 1988.

3. Background. In 1987, the State of Minnesota amended its unemployment compensation law to permit the withholding of up to 50 percent of the unemployment compensation otherwise payable to an individual "for unpaid contributions, interest, penalties, and costs which the individual has been determined liable to pay." These liabilities were based on the individual's prior status as an employer.

The Department of Labor (DOL) challenged this provision under several provisions of Federal law. The "withdrawal standard" in Section 3304(a)(4), FUTA, and Section 303(a)(5), SSA, requires State law to provide that all money withdrawn from the unemployment fund of the State shall be used solely in the payment of unemployment compensation (with exceptions which were not germane to this issue). "Compensation" is defined in Section 3306(h), FUTA, as "cash benefits payable to individuals with respect to their unemployment." Section 303(a)(1), SSA, requires State law to include provision for "Such methods of administration... as are found by the Secretary of Labor to be reasonably calculated to insure full payment of unemployment compensation when due."

DOL argued that these provisions require the payment of unemployment compensation as a matter of right to eligible claimants, and therefore prohibit any levy, attachment or other remedy for the collection of public or private debts,
prior to the receipt by the claimant of the benefits otherwise payable. DOL further argued that exceptions to the requirement that withdrawals from a State's unemployment fund be limited to compensation payable to eligible claimants are permitted only as specifically authorized or required by Section 303, SSA, and Section 3304, FUTA, and that DOL has no authority to grant any exceptions to the required payment of benefits to claimants as a matter of right.

Briefs and reply briefs were filed with a Department of Labor administrative law judge (ALJ). Minnesota waived its right to a hearing. On November 14, 1988, the ALJ issued a recommended decision upholding DOL's position. On December 16, 1988, the Secretary issued her Decision.

4. The Secretary's Decision. The Secretary adopted, with certain technical corrections, the ALJ's decision and held that Minnesota law "no longer contains the provisions specified in Section 3304(a)(4) of FUTA and in sections 303(a)(1) and (a)(5) of SSA."

In the event States face litigation involving the withdrawal standard, the States should note the discussion of Brewer v. Cantrell, 622 F.Supp 1320 (W.D. Va), aff'd 796 F.2d 472 (4th Cir. 1986), on page 4 of the ALJ's decision. DOL was not a party to Brewer, in which the plaintiffs claimed that Section 3304(a)(4) prohibited the offset of prior overpayments from compensation. In dismissing this claim, the Brewer Court reasoned that, to have a violation of Section 3304(a)(4), "money must be withdrawn from the unemployment funds." On this point, the ALJ stated that "the Brewer Court's interpretation of the withdrawal standard is deemed erroneous." (Although DOL agrees with the result in Brewer, DOL disagrees with other interpretations of Federal law in that case. These other interpretations were not addressed in the Minnesota proceeding and are not, therefore, discussed here.)

5. Action Required. State administrators are requested to provide the above information to appropriate staff.

6. Inquiries. Direct inquiries to the appropriate Regional Office.

In the Matter of Minnesota Conformity

Before: The Secretary of Labor

Decision

Pursuant to a Notice of Hearing issued on September 21, 1988, proceedings were instituted with respect to the conformity of the State of Minnesota with those requirements of the Federal Unemployment Tax Act (FUTA) codified at section 3304(a)(4) of the Internal Revenue Code of 1986, 26 U.S.C. § 3304(a)(4) (Supp. IV 1983-1987), and the requirements of section 303(a)(1) of the Social Security Act (SSA), 42 U.S.C. § 503(a)(1) (1982 & Supp. IV 1983-1987) and of section 303(a)(5) of the SSA, 42 U.S.C. § 303(a)(5) (Supp. IV 1983-1987). This notice established the rules of procedure for and the date of a hearing on the issues raised in the notice. By subsequent agreement of the parties, however, the hearing was cancelled, a stipulated record was filed, and the case was submitted on briefs. On November 14, 1988, Administrative Law Judge (ALJ) Edward Terhune Miller issued a Recommended Decision (R.D.) finding that the Minnesota unemployment compensation law is not in conformity with applicable Federal law. The State of Minnesota has filed exceptions to the ALJ’s recommended finding, and the Associate Solicitor for Employment and training Legal Services of the United States Department of Labor (Associate Solicitor) has filed a response to Minnesota’s exceptions. The matter is now before me for decision for purposes of certification under section 3304(c) of FUTA and section 303(b) of SSA.

Specifically before me is whether Minnesota’s recoupment provision, section 268.165 of the Minnesota employment compensation law, Minn. Stat. Ann. 266.165 (West 1986 Supp.), meets the requirements of section 3304(a)(4) of FUTA and the requirements of section 303(a)(1) and (a)(5) of the SSA. Under section 3304(a)(4) of FUTA and under section 303(a)(5) of SSA, all money withdrawn from the unemployment fund must be used in payment of unemployment compensation. Compensation is defined in section 3306(h) of FUTA as “cash benefits payable to individuals with respect to their unemployment.” 26 U.S.C. § 3306(h). Section 303(a)(1) of the SSA requires that a state unemployment compensation law provide for such methods of administration as will ensure full payment of unemployment compensation when due. Certain exceptions to the requirement that funds be used exclusively in the payment of unemployment compensation are statutorily provided for but none of these are applicable here. 1

Subdivision 1 of section 268.165 of the Minnesota law permits the deduction and withholding of up to 50 percent of an individual’s unemployment compensation payment for unpaid contributions, interest, penalties and costs for which the individual has been determined to be liable. Thus, an unemployed claimant would not receive in hand the full amount of his or her cash benefits if the claimant owed contributions to the unemployment fund from a prior period when the claimant had been an employer. The question, therefore, arises whether the reduction in the claimant’s cash benefits for the purpose of recouping contributions owed conforms to the Federal statutory prescriptions as to use of unemployment fund monies.

The ALJ’s recommendation, that I find Minnesota’s recoupment provision in nonconformity with Federal law, is based on the ALJ’s analysis of the applicable FUTA and SSA provisions. Specifically, the ALJ concluded that the statutory language is clear and unambiguous, and that the legislative history and historical application of the FUTA and SSA provisions support the limiting of the use of unemployment fund monies to cash benefits for unemployed claimants or to certain other specifically stated expenditures. The ALJ then found that Minnesota’s recoupment provision involves the constructive withdrawal of funds for a purpose other than permitted by law and resulted in the unemployed claimant failing to receive full benefits when due.

Upon review of the entire record in this case, I agree with the analysis and conclusions of the administrative law judge. I thus adopt, and append hereto, the ALJ’s decision but with certain technical corrections requested by the Associate Solicitor. See U.S. Department of Labor’s Response to Minnesota’s Statement of exceptions at 8-9. These corrections are:

1. At page 2, line thirteen is changed to read: “payment of grant monies under § 303(b) of SSA, and with.”

2. At page 10, the first sentence of the first full paragraph is changed to read: “Sections 3303(b) and 3304(c) of FUTA require that the state laws conform to Federal requirements governing the use of unemployment funds in order for employers to receive normal and additional tax credits with respect to their rates of contributions.”

3. At page 14, line 8 is changed to read: “certification under section 303(b) of SSA and section 3304(c) of FUTA, regardless of.”

4. At page 18, line 16, “§ 3306(b)” is changed to read: “§ 3306.”

5. At page 18, line 10, from line 5 “§§ 3302(a), 3302(b), and” are omitted, and from line 6 “or certified as provided in § 3303(b) of FUTA” are omitted.

6. All references to “unemployment compensation fund” are changed to “unemployment fund.”

1 therefore, find that the Minnesota unemployment compensation law no longer contains the provisions specified in sections 3304(a)(4) of FUTA and in sections 303(a)(1) and (a)(5) of SSA, and that the State of Minnesota has failed to substantially comply with such sections. Accordingly, the state of Minnesota will not be included in the listing of those states which will be certified by me to the Secretary of Treasury for the year ending October 31, 1989, in accordance with section 3304(c) of FUTA, and, furthermore, certification in accordance with section 303(b) of SSA is withheld.

Ann McLaughlin,
Secretary of Labor.
Washington, DC
from otherwise eligible claimants to satisfy indebtedness for unpaid contributions to the State's unemployment compensation fund. Notice of hearing was also sent by the Secretary to the Minnesota Department of Jobs and Training in conformity with 29 C.F.R. § 801.5(f)(d). In response to that notice, Minnesota filed a timely request for a hearing. Jurisdiction is assumed under 20 U.S.C. § 3054(c) (1988), 42 U.S.C. § 503(b) (1988), and 20 C.F.R. 601.5(f). Pursuant to the request of the parties and Order dated September 30, 1988, a stipulated record was timely filed by the parties on October 13, 1988, and the oral hearing scheduled by the Notice of Hearing for October 4, 1988, was canceled. The parties filed timely briefs and reply briefs in conformity with the Notice of Hearing and the Order dated September 30, 1988. There has been no request to participate as intervenor or amicus curiae.

This Determination is based upon the stipulated record, and applicable law and regulations, taking due consideration of the contentions of the parties as set forth in their respective briefs and reply briefs.1

Issue
The question presented for resolution in this proceeding is whether, with respect to certification for payment of grant moneys under 302(a) of SSA, and with respect to certification of States on October 31, 1988, under 3304(c) of FUTA, the law of Minnesota has been amended so that it no longer includes the provisions required by 303(a)(1) and 303(a)(5) of SSA and 3304(a)(4) of FUTA relating to the State's provision of unemployment compensation. The parties agree that the issue to be decided is one of statutory construction and that the facts are not in dispute.

The Secretary's Brief
The Secretary contends that 303(a)(5) of SSA and 3304(a)(4) of FUTA require the Minnesota unemployment compensation law to provide that all money withdrawn from the unemployment fund of the State be used solely in the payment of unemployment compensation. The only exceptions to this general requirement are authorized or required by statute as enacted by Congress. The Secretary has no discretion to grant exceptions to this general requirement. States are also without authority to enact exceptions to the requirement. The Minnesota recoupment amendment, by its provisions and method of administration, impermissibly deprives a claimant of the full payment when due of unemployment compensation to which the claimant is entitled with respect to his or her unemployment, and, in effect, withdraws such funds not paid to the claimant from the fund for the purpose of paying unpaid contributions, interest, penalties, and costs owed by the claimant, but which relate to when the claimant was an employer.

In allowing such reductions in payments and withdrawals from the Minnesota unemployment compensation fund, the recoupment amendment contravenes § 303(a)(1) of SSA, which requires that the Minnesota unemployment compensation law provide methods of administration which will reasonably insure full payment of unemployment compensation. The legislative history of the applicable federal laws confirms the strict and fundamental statutory mandate that moneys withdrawn from the State's unemployment fund must be expended, with limited exceptions, for the payment of unemployment compensation to which claimants are entitled as a matter of right by reason of their unemployment, without regard to criteria unrelated to such unemployment. The purpose of the legislation, as established by its pertinent legislative history, is to provide temporarily for the immediate basic necessities of persons who have become unemployed.

These principles of interpretation have been consistently applied by the Secretary of Labor throughout the history of the unemployment compensation program. Since exceptions to the application of these principles in the Federal laws are established by Federal statute only, the policy justifications advanced by Minnesota in support of its recoupment amendment are irrelevant.

A reduction of a claimant's benefits for reasons unrelated to the individual's unemployment is deemed tantamount to an impermissible withdrawal of moneys from the State's unemployment compensation fund. Prior erroneous payments of benefits, however, are tantamount to advance payment of benefits related to the individual's perceived unemployment. On the other hand, collecting unpaid tax contributions, interest, penalties, and costs by a reduction of cash benefits as provided by the recoupment amendment is related to a claimant's prior status as an employer, and not to his or her unemployment. To the extent that Brewer v. Cantrell1 implies that some physical withdrawal of moneys from the fund is required to establish a violation of Federal requirements, the Brewer Court's interpretation of the withdrawn standard is deemed erroneous.

Minnesota's Brief
Minnesota contends that the Secretary's interpretation of the applicable provisions of SSA and FUTA is not dispositive, and that the recoupment amendment does not render the law nonconforming to SSA or FUTA. Moneys in the Minnesota unemployment compensation fund are, and would be, used for payment of cash benefits when due, in accordance with applicable requirements for timeliness, as required by SSA and FUTA.

Minnesota contends further that the recoupment amendment merely treats persons who have failed to contribute to the state's unemployment compensation fund as required by law in the same manner as those persons who have been overpaid benefits from the fund. Such treatment avoids the anomalous situation which allows employers to retain contributions required by the fund to provide benefits to their employees, but to receive benefits from that fund regardless of personal indebtedness to the fund incurred while the claimant was an employer. The recoupment amendment is patterned after and analogous to the exception to SSA and FUTA under 3304(a)(4)(D), which provides that amounts may be deducted from unemployment benefits and used to repay overpayments as allowed by 303(g) of SSA. The Minnesota recoupment provision merely reduces the benefits payable to a Claimant liable for delinquent contributions up to fifty percent of the benefits to which he or she would otherwise be entitled, but does not require that amount to be withdrawn from the fund. This critical distinction prevents the Minnesota law from being nonconforming.

To refute the Secretary's assertion that she does not have discretion to approve the recoupment amendment as an exception to established Federal requirements, Minnesota cites the Secretary's authorization of the use of compensating bank balances and the use of interest on fund deposits for administrative expenses as an exercise of authority.

1 The stipulated record consists of thirteen documents, numbered one through thirteen. These documents are referred to as Exhibits ("EX") 1-13, respectively.

of discretion affecting the use of moneys in an unemployment compensation fund under the applicable Federal laws. Minnesota also contends that the recoupment amendment was carefully developed with the assistance of representative interests of the state, and that its implementation has enabled, and will in the future enable, the State to recover substantial sums from delinquent claimants who have personal liability for unpaid employers’ contributions. The recoupment amendment is also consistent with the intention of Congress regarding the expenditure of moneys in the unemployment compensation fund. Such recent exceptions as the application of benefits to recovery of overissuance of food stamps and for child-support payments reflects a liberal Congressional attitude toward the basic restrictions on expenditures of moneys in the fund.

Findings of Fact


2. Minn. Stat. § 268.165 provides: Subdivision 1. Withholding of unemployment benefits. Notwithstanding section 268.17, the commissioner may deduct and withhold up to 50 percent of each unemployment compensation payment payable to an individual under this chapter for unpaid contributions, interest, penalties, and costs which the individual has been determined liable to pay.

Subd. 2. Effect of payments. Any amounts deducted and withheld under this section shall be treated as if paid to the individual as benefits and paid by the individual to the department in satisfaction of the individual’s delinquent contributions, interest, penalties, and costs.

Subd. 3. Priority of withholding. Any amounts deducted and withheld under this section have priority over any other levy, garnishment, attachment, execution, or setoff, except for the recoupment of benefit overpayments allowed under section 268.18.

3. At the same time, Minn. Stat. § 268.18 (1986) was amended to limit to 50% the amount withheld from unemployment compensation benefit payments to repay benefit overpayments (Ex. 11).

4. Minnesota has recovered substantial amounts of delinquent employers’ contributions since enactment of the recoupment amendment (Ex. 12).

5. § 3304(a)(4) of FUTA provides in relevant part:
The Secretary of Labor shall approve any State law * * * which he finds provides that * * all money withdrawn from the unemployment fund of the State shall be used solely in the payment of unemployment compensation, exclusive of expenses of administration * * [with certain specified exceptions].

§ 3304(c) of FUTA provides in relevant part:
On October 31 of each taxable year the Secretary of Labor shall certify to the Secretary of the Treasury each State whose law he has previously approved, except that he shall not certify any State which, after reasonable notice and opportunity for hearing to the State agency, the Secretary of Labor finds has amended its law so that it no longer contains the provisions specified in subsection (a) or has with respect to the 12-month period ending on such October 31 failed to comply substantially with any such provision in such subsection * * *

§ 3306(h) of FUTA provides in relevant part:
For purposes of this chapter, the term “compensation” means cash benefits payable to individuals with respect to their unemployment.

§ 302(a) of SSA provides in relevant part:
The Secretary of Labor shall from time to time certify to the Secretary of the Treasury for payment to each State which has an unemployment compensation law approved by the Secretary of Labor under the Federal Unemployment Tax Act such amounts as the Secretary of Labor determines to be necessary for the proper and efficient administration of such law . . .

§ 303(c) of SSA provides in relevant part:
The Secretary of Labor shall make no certification for payment to any State unless he finds that the law of such State, approved by the Secretary of Labor under the Federal Unemployment Tax Act, includes provision for * * * (1) such methods of administration * * * as are found by the Secretary of Labor to be reasonably calculated to insure full payment of unemployment compensation when due; and * * * (5) Expenditure of all money withdrawn from an unemployment fund of such State in the payment of unemployment compensation, exclusive of expenses of administration * * * [and for certain refunds, and subject to certain provisions].

6. Congress has enacted several exceptions to the withdrawal standard established by §303(a)(5) of the SSA and §304(a)(4) of FUTA. These statutory exceptions are payment of disability benefits pursuant to §30(a)(5) of SSA and §304(a)(4)(A) of FUTA; payment of health insurance pursuant to §303(a)(5) of SSA and §304(a)(4)(C) of FUTA; repayment of overpayments of benefits pursuant to §303(a)(5) and (g) of SSA and §304(a)(4)(D) of FUTA; repayment of food stamps overissuances pursuant to §303(d)(2)(B) of SSA; payment of child support obligations pursuant to §305(c)(2)(A) of SSA; and self-employment allowances pursuant to §9152(e)(a), Pub. L. 100–203 (1987).

7. On May 27, 1987, prior to the enactment of the recoupment amendment, the Acting Regional Administrator, on behalf of the Secretary, informed Minnesota that the proposed Minnesota recoupment amendment conflicted with the Federal requirements of § 303(a)(1) and 303(a)(6) of the SSA, and § 3304(a)(4) of FUTA (Ex. 8). The Commissioner of the Minnesota Department of Jobs and Training provided an explanatory response dated November 23, 1987. The response sought to justify the recoupment amendment and stated that for technical reasons there would be no future recoveries under the recoupment amendment of penalties, interest, or costs due from benefits payable to unemployed claimants (Ex. 7).

8. On July 13, 1988, the Acting Assistant Secretary informed Minnesota that, unless Minnesota took action to resolve the conflict with the Federal requirements, he would recommend that the Secretary institute a conformity proceeding (Ex. 6).

9. The Secretary, on August 25, 1988, notified the Governor of Minnesota that she had reason to believe that the State of Minnesota might not be certified under § 3304(c) of FUTA for the twelve month period ending on October 31, 1988, and that she had reason to believe that certification might not be made in the future for the payment of administrative grants to the State of Minnesota under Title III of the SSA, because of the apparent conflict of §268.165.1 of the Minnesota Jobs and Training Law with the requirements of §303(a)(4) of FUTA, and §§ 303(a)(1) and 303(a)(5) of SSA. (Ex. 4)

10. The Secretary advised the Governor that “[t]hese sections of Federal law have long been interpreted as prohibiting any levy, attachment or other remedy for the collection of public or private debt, prior to the receipt by the claimant of the benefits otherwise payable.” (Ex. 4)

11. The Secretary also advised the Governor that withholding such certificates would result in all employers
who are subject to the Federal tax imposed by § 3301 of FUTA losing all tax credits otherwise allowable pursuant to § 3302 of FUTA. She advised that withholding certification might also affect reimbursement under the Federal law of the Federal share of extended benefit expenditures made by the State. She advised that as to the issue arising under the SSA, her findings would affect the certification of payment of grant funds to the State under Title III of the SSA, and might affect grants under the Wagner-Peyser Act, 29 U.S.C. § 49d(b). (Ex. 4).

12. The Secretary advised the Governor that she had offered the Minnesota Department of Jobs and Training an opportunity to participate in the proceedings which would lead to a determination of the issues in question. (Ex. 4).

A similar notice was sent on August 25, 1988, to the Commissioner, Department of Jobs and Training, of Minnesota, advising him that with the notice, the Secretary was commencing conformity proceedings and offering the Minnesota agency an opportunity for a hearing. The Secretary announced that the purpose of the proceedings would be to determine whether the law of Minnesota conforms to the requirements of §§ 303(a)(1) and 303(a)(5) of SSA, as a condition for receiving administrative grants. (Ex. 5).

14. On September 7, 1988, Minnesota requested a hearing (Ex. 5). A Notice of Hearing dated September 21, 1988, was issued pursuant to § 303(b) of SSA, § 3304(c) of FUTA, and 20 C.F.R. § 601.5(a), and was served upon all interested parties in a timely manner (Ex. 1; Ex. 2).

13. On October 13, 1988, the parties submitted the case to the Administrative Law Judge on a stipulated record, and filed briefs and reply briefs in accordance with the requirements specified in the Notice of Hearing. This Recommended Decision is also timely filed in accordance with the requirements of that Notice of Hearing. Discussion

Application of Strict Controls Over the Use of Unemployment Compensation Funds Is Not Discretionary

Sections 3303(b) and 3304(c) of FUTA provide that, in order to receive subsidized Federal assistance related to State unemployment compensation programs and the administration of those programs, State laws must conform to the Federal requirements governing the use of unemployment compensation funds. The Secretary must certify annually that a State's unemployment compensation laws are in conformity with, and are administered in a manner which satisfies these Federal requirements, so that the State may be eligible for the Federal benefits. The language of the governing Federal statutes does not expressly or by implication provide any discretion to the Secretary or to the States with unemployment compensation programs in complying with the explicit Federal statutory requirements.

The issue presented in this case is one of statutory interpretation. Therefore, the Secretary's interpretation of the relevant statutory provisions is not dispositive. However, the Secretary's interpretation of the statutory requirements has historically been consistently strict and uncompromising (See Ex. 9, Ex. 10). There is insufficient basis in this record to determine, whether, as Minnesota suggests, the use of compensating balances would constitute a non-statutory exception to the general restriction that could be deemed analogous to the Minnesota recoupment amendment. The only relevant evidence is, on its face, a proposal and solicitation for comment, not an implementing instruction or order (Ex. 13).

The Statutory Language Specifying the Federal Requirements Is Plain and Unambiguous

The language of §§ 303(a)(5) of SSA and § 3304(a)(4) of FUTA, which govern the use of unemployment compensation funds, is plain and unambiguous in its requirement that moneys in a State's unemployment compensation fund be applied, exclusive of administrative costs, and except for certain express exceptions, exclusively to the payment of unemployment compensation benefits. Section 3306(h) of FUTA states that the right of a claimant to payment of unemployment compensation, is the right to a cash benefit payable to the individual by reason of his unemployment. There is no provision for application of other criteria not related to his unemployment. Under the express formulation of § 303(a)(1) of SSA, those benefits must be paid in full when due, that is, promptly and directly to the claimant, without deferral, as a matter of right. 4

4 The administrative requirement for full payment of unemployment compensation "when due" is basically a requirement for timeliness. See Fusari v. Exception for Certain Statutory Exceptions, Unemployment Benefits Must be Used Exclusively for the Payment of Unemployment Compensation Benefits

The parties have cited certain specific statutory exceptions to the categorical restrictions imposed by §§ 303(a)(5) of SSA and § 3304(a)(4) of FUTA. Those exceptions authorize withholding unemployment compensation benefit payments for the following purposes: to offset prior overpayments of benefits; to recoup overissuance of food stamps; for self-employment allowance; for application to health insurance costs; for payment of disability benefits; and for application to child support payments.

Some of these exceptions involve the application of moneys from the State's unemployment compensation fund to the kind of immediate necessities of the claimant and his or her family, i.e. child support or health insurance, for which the unemployment compensation program was intended to provide. The others involve withholding benefit payments when due and crediting the amount withheld against amounts deemed to be benefit payments previously advanced in error. In such cases a claimant is deemed to have received all payments to which he is entitled when due, and not to be deprived of benefits to which he is entitled under the established purpose of the applicable Federal statutes. In neither case do these statutory exceptions do violence to the purposes of the Federal statutory requirements.

Stautberg, 419 U.S. 373 (1975). However, the right to timely payment subsides a threefold purpose: (1) To give prompt partial wage replacement so that the unemployed and their families would not be forced to fend for immediate necessities of the household; (2) To provide security to the wage earners in finding work; and (3) To help stabilize industry by providing purchasing power to the unemployed when most needed (footnote omitted). See UAW v. Michigan Employment Security Comm'n, 517 F. Supp. 12,17 (E.D. Mich. 1980), citing California Dep't of Human Resources Dev. v. Java, 402 U.S. 121 (1971).

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Some of these exceptions involve the application of moneys from the State's unemployment compensation fund to the kind of immediate necessities of the claimant and his or her family, i.e. child support or health insurance, for which the unemployment compensation program was intended to provide. The others involve withholding benefit payments when due and crediting the amount withheld against amounts deemed to be benefit payments previously advanced in error. In such cases a claimant is deemed to have received all payments to which he is entitled when due, and not to be deprived of benefits to which he is entitled under the established purpose of the applicable Federal statutes. In neither case do these statutory exceptions do violence to the purposes of the Federal statutory requirements.

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On the other hand, neither of these
types of deductions and withholdings
have purposes which are analogous to
the purpose of Minnesota's recoupment
amendment. That law purports to reduce
benefit payments in order to recoup
amounts owed to the State's
unemployment compensation fund by
reason of obligations incurred while the
claimant, in a prior distinguishable
incarnation, was an employer. Such a
purpose is manifestly unrelated to a
claimant's unemployment which entitles
him to unemployment compensation.
Congress itself has defined the only
exceptions to the fundamental
requirements of the legislation. SSA and
FUTA neither explicitly nor implicitly
authorize either the Secretary or the
individual States to modify or augment
those exceptions. The pertinent
legislative history buttresses this
restrictive view. However rational or
persuasive the policy considerations for
certain as an exception might seem, the
sole source of any additional exceptions
must be Federal legislation if history is
considered and the essential purpose of
the legislation is to be respected. It is
evident that if exceptions were
permitted on convenient rationales
conceived ad hoc by authorities other
than Congress, the strictures reflected in
the statutory language and its legislative
history would probably dissipate and
become virtually meaningless and
unenforceable. Minnesota's attempt to
justify an exception by analogizing its
recoupment amendment to the
authorization for recoupment of benefit
overpayments under § 303(a)(5) of SSA
exemplifies this danger. By making that
analogy, Minnesota, in effect, concedes
that its recoupment amendment
constitutes a new and distinguishable
exception to the existing list of statutory
exceptions. By contrast, in §303(a)(5) of
SSA, Congress has specifically
authorized deductions from
unemployment benefits to be used to
recover overpayments of benefits, but
only under strictly controlled
procedures.

The Recoupment Amendment
Contemplates an Unauthorized
Withdrawal and Application of Moneys
From Minnesota's Unemployment
Compensation Fund

Minnesota's contention that the
moneys withheld from an unemployed
claimant are not actually withdrawn
from the unemployment compensation
fund and that their retention actually
benefits the fund does not validate the
recoupment amendment. Withholding
benefits is in conformity with the
recoupment amendment involves at
least a constructive withdrawal of funds
from the unemployment compensation
fund for a purpose other than the
payment of unemployment
compensation or one allowed by
existing statutory exceptions. The
violation occurs because the recoupment
amendment allows the State not to pay
when due all benefits to which a
claimant is entitled by right because of
his unemployed status. The cause of
such nonpayment is the application of
criteria which purport to modify the
unemployed claimant's entitlement by
reason of circumstances not related to
his unemployed status. That is sufficient
to disqualify the recoupment
amendment for certification, under
§3302(a)(1) of FUTA, regardless of
whether withholding such moneys
constitutes a technical withdrawal from
Minnesota's unemployment
compensation fund.

However, Minnesota's assertion that
withholding is in conformity with the
recoupment amendment does not
involve a withdrawal from the
unemployment compensation fund
cannot, in any event, be reconciled with
subsection 2 of the recoupment
amendment. That provision explicitly
mandates that "[a]ny amounts deducted
and withheld under this section shall be
credited to the individual as
benefits and paid by the individual to
the department in satisfaction of the
individual's delinquent contributions.
* * * * (Emphasis supplied.) Thus, the
recoupment amendment explicitly
provides for a technical withdrawal
from the fund for the unauthorized
purpose of recovering the unpaid
contributions of an employer.

The Legislative History Reinforces the
Plain Meaning of the Federal Statutory
Provisions

A strict and literal interpretation of
the applicable statutory language to
preclude exceptions to the basic
restriction upon use of moneys from
State unemployment compensation
funds for other than timely payment of
unemployment compensation is
reinforced by the legislative history of
the relevant unemployment legislation.
The Federal requirements at issue were
enacted as a part of the Social Security
Act of 1935. The impetus for the Social
Security Act was the Committee on the
Economic Security, established by
President Franklin D. Roosevelt. The
Committee recommended a program of
unemployment compensation as a
"valuable first line of defense for
* * * [a worker] ordinarily steadily employed.
Unemployment benefits, in the opinion of
the Committee, should be made
available to all workers who become
unemployed, to draw a cash benefit for
a limited period during which there is
expectation that he will soon be
reemployed. This should be a
contractual right not dependent on any
means test." Report of the Committee on
Economic Security, Hearings on S. 1130
Before the Senate Committee on
Finance, 74th Cong., 1st Sess. 1011, 1021
(1935).

During the Senate debate on the
passage of the Social Security Act, the
original sponsor, Senator Wagner,
stated that the "only important
requirement [of the Social Security Act]
that is the State law shall be genuinely
protective, and that its revenues shall be
deduced exclusively to the payment of
insurance benefits." 79 Cong. Rec.
9284 (June 14, 1935); see also 79 Cong.Rec.
9277 (June 14, 1935) (remarks of Sen.
Harrisan). Division of such payments to
discharge preexisting private debts of
an unemployed claimant, even to a
public entity, is manifestly inconsistent
with such purposes and requirements.
There is thus no basis for a broad or
flexible interpretation of the Federal
statutory language in issue, and the
argument of Minnesota to the contrary
must be rejected.

Conclusions of Law

1. The Secretary has satisfied the
requirements of 20 CFR § 601.5 for
reasonable notice to the responsible
state agency, the Minnesota Department
of Jobs and Training, and opportunity
for hearing following reasonable efforts
by regional and central office
representatives of the Secretary to
resolve with appropriate officials of
Minnesota the issues subject to
determination in this proceeding.

2. Section 303(a)(5) of SSA requires
that the Minnesota unemployment
compensation law, in order to be in
conformity with Federal standards,
provide for the "[x]pense of all
money withdrawn from the [the State's]
unemployment fund * * * in the
payment of unemployment
compensation. * * * " Similarly, sec.
3303(a)(4) of FUTA requires that the
Minnesota law, in order to be in
conformity with Federal standards,
provide that "all money withdrawn from
the unemployment fund of the State
shall be used solely in the payment of
unemployment compensation." A State
statute authorizing the reduction by the
State of benefits otherwise due in order
to apply the amount of such reduction to
an independent debt of the claimant to
an agency of the State is inconsistent
with these provisions.

3. Section 303(a)(1) of SSA requires
that the Minnesota law, in order to be in
conformity with Federal standards,
provide for "methods of administration
* * * to be reasonably calculated to insure full payment of unemployment compensation when due.*\

Compensation, as defined in section 3306(h) of FUTA means "cash benefits payable to individuals with respect to their unemployment." The only exceptions to the general restriction limiting withdrawals from the unemployment fund to use only for the payment of unemployment compensation benefits are those explicitly authorized or required by Federal statute, such as the authorization for recovery of benefit overpayments pursuant to sections 303(a)(5) and 303(g) of SSA. The Minnesota recoupment amendment authorizes a method of administration which allows moneys otherwise payable from the State's unemployment compensation fund for unemployment benefits to be diverted and applied to curtail preexisting and independent obligations to the fund, a State agency. Such administration of the fund is tantamount to allowing a levy or attachment of the claimant's unemployment benefits and is inconsistent with the standards prescribed by sections 303(a)(1) and 303(a)(5) of SSA and the definition in section 3306(h) of FUTA.

4. The legislative history relating to these statutory provisions supports the Secretary's interpretation of the relevant statutes and establishes that the intent of Congress in enacting the Federal requirement was to insure that all moneys committed by the State for unemployment compensation purposes would be used, subject only to certain specifically authorized exceptions, solely for the payment of benefits and that individuals would be entitled to full payment of benefits as a matter of right after being determined to be eligible.

5. The Federal requirements have consistently been interpreted by the Secretary to limit withdrawals from the unemployment fund to insure that such withdrawals would be expended solely for the payment of unemployment compensation benefits. The only exceptions to this limitation which have been and are deemed valid by the Secretary have been those specifically authorized or required by Federal statute.

6. Since the applicable provisions of the SSA and FUTA do not provide for the exercise of discretion in the application of moneys for the unemployment compensation fund to unemployment compensation benefits by the Secretary or any other authority, only Congress has the authority to authorize or require exceptions to the general withdrawal standard by legislative action. No Federal existing law has been cited or discovered which gives the Secretary authority to approve an attempted exercise of such authority by any state on policy grounds or otherwise create, or permit to the created, any exception to the limitation applicable to the expenditure of moneys in the state's unemployment compensation fund.

7. In the absence of authority to create exceptions to the limitations upon the uses of moneys in Minnesota's unemployment compensation fund, the policy considerations alleged to justify the Minnesota recoupment law are irrelevant to this proceeding.

8. Since the recoupment amendment provides that Minnesota may deduct and withhold up to 80 percent of each unemployment compensation payment to an individual for unpaid contributions, interest, penalties, and costs which the individual owed as an employer, the recoupment amendment conflicts with the requirements of sections 303(a)(1) and 303(a)(5) of SSA and section 3304(a)(4) of FUTA. The legal effect of the Minnesota statute is to allow Minnesota to apply moneys from the unemployment fund, not to pay unemployment compensation benefits, but to pay unpaid contributions, interest, penalties and costs for which the individual is liable as an employer. Thus, the unemployed claimant does not receive full payment of benefits to which the individual is entitled with respect to his unemployment at the time those benefits are due.

9. Minnesota's withholding of unemployment benefits to which a claimant would otherwise be entitled by reason of his unemployment, and the application of those moneys to curtail in whole or in part an alleged debt of that claimant in his individual or private capacity to the State's unemployment compensation fund, a public entity, constitutes a constructive or technical withdrawal from the fund, even though the fund retains such moneys as the ultimate recipient and beneficiary. However, even if such an application of moneys from the fund were not deemed technically to be a withdrawal from Minnesota's unemployment compensation fund within the meaning of section 303(a)(5) of SSA and section 3304(a)(4) of FUTA, recoupment amendment authorizes and expenditure from the Minnesota unemployment fund to pay other than unemployment compensation (or administrative costs) in violation of section 303(a)(5) of SSA and section 3304(a)(4) of FUTA. It thus violates the requirement for administration insuring full payment of unemployment compensation when due within the meaning of section 303(a)(1) of SSA, and it applies criteria for payment of benefits other than the claimant's unemployment contrary to the definition in section 3306(b) of FUTA. In effect, it is tantamount to a levy or attachment of unemployment benefits that a claimant would otherwise be entitled to receive in frustration of the fundamental purpose of the unemployment compensation statutes.

10. Because of the enactment and continuing effect of the recoupment amendment, Minn. Stat. § 266.155 (1987 Supp.), the Minnesota unemployment compensation law is not in conformity with applicable Federal law, with respect to certification pursuant to sections 3302(a), 3302(b), and 3304(c) of FUTA or certified as provided in section 3303(b) of FUTA.

11. Because of the enactment and continuing effect of the recoupment amendment, Minn. Stat. § 266.155 (1987 Supp.), the Minnesota unemployment compensation law does not include certain specified provisions as required by sections 303(a)(1) and 303(a)(5) of SSA, it is not in conformity with the requirements of that law with respect to certification for purposes of grants or payment of funds to Minnesota in accordance with section 302(a) of SSA and 20 C.F.R. §§ 601.3, 601.5(a)(1) and (2).

Edward Terhune Miller,
Administrative Law Judge.
[FR Doc. 89-12718 Filed 5-26-89; 8:45 am]
BILLING CODE 4510-30-M

Job Corps Advisory Committee

A public meeting of the Job Corps Advisory Committee will be held on June 27, 1989, commencing at 8:30 a.m., at the U.S. Department of Labor, Frances Perkins Building, 3rd and Constitution Ave. NW., Room C5515, Seminar Room 3, Washington, DC 20210.

The purpose of the meeting, as part of a long-range training process, is to provide the opportunity for the Job Corps Advisory Committee and its subgroups to meet to discuss the Preliminary Report to the Secretary of Labor.

The Job Corps Advisory Committee's Subgroups have conducted a number of meetings and made findings and conclusions to the Advisory Committee prior to the Job Corps Advisory Committee making its report to the Secretary of Labor.
Individuals or organizations wishing to submit written statements pertaining to Job Corps center assessment should send 20 copies to Peter E. Reel, Director, Office of Job Corps, U.S. Department of Labor, Room N-4508, Washington, DC 20210, telephone (202) 535-0550. Papers will be accepted and included in the record of the meeting if received on or before June 24, 1989.

Roderick T. Jones, Assistant Secretary of Labor.

Signed at Washington, DC, this 23rd day of May 1989.

[FR Doc. 89-12717 Filed 5-26-89; 8:45 am]
BILLING CODE 4510-30-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Literature Advisory Panel; Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Literature Advisory Panel (Fellowships for Translators Section) to the National Council on the Arts will be held on June 22, 1989, from 9:00 a.m.—3:00 p.m. and on June 23, 1989, from 9:00 a.m.—3:00 p.m. in Room M14 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

A portion of this meeting will be open to the public on June 23, 1989 from 1:00 p.m.—3:00 p.m. The topics for discussion will be policy issues.

The remaining portion of this meeting on June 22, 1989 from 9:00 a.m.—5:30 p.m. and on June 23, 1989, from 9:00 a.m.—3:00 p.m. in Room M14 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the Federal Register of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682-5433.

Yvonne M. Sabine, Director, Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 89-12676 Filed 5-26-89; 8:45 am]
BILLING CODE 7537-01-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Media Arts Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Media Arts Advisory Panel (Challenge III Section) to the National Council on the Arts will be held on June 20, 1989, from 10:00 a.m. to 5:30 p.m. in Room 716 of the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the Agency by grant applicants. In accordance with the determination of the Chairman published in the Federal Register of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

If you need special accommodations due to a disability, please contact the Office for Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, or call (202) 682-5532, TTY 202/682-5496 at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682-5433.

Yvonne M. Sabine, Director, Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 89-12678 Filed 5-26-89; 8:45 am]
BILLING CODE 7537-01-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Public Partnership Office Advisory Panel; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Office of Public Partnership Advisory Panel (Local Programs Section) to the National Council on the Arts will be held on June 14, 1989, from 8:00 a.m.—5:30 p.m., on June 15, 1989, from 8:00 a.m.—5:00 p.m., and June 16, 1989, from 8:00 a.m.—4:30 p.m. in Room MO7 of the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

A portion of this meeting will be open to the public on June 14, 1989 from 6:00 a.m.—3:15 p.m. and from 4:30 p.m.—5:30 p.m. on June 15, 1989, from 8:00 a.m.—2:30 p.m.; and on June 16, 1989, from 8:00 a.m.—4:30 p.m. The topics for discussion will be guidelines and policy issues.

The remaining portions of this meeting on June 14, 1989, from 3:15 p.m.—4:30 p.m. and on June 15, 1989, from 2:00 p.m.—5:00 p.m. are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the Federal Register of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

If you need special accommodations due to a disability, please contact the Office for Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, or call (202) 682-5532, TTY 202/682-5496 at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682-5433.

Yvonne M. Sabine, Director, Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 89-12677 Filed 5-26-89; 8:45 am]
BILLING CODE 7537-01-M

NATIONAL SCIENCE FOUNDATION

Materials for Middle School Mathematics Instruction; Program Solicitation

This document is one of a series of targeted program solicitations designed to elicit proposals dealing with important problems and opportunities facing mathematics, science, and technology education in the nation’s schools. These solicitations are intended to supplement, not to supplant, the current guidelines and announcements that describe the broad range of interests of NSF’s Divisions of Materials
Program to focus on the creation of improved materials and model programs for mathematics instruction. It is one of several new thrusts consistent with the conclusions of the SRI International study of education options for the National Science Foundation. An earlier solicitation NSF 85-60 was targeted on elementary school mathematics. That solicitation resulted in six projects which are listed in "Summary of Grants, FY 1984-86, Instructional Materials Development Program" (NSF 86-65). The target of the current solicitation is middle school mathematics.

The Need for a Focus on Middle School Mathematics

Middle schools have evolved for a variety of reasons including the development and maturational needs of growing young adults. The middle school mathematics curriculum bridges the gap between the elementary skill development of the primary years and the more rigorous, abstract study found in the secondary grades. Recently, the quality of mathematics education offered by these schools has been criticized.

1. In international comparisons, our eighth graders have had only average scores in arithmetic, algebra, and geometry, and have been in the bottom quartile in measurement. They have performed best on computational work, but have done poorly in situations demanding reasoning and problem solving skills. These performances have shown no improvement in the past decade.

2. Although children in the earliest grades say that mathematics is their favorite subject, after the eighth grade many quit the subject, and from among those who continue, on the average about half are lost each year.

3. One probable reason for this attrition is the great amount of repetition in the middle school mathematics curriculum. Only 35 percent is new material. The rest is review of elementary computation.

4. Many graduates from our schools lack sufficient problem-solving skills to cope with on-the-job demands in American industry. Adults with only elementary mathematical skills have very few job options.

Background on Middle School Mathematics

Many issues of curricular change have been widely discussed and are relevant to middle school mathematics. To provide a context for this solicitation, prospective developers of middle school materials may wish to consider the following points.

1. Curriculum Structure

The variety of currently supported National Science Foundation awards in mathematics for materials development and for teacher enhancement indicates a clear trend toward broadening the topics covered at all levels of mathematics education. In the middle school a wide spectrum of topics are being incorporated including: number relationships and number theory, estimation and computation, patterns and functions, geometry and measurement, probability and statistics, and algebra and symbolic reasoning. In addition, people are thinking about the relationships between mathematics and other middle school subjects such as science, social studies, and English.

These trends present opportunities for integrating knowledge from science, technology, and the humanities to lend context and relevance to a mathematical education. Since the middle school mathematics curriculum is not well-defined in the United States, there are opportunities to combine appropriate topics into coherent units which tell a real mathematical story. The novel ways in which these topics are being introduced and the range of choice provide exciting options for mathematical content in the middle school mathematics curriculum.

There is emerging agreement that studying mathematics enhances reasoning and communication, forges links within itself and among other bodies of knowledge, and provides a wonderful environment for formulating and solving problems. Middle schools offer special opportunities in both topics of study and required forms of reasoning for students to grow from concrete experiences and modes of knowledge to abstract thinking.

Emphasis is shifting from developing computational skill to building a deeper understanding and enhancing greater connections which support creative use of knowledge. Students have a store of current experiences and modes of thinking which form the basis for further learning. With deeper insight students more successfully communicate their understanding with each other. From this comes an ability to formulate real problems as well as obtain both discursive and computational answers.

Within the United States and throughout the world, a wide variety of curricular materials has been prepared and tested. Some of these contain excellent ideas, problems, and methods. New curricula are appearing which will alter the mathematical preparation of students at all levels. There is a growing awareness that improvements come...
from building upon the best from the past.

Students come to school with differing talents and from varying home environments. These factors, in turn, cause wide variation both in rate and amount of student learning. Within middle school, students are grouped into heterogeneous classrooms with tremendous variation in accumulated student knowledge. It is not likely that this organization of our schools will change in the near future. Some, but not enough, attention has been paid to the education of students who fall below the average of the class. One the other hand, because the above average students sometimes do not receive a demanding education, it may be incorrectly assumed they are easy to teach. Middle school teachers are asked daily to find ways in which both below-average and above-average students can learn, be challenged, and experience achievement with mathematics.

Research on middle school teaching and learning 44 provides a framework for instructional materials development. For example, there is evidence that on certain types of mathematical problems, ten-year-old students outperform not only younger children but also youngsters a year or two older. 46 In this age period, students move from a concrete to a more abstract view of mathematics. A single middle school class of students may have youngsters at all phases of this developmental change. 47 Developing and testing materials provides a special opportunity to investigate coupled issues of teaching and learning.

The middle school environment, new notions about the content of the middle school mathematics curriculum, and a sound foundation of research in teaching and learning provide an exciting background for course development. The time is right for a rethinking of the complete middle school mathematics curriculum.

2. Teaching Methods

The developmental stages of the early adolescent or late preadolescent have been studied for some time. Emphasis in teaching methods is shifting to instruction which stresses individual or small group activities, manipulation of objects, experiments with computers or calculators, solving problems, and the generation of new problems. Students needing concrete experiences sit together in the same class with those striving for greater abstraction. An opportunity exists to combine the well-established with newer techniques to educate more successfully this wide ranging audience.

In exploring the potential for broad change in mathematics education, there is a need to discover the real world potential and limitations of technology in education. Innovative methods will provide an opportunity to investigate the impact of technology on teaching. By emphasizing mathematical content, there is an opportunity to enhance the middle school mathematical experience through creative applications of technology. Programs can be developed which incorporate significant applications of computer software tools, computer teaching software, interactive video disks, advanced calculators, and other modern technologies.

3. Support for Teachers

The explosion of knowledge occurring in twentieth century science, mathematics, and engineering and the rapid introduction of technology into our economy are forcing rapid changes in the knowledge now viewed as appropriate for school curricula. Even the best prepared teachers find it difficult to stay abreast of new topics. The National Science Foundation, through its Teacher Enhancement Program, addresses this problem. However, the demand and need for such activities far exceeds their availability.

School districts face a variety of problems in implementing a new curriculum. Instructional materials are rarely written to either give or emphasize significant teacher inservice direction or support. Further, there is seldom reference in materials addressing the need for school districts to engage actively in inservice efforts. There may be ways in which materials can give appropriate guidance to school districts on ways to support their teaching staffs.

Teachers do become excited by relevant, interesting, and challenging open ended mathematical problems. Like students, they should have the opportunity to learn, to solve problems, and to live mathematics. Since materials developers are sometimes distant from the user classrooms, they have little control over how their materials are used. To counteract this, they may like to think more deeply about and experiment with instructional materials, including a variety of possible media, as enrichers of the teacher's mathematical experience. A classroom provides opportunities for both the teacher and students to learn. It may be possible through creative use of instructional materials to support teachers' needs for renewal and enhancement.

4. Methods and Materials for Assessment

Currently there is a national debate over standardized testing of students. Teachers, administrators, communities, and the nation receive mixed messages about the importance of testing. In the hands of the classroom teacher, the primary purpose of assessment is diagnostic. Student learning can best be guided if there is an understanding by the teacher of the successes and difficulties of each student. On the other hand, measurement is made not only of a student relative to classmates, but also on an absolute scale relative to expectations in a large society, i.e., for reasons of policy and administration.

Teachers generally do not create all their own instruments and methods for evaluating student performance. Such assessment requires a substantial background in mathematics, cognitive psychology, and sociology. They look to outside sources including the suppliers of teaching materials. Almost all evaluation is now done using multiple choice tests, pencil and paper computations, and single answer problems. With the current interest in altering methods of student evaluation, there is an opportunity to couple materials development with student assessment in innovative ways.

5. Experiences in Implementing New Materials

Most authors implement and modify instructional materials in districts and classrooms while they are under development. Experience indicates that the more widely materials are evaluated, the better chance they have of success. If all teachers using new materials are committed to their success, the results will markedly differ from a uniform adoption in an indifferent school system. In an ideal world, new materials not only need to be evaluated for teachability in a wide variety of classrooms with a broad range of students, but also should be assessed in the adoption, inservice, and implementation phases.

Through the development process authors gain valuable experience on the implementation of and support required for their materials. They often become experienced in dealing with students, parents, teachers, principals, and district administrators. They discover requirements for equipment and maintenance costs. This experience could prove invaluable to the publishers of the materials and the school districts adopting them. Consideration of these factors may modify what constitutes
Evaluation Standards

mathematics education in our schools,
The Solicitation

effective instructional materials and,
mathematics curriculum, shifting
teaching and learning. They provide a
the cognitive factors which enter into
emphasis from computational to
Counts

signal high current interest in
content, method, and assessment. They
sound philosophical basis for changes in

the critical middle school years. We
curricular knowledge and experience in
projects that propose to do most or all of
expect to support a small number of key
methods, possibly including new uses of
curriculum.

complete middle school 30 mathematics

What elementary preparation will your
levels of students in differing groups?
materials be adaptable to serve varying
materials assume? How will it prepare
students, beginning with an elementary

and texts, panelists will want to know
your materials for preparing a variety of
possible outcomes, and the expected
procedure to evaluate the success of
materials will reflect sound research in
middle school mathematics curriculum. However, panelists would like to know
which issues you consider most critical in
curriculum, its content, and its
innovations. In addition to your
proposal, reviewers are especially
appreciative of sample materials which
indicate the kinds of approaches you
envision.

Since curriculum now encompasses a
very broad scope of methods, devices,
and texts, panelists will want to know
what you will produce. How will your
materials be adaptable to serve varying
levels of students in differing groups?

What elementary preparation will your
materials assume? How will it prepare
students, beginning with an elementary
conception of mathematics, for a high
school curriculum? How are you
anticipating the changes which will take
place in both the elementary and high
school mathematics curriculum? Indicate
how your materials will address the
needs of all students, including females,
minorities, the disabled, and the gifted
and talented.

Projects will involve activities in
colaboration with school systems,
teachers, and classrooms. It is important
to describe this trial environment and its
interaction with your project. Describe
who will be involved, their
qualifications, how they will be
involved, and evidence confirming the
extent and nature of their commitment.
From experience with your trial
environment you will gain insights on
the adoption, implementation, use, and
maintenance of your materials. How
will you reflect these insights in your
materials for the benefit of future users?

You should give a carefully prepared
procedure to evaluate the success of
your materials for preparing a variety of
middle school students for their high
school experience. If research on
learning will be a part of your project,
you should clearly explain the questions
to be posed, the methods to be used, the
possible outcomes, and the expected
contribution to your materials
development.

Projects should have a well-formed
dissemination plan. There is a strong
presumption that instructional materials
will be disseminated and used in a
variety of settings have committed
services and funds to their preparation
and publication. For example, proposals
which have firm commitments in writing
from distributors or publishers have a
greater chance of widespread distribution and
use.

Individuals with extensive
mathematical knowledge are expected
to play a key role. Project personnel
individually or jointly, are expected to
provide from mathematical knowledge,
wide experience in the needs of teachers
and students, and broad background on
the problems of educational change at
the elementary and middle school
levels. Be sure to list not only the
qualifications of your staff and advisors
but also the tasks they are expected to
perform. List qualifications in such areas
as: mathematics, mathematics
education, technology, evaluation,
school policies and procedures, and
classroom teaching at relevant levels. If
you have an advisory committee,
describe the way it will participate in
the project.

Include in your proposal the amounts
and extent of cost sharing and describe
any cooperative agreements you have
made. Contributions from participants,
beneficiaries, or other sources are
strongly encouraged. These might be in
the form of cash contributions, in-kind
services, facilities, equipment, release
time, and etc. Such additional support is
convincing evidence of the importance of
a project. To simplify the panelists
task, in your budget justification, list
shared costs and NSF cost side by side.

A preliminary proposal is required by
this solicitation, and should be a brief
description of the project you propose.

Panelists often approach long
proposals with trepidation and negative
feelings. Organize your proposal so that
it is concise, each to read, makes your
most important points prominently, and
falls within the prescribed page limits.
Appendices can be condensed by giving
sample supporting documents then
summarizing equivalent documents.
How to Submit

Both of these reasons, intensive and demanding review. For Preliminary Proposals, proposals will receive a particularly costly effort. In addition, formal proposals require a laborious and costly effort. Proposers are strongly encouraged to involve participation from more than one of these areas, as well as appropriate schools or school systems. The Foundation welcomes proposals from all qualified scientists and science educators, and strongly encourages women, minorities and persons with disabilities to compete fully in the development programs described in this document. In accordance with Federal statutes and regulations and NSF policies, no person shall be excluded on grounds of race, color, age, gender, national origin, or disability from participation under any program or activities receiving financial assistance from the National Science Foundation.

Facilitation Awards for Handicapped Scientists and Engineers

(FAH) provides funding for special assistance or equipment to enable persons with disabilities (investigators and other staff, including student research assistants) to work on an NSF project. See the FAH announcement (NSF 84-62), or contact the FAH Coordinator in the Directorate for Scientific, Technological, and International Affairs (202/357-7460).

How to Submit

Preliminary Proposals

By their nature, proposals appropriate to this solicitation are likely to be complex and require a laborious and costly effort. In addition, formal proposals will receive a particularly intensive and demanding review. For both of these reasons, a preliminary proposal and a response from the Instructional Materials Development Program are required before a formal proposal will be accepted.

A preliminary proposal may be in the form of a comparatively brief and informal letter-of-inquiry, outlining the concept and general structure of the contemplated project, as well as the organization(s) and personnel contemplated, and the order of magnitude of support required. This preliminary proposal should not exceed eight double spaced pages in length. The Program will respond with comments on the concept and a staff opinion of the general competitive status of such a proposal. Since supported projects will require major commitments and time prior to submission of a successful proposal, Program comments should assist proposers in deciding whether to undertake the cost and effort of a formal proposal.

Formal Proposals

For guidance on the specifics of formal proposal preparation, proposers should consult the two publicationsfn1, Program Announcement, Division of Materials Development, Research, and Informal Science Education (NSF 88-29); and Grants for Research and Education in Science and Engineering (NSF 83-57, latest edition). The first of these publications (NSF 88-29) includes required forms that should accompany each proposal and a discussion of the criteria that are used in evaluating proposals. One of these required forms is a Cover Page. In the upper left hand block of this Cover Page, labeled "For Consideration by NSF Organizational Unit," it is important to identify the Division and the solicitation target to which you are responding, i.e., "Division of Materials Development, Research, and Informal Science Education; Materials for Middle School Mathematics Instruction." Another required form is NSF Form 1225 (Information about Principal Investigators/Project Directors), be sure to include one copy of this form when you submit your proposal (proposals cannot be processed without this form). The second publication (NSF 83-57) provides detailed information on proposal preparation and processing and on grant administration. Except as modified by the guidelines set forth herein and in NSF 88-29, standard NSF guidelines on proposal preparation (content, format, budget, other sources of support, submission, evaluation, NSF awards [general information and highlights], declinations, and withdrawals contained in NSF 83-57 are applicable.

These publications may be obtained from the Forms and Publications Unit, Room 232, National Science Foundation, 1800 G Street NW, Washington, DC 20550.

When to Submit

Early submission of the required preliminary proposal is encouraged, in order to allow adequate time after a response has been received for the careful preparation of a formal proposal. Preliminary proposals are due by January 1, 1990.

Formal proposals responding to this program solicitation are due on June 1, 1990 which must be at least eight months prior to an anticipated project starting date to allow for processing.

Where to Submit

Preliminary proposals should be sent to: Instructional Materials Development Program, Room 635A, National Science Foundation, Washington, DC 20550.

Formal proposals, when submitted, should be addressed to: Proposal Processing Unit, Room 223, National Science Foundation, Washington, DC 20550.

Covering letters for both the preliminary and formal proposals should clearly identify them as responses to the "Program Solicitation, Materials for Middle School Mathematics Instruction."

For Additional Information

Questions not addressed in this publication or in the publications NSF 88-29 and NSF 83-57 may be directed to the Program Director for Mathematical Sciences by writing to the Instructional Materials Program at the address above, by calling 202/357-7066, or by using electronic mail to midmath@nsf on BITNET and midmath@note.nsf.gov on NewsNet. Such direct contact to discuss potential projects is welcomed.

NSF has TDD (Telephonic Device for the Deaf) capability, which enables individuals with hearing impairment to communicate with the Division of Personnel and Management for information relating to NSF programs, employment, or general information. This number is 202/357-7942.

The National Science Foundation provides awards for research and education in mathematics, engineering, and the sciences. The awardee is wholly responsible for the conduct of such activities and for the preparation of the results for publication. The Foundation, therefore, does not assume responsibility for such findings or their interpretation.
South Texas Project. Unit No. 1, located in Matagorda County, Texas.

The proposed amendment would have revised Facility Operating License No. NPF-76 by transferring the City of Austin's ownership interest of South Texas Project to Houston Lighting & Power Company.

The Commission has previously issued a Notice of Consideration of Issuance of Amendment published for Unit 1 in the Federal Register on July 26, 1988 (53 FR 26090). However, by letter dated November 2, 1988, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated June 9, 1988, and the licensee's letter dated November 2, 1988, which withdrew the application for license amendment. The above documents are available for public inspection at the Commission's Public Document Room, 2120 L Street, NW., Washington, DC, and the Local Public Document Rooms, Wharton Junior College Library, Wharton, Texas 77488 and Austin Public library, 810 Guadalupe Street, Austin, Texas, 78701.

Dated at Rockville, Maryland this 6th day of May, 1989.

For the Nuclear Regulatory Commission.

George F. Dick, Jr.,
Project Manager, Project Directorate-IV
Division of Reactor Projects—III, IV, and Special Projects, Officer of Nuclear Reactor Regulation.

[FR Doc. 89-12766 Filed 5-28-89; 8:45 am]
BILLING CODE 7590-01-M

Iowa Electric Light and Power Co., et al.; Withdrawal of Application for Amendment to Facility Operating License

[Docket No. 50-271]

The U.S. Nuclear Regulatory Commission (the Commission) has granted the request of Iowa Electric Light and Power Company, Central Iowa Power Cooperative, and Corn Belt Power Cooperative (the licensee) to withdraw its December 30, 1985 application for an amendment to Facility Operating License No. DPR-49, issued to the licensee for operation of the Duane Arnold Energy Center, located in Linn County, Iowa. Notice of consideration of issuance of this amendment was published in the Federal Register on February 12, 1986 (51 FR 5275).

The purpose of the licensee’s amendment request was to revise the Technical Specifications (TS) to reflect the DAEC conformance to 10 CFR Part 50, Appendix R, Fire Protection Requirements.

Subsequently the licensee informed the staff that the amendment is no longer requested. Thus, the amendment application is considered to be withdrawn by the licensee.

For further details with respect to this action, see (1) the application for amendment dated December 30, 1985, as revised August 6, 1986 and January 5, 1987, and (2) the staff’s letters dated April 26, 1989 and May 18, 1989.

These documents are available for public inspection at the Commission’s Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the Cedar Rapids Public Library, 500 First Street, SE, Cedar Rapids, Iowa 52401.

Dated at Rockville, Maryland, this 10th day of May, 1989.

For the Nuclear Regulatory Commission.

James R. Hall,
Project Manager, Project Directorate III-3,
Division of Reactor Projects—III, IV, and Special Projects, Office of Nuclear Reactor Regulation.

[FR Doc. 89-12766 Filed 5-28-89; 8:45 am]
BILLING CODE 7590-01-M

Vermont Yankee Nuclear Power Corp.; Environmental Assessment and Finding of No Significant Impact

[Docket No. 50-331]

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of exemptions from certain requirements of 10 CFR Part 50, Appendix R, to the Vermont Yankee Nuclear Power Corporation (VY/ licensee) for the Vermont Yankee Nuclear Power Station located at the licensee’s site near Vernon, Vermont.

Environmental Assessment

Identification of the Proposed Action

The proposed action would grant exemptions from certain requirements of Appendix R of 10 CFR Part 50. Specifically, exemptions were requested from section III.J and section III.G.2.a. to the extent that it requires:

- Section III.J.—Emergency lighting units having at least an 8-hour battery power supply in all areas needed for operation of and access to and from safe shutdown equipment.
- Section III.G.2.a.—Separation of cables and equipment and associated non-safety circuits of redundant trains by a fire barrier having a three-hour rating.

Environmental Impacts of the Proposed Action

The proposed exemptions would provide an equivalent level of fire safety such that there is no increase in the risk of not achieving safe shutdown at the Vermont Yankee Station. Consequently, the probability of achieving safe shutdown has not been decreased and the post-accident radiological releases would not be greater than previously determined and thus do not affect radiological plant effluents. The proposed exemptions otherwise affect radiological environmental impacts associated with the proposed exemptions.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed exemptions, other alternatives need not be evaluated. The principal alternative to the exemptions would be to require rigid compliance with the Appendix R requirements. Such action would not enhance the protection of the environment and would result in unjustified costs for the licensee.

The proposed action (a) is needed to allow the licensee to supply emergency power from the emergency diesel generators rather than from an 8-hour battery power supply. The diesel generator would be available throughout the period emergency lighting is needed and greatly in excess of 8 hours should the need arise.

To meet the requirements of III.G.2.a of Appendix R, the wall between the Reactor Building and the Turbine Building, designated as a vital fire barrier wall would require a 3-hour fire rating, including penetrations in the wall.

The proposed action (b) is needed to permit qualification of a wall penetration so that the licensee can be relieved of maintaining a costly manned fire watch as required by the plant technical specifications. The licensee demonstrated in its February 2, 1989 submittal that the penetration in question provides the equivalent of three-hour separation required by Appendix R.
Alternative Use of Resources

This action does not involve the use of resources not considered previously in the Final Environmental Statement related to the operation of the Vermont Yankee Nuclear Power Station.

Agencies and Persons Consulted

The NRC staff reviewed the licensee's requests and did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed exemptions. Based upon the foregoing environmental assessment, the NRC staff concludes that the proposed action will not have a significant effect on the quality of the human environment.

For further details with respect to this proposed action, see the licensee's letters dated June 29, 1988 and February 2, 1989. These letters are available for public inspection at the Commission's Public Document Room, 2120 L Street NW., Washington, DC and at the Brooks Memorial Library, 224 Main Street, Brattleboro, Vermont 05301.

Dated at Rockville, Maryland, this 22nd day of May, 1989.

For the Nuclear Regulatory Commission.

Daniel G. McDonald,
Acting Director, Project Directorate I-3, Division of Reactor Regulations I/II.

[FR Doc. 89-12767 Filed 5-26-89; 8:45 am]
BILLING CODE 7590-01-M

Applications for Licenses To Export Nuclear Material

Pursuant to 10 CFR 110.70(b) "Public notice of receipt of an application", please take notice that the Nuclear Regulatory Commission has received the following application for an export license. Copies of the application are on file in the Nuclear Regulatory Commission's Public Document Room located at 2120 L Street, NW., Washington, DC.

A request for a hearing or petition for leave to intervene may be filed within 30 days after publication of this notice in the Federal Register. Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; the Secretary, U.S. Nuclear Regulatory Commission; and the Executive Secretary, U.S. Department of State, Washington, DC 20520.

In its review of applications for licenses to export production or utilization facilities, special nuclear materials or source materials, noticed herein, the Commission does not evaluate the health, safety or environmental effects in the recipient nation of the facility or material to be exported. The information concerning these applications follows.

NRC EXPORT LICENSE APPLICATIONS

<table>
<thead>
<tr>
<th>Name of Applicant</th>
<th>Date of Application Received</th>
<th>Material Type</th>
<th>Total Element Material in Kilograms</th>
<th>Total Isotope</th>
<th>End Use</th>
<th>Country of Destination</th>
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</thead>
<tbody>
<tr>
<td>Transnuclear, Inc.</td>
<td>6/19/89</td>
<td>93.30% Enriched Uranium</td>
<td>32.080</td>
<td>29.931</td>
<td>Fuel for HFR-Grenoble Reactor</td>
<td>France</td>
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</tbody>
</table>

For the Nuclear Regulatory Commission.

Michael B. Congdon,

Dated this 23 day of May 1989, at Rockville, Maryland.

[FR Doc. 12807 Filed 5-26-89; 8:45 am]
BILLING CODE 7590-01-M

PACIFIC NORTHWEST ELECTRIC POWER AND CONSERVATION PLANNING COUNCIL

Protected Areas Amendments


SUMMARY: On November 15, 1982, pursuant to the Pacific Electric Power Planning and Conservation Act (the Northwest Power Act, 16 U.S.C. 839, et seq.) the Pacific Northwest Electric Power and Conservation Planning Council [Council] adopted a Columbia River Basin Fish and Wildlife Program (program). The Council adopted the Northwest Conservation and Electric Power Plan (power plan) on April 27, 1983. The program and the power plan have been amended from time to time since then. Major revisions of the program were adopted in 1984 and 1987, and a major revision of the power plan was adopted in 1988. On August 10, 1988, the Council adopted amendments pursuant to section 4(d)(1) of the Northwest Power Act to amend the program and the power plan to incorporate measures to protect critical fish and wildlife habitat from new hydropower development. The protected areas, provisions adopted in August require a vote of the Council to make corrections that "change the protected or unprotected status or the reason for protection of a river reach."

On March 27, 1989, the Council published notice of a proposed rulemaking to correct portions of the protected areas data base, changing the status of certain river reaches. This notice contains a brief description of the final amendments adopted in this rulemaking.

The Council held hearings on the proposed amendments on March 29 in Helena, Montana and Portland, Oregon, on March 30 in Boise, Idaho, on April 5 in Olympia, Washington, and on April 13 in Salem, Oregon. Written comment was received through April 12.

On April 13, the Council adopted all of the proposed corrections except those relating to Deep Creek in Idaho, Walker Creek in Oregon, and Canyon Creek in Washington. On May 10, the Council adopted a correction relating to Canyon Creek in Washington and adopted a response to comments concerning all the proposed corrections in the rulemaking.

Final amendments: The following is a summary, by state, of the final amendments adopted by the Council.

1. Idaho corrections.

Deep Creek in Adams County. The lower portion of Deep Creek outside the wilderness area, is now designated as being unprotected.
Deadwood River, a 15.7-mile-long tributary of the South Fork of the Payette River: The river is now designated as protected for resident fish.


Eddy Creek across from the Thompson River is now designated as unprotected. Eddy Creek along the north side of the Clark Fork River just upstream of Superior, Montana, between Second Creek and Deep Creek is now designated as protected. Mayo Gulch near St. Regis is now designated as unprotected. Mayo Gulch on the lower Clark Fork just west of St. Regis, is now designated as protected. Rock Creek (a tributary to the lower Clark Fork across from O’Keefe Creek below Missoula) remains protected, and has been assigned the correct river reach identification number.

The East Fork, Rock Creek, a tributary of the Rock Creek which joins the Clark Fork, near the Bull River, is now designated as protected for resident fish.


Walker Creek, a tributary which joins the Nestucca River near its headwaters, was proposed for a change in status. No changes were adopted by the Council in this rulemaking, but the status of the reach remains under study by the Council.


Wells Creek, a tributary of the North Fork of the Nooksack River in the Puget Sound Basin: That portion of the reach within the area of the Wells Creek Hydroelectric Project, which is located within the 4.8 mile reach of Wells Creek between its mouth and Bar Creek, is now designated as unprotected.

Canyon Creek, a tributary to the Middle Fork of the Nooksack River in the Puget Sound Basin: That portion of the reach within the area of the Canyon Lake Hydroelectric project (from approximately river mile 1.9 to river mile 3.66) is now designated as unprotected.

FOR FURTHER INFORMATION CONTACT:

For further information, including river reach numbers for the affected reaches, please call Dr. Peter Paquet in the Council’s central office, at (503) 222-5181 (toll from 1-800-222-3355 in Idaho, Montana and Washington or 1-800-452-2324 in Oregon). For a copy of the Council’s response to comments contact Judi Hertz at the Council’s central office, 851 SW. Sixth Avenue, Suite 1100, Portland, Oregon, 97204 or the above telephone numbers.

Edward Sheets, Executive Director
[FR Doc. 89-12714 Filed 5-26-89; 8:45 am]
BILLING CODE 0000-00-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-26852; File No. SR-Amex-89-6]

Self-Regulatory Organizations: American Stock Exchange, Inc.; Notice of Filing of Proposed Rule Change Relating to Disciplinary Fines

Pursuant to Sections 19(b)(1) and (d)(1), 15 U.S.C. 78s(b)(1), (d)(1), of the Securities Exchange Act of 1934 (“Act”) and Rules 19b-4 and 19d-1(c)(2) thereunder, 17 CFR 240.19b-4, 19d-1(c)(2), notice is hereby given that on April 24, 1989, the American Stock Exchange, Inc. (“Amex” or “Exchange”) submitted to the Securities and Exchange Commission (“Commission” or “SEC”) a proposed rule change as described in Items I, II and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Change

The Exchange is proposing to amend its disciplinary system for minor rule violations. The text of the proposed rule change and a copy of the “traffic ticket” fine ranging from $100 for a first offense to $500 for a third and any subsequent offense within a rolling 12-month period. The member or member organization may plead guilty and pay the fine or contest the charge and request a hearing before an Exchange Disciplinary Committee.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

(1) Purpose. In 1976, the Exchange established a simplified fine system pursuant to Article V, Section 1(e) of the Exchange Constitution (Summary Disciplinary Procedure) for the disposition of minor rule violations. Minor rule violations under this “traffic ticket” fine system include (1) any act or omission tending to disrupt the orderly conduct of business on the Floor or which causes serious injury to the personal comfort or safety of other persons on the Floor (“floor decorum violations”), and (2) any failure to comply with any on-floor or off-floor operational procedure established by the Exchange (“operational violations”). Running on the trading floor and smoking in unauthorized areas are examples of floor decorum violations. A typical operational violation under this procedure would be the failure to be properly represented in the Exchange’s option reconciliation room at scheduled times to resolve rejected option trades.

Under the Exchange’s current procedure administered by the Market Operations Division, Floor Governors and Exchange Officials are authorized to charge members and member organizations with floor decorum and operational violations and to assess a fine ranging from $100 for a first offense to $500 for a third and any subsequent offense within a rolling 12-month period. The member or member organization may plead guilty and pay the fine or contest the charge and request a hearing before an Exchange Disciplinary Committee.

In 1982, the Exchange established a “traffic ticket” fine system for the late filing of reports required to be submitted to the Exchange under Rule 30. The reporting violation fine system authorizes the Exchange Department responsible for receiving reports to impose a fine of $50 a day for delinquent reports. Again, the member or member organization may plead guilty and pay the fine or contest the charge and request a hearing before an Exchange Disciplinary Committee.

In 1985, the SEC approved a minor rule violation plan submitted by the Exchange pursuant to SEC Rule 19d-1 specifying uncontested minor rule violations with sanctions not exceeding $2,500 which would be subject to quarterly rather than current reporting to the SEC. The Exchange’s minor rule violation plan covers both its existing floor decorum and reporting violation fine systems. The NYSE and other regional exchanges also adopted minor rule violation fine systems (and SEC approved plans), based on the Amex model.

The Amex’s floor decorum and reporting violation fine systems have worked well over the years, providing for convenient and quick resolution of minor rule violations. The fine systems provide members with a simple,
equitable method under which they can plead guilty to a minor rule violation charge and pay an appropriate fine. They enable the Exchange to deal more efficiently with minor rule violations, as well as providing it with a more meaningful deterrent. The Exchange feels that an expression of its minor rule violation plan to cover more substantive violations would allow for quick and effective resolution of a broader range of minor rule violations.

In place of the current summary disciplinary procedure contained in Article V, section 1(c) of the Constitution, presently utilized by the Enforcement Department to charge members with minor substantive rule violations, new Rule 590 sets forth three separate fine systems—for general rule violations (Part 1), floor decorum violations (Part 1), and reporting violations (Part 3). The current floor decorum and reporting violation fine systems will remain the same, continuing to be administered by Market Operations and the various Exchange departments responsible for receiving Exchange reports. The new general rule violation fine system permits the Exchange's Enforcement Department, after a matter has been referred to it, to impose fines ranging from $500 to $2,500 against individuals and from $1,000 to $5,000 against member firms, depending on the number of similar violations within a rolling 12-month period. The maximum fine (i.e., for violations subsequent to a second offense) may be imposed for a first or second offense if warranted under the circumstances in the view of the Exchange's Enforcement Department. As in the floor decorum and reporting violation fine systems, the member or member organization may plead guilty and pay the fine or contest the charge and request a hearing before an Exchange Disciplinary Panel.

The list of general rule violations and applicable fines that can be imposed by the Exchange is set forth in Part 1, Paragraph (g) of new Rule 590.

(2) Basis. The proposed rule change is consistent with section 6(b) of the Act in general and furthers the objectives of section 6(b)(6) in particular in that it is intended to assure that Exchange members and member firms are appropriately disciplined for rule violations.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change will have no impact on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street NW., Washington, DC 20549. Copies of such filings will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by June 19, 1989.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,
Secretary.


[FR Doc. 89-12679 Filed 5-26-89; 8:45 am]
BILLING CODE 8010-01-M

[Release No. IC-16967; 811-4799]

Collective Investment Trust for First Union IRAs' Application for Deregistration

May 19, 1989.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for deregistration under the Investment Company Act of 1940 (the "Act").

Applicant: Collective Investment Trust for First Union IRAs ("Applicant").

Relevant 1940 Act Sections: Deregistration under section 8(f).

Summary of Application: Applicant seeks an order declaring that it has ceased to be an investment company subject to the Act.

Filing Date: The application was filed on Form N-8f on April 12, 1989. A supplementary letter clarifying certain technical points of the application will be filed during the notice period.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing the SEC's Secretary and serving Applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on June 12, 1989, and should state the nature of the requester's interest, the reason for the request, and the issues contested. Hearing requests also should be accompanied by proof of service on the Applicant in the form of affidavit or, for lawyers, certificate of service. Requests for notification of hearing may be made by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549; Applicant, Collective Investment Trust for First Union IRAs, One First Union Center, 301 South College Street, Charlotte, N.C. 28202.


ADDRESSES: [Office of Investment Company Regulation]
SUPPLEMENTARY INFORMATION: The following is a summary of the application: the complete application on Form N-8F is available for a fee from either the SEC's Public Reference Branch in person, or the SEC's commercial copier (800) 231-3282 (in Maryland (301) 258-4300).

Applicant's Representations

1. Applicant is registered under the Act as a open-end, diversified management investment company.

2. On August 14, 1986, Applicant filed a registration statement under the Act which was declared effective on November 25, 1986. On August 14, 1986, Applicant registered an indefinite number of shares divided into one or more portfolios pursuant to a registration statement under the Securities Act of 1933. The registration statement became effective on November 25, 1986 and the public offering of the units of First Union IRA Income Fund (the "Income Fund") covered by such registration statement commenced immediately thereafter. In August, 1987, the registration statement was amended to provide for the offering of the units of First Union IRA Equity Fund (the "Equity Fund").

3. At a meeting on June 22, 1988, the Board of Directors of the Applicant approved the sale of assets of Applicant to The Salem Funds.

4. No action is required by Applicant under the law of the State of North Carolina, the law under which Applicant is organized, in connection with the transaction with The Salem Funds and Applicant's liquidation except for compliance with the applicable provisions of Applicant's Declaration of Trust. Applicant complied with the provisions of its Declaration of Trust by having the unitholders of each of its Equity Fund and Income Fund approve the transaction as well as having the transaction approved by its supervisory committee.

5. The unitholders of each of the Equity Fund and Income Fund approved the transfer of the assets of their respective funds to The Salem Funds in exchange for shares of the Growth Portfolio and Fixed Income Portfolio, respectively, of the Salem Funds at separate meetings held on November 30, 1988. The vote of the unitholders of the Equity Fund with respect to the transaction was 1,068,461.375 units in favor, 447,382 against, and 16,033,845 abstaining. The 1,068,461.375 units in favor of the transaction represented a majority interest of the unitholders of the Income Fund as required by the Declaration of Trust. The vote of the unitholders of the Income Fund with respect to the transaction was 1,068,461.375 units in favor, 447,382 against, and 16,033,845 abstaining. The 1,068,461.375 units in favor of the transaction represented a majority interest of the unitholders of the Income Fund as required by the Declaration of Trust.

6. Applicant exchanged all of its assets for shares of the Growth Portfolio and Fixed Income Portfolio of The Salem Funds based upon the net asset value of Applicant and the net asset value per share of the shares of such portfolios of The Salem Funds as of the close of business on January 27, 1989. Applicant is divided into two portfolios or series of units, the Equity Fund and the Income Fund. The assets of the Equity Fund were exchanged for shares of the Growth Portfolio of The Salem Funds and the assets of the Income Fund were exchanged for shares of the Fixed Income Portfolio of The Salem Funds. Immediately thereafter, Applicant distributed the shares of the Growth Portfolio of The Salem Funds received pro rata to the unitholders of the Equity Fund and the shares of the Fixed Income Portfolio of The Salem Funds received pro rata to the unitholders of the Income Fund. All security holders have received any distributions due.

7. The expenses incurred in the merger were primarily legal, printing and mailing costs involved with the solicitation of proxies for meetings of the unitholders of Applicant's Equity Fund and Income Fund held for purposes of approving the transactions with The Salem Funds and the liquidation of the Applicant. All expenses incurred by Applicant were allocated between the Equity Fund and the Income Fund based on their respective net asset values. All expenses incurred by The Salem Funds were paid by it directly. Approximate total costs to the Equity Fund were $64,350 and to the Income Fund were $289,936.

8. As of the time filing the application, Applicant had no securityholders. No assets have been retained by Applicant and no liabilities remain outstanding. Applicant is not a party to any litigation or administrative proceedings. Applicant is not presently engaged in, nor does it propose to engage in, any business activities other than those necessary for the winding up of its affairs.

9. Applicant will file notice of its liquidation with the United States Comptroller of the Currency and with the appropriate securities authorities of the states in which its units have been offered for sale.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 89-12773 Filed 5-26-89; 8:45 am]
BILLING CODE 8010-01-M

Colonial Government Mortgage Trust; Application for Deregistration

May 19, 1989.
Agency: Securities and Exchange Commission ("SEC").

Action: Notice of Application for Deregistration under the Investment Company Act of 1940 (the "1940 Act").

Applicant: Colonial Government Mortgage Trust ("Applicant").

Relevant 1940 Act Section: Section 8(f).

Summary of Application: Applicant seeks an order declaring that it has ceased to be an investment company under the 1940 Act.

Filing Dates: The application on Form N-8F was filed on April 3, 1989.

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, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on June 12, 1989, and should be accompanied by proof of service on the 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 who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

For Further Information Contact: Patricia Copeland, Legal Technician, (202) 272-3009, or Karen Skidmore, Branch Chief, (202) 272-3023 (Office of Investment Company Regulation).

Supplementary Information: Following is a summary of the application: the complete application is available for a fee from either the SEC's Public Reference Branch in person or the SEC's commercial copier (800) 231-3282 (in Maryland (301) 258-4300).

Applicant's Representations

1. Applicant is a business trust organized under the laws of the Commonwealth of Massachusetts. Applicant is registered under the Act as an open-end, diversified management investment company. On December 31,
Franklin Corporate Cash Management Fund; Notice of Application

May 19, 1989.

AGENCY: Securities and Exchange Commission (“SEC”).

ACTION: Notice of Application for Deregistration Under the Investment Company Act of 1940 (“1940 Act”).

APPLICANT: Franklin Corporate Cash Management Fund (the “Fund”).

RELEVANT 1940 ACT SECTION: Section 8(f) and Rule 8f-1 thereunder.

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company.

FILE DATE: The Application was filed on March 27, 1989.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing.

INTERESTED PERSONS: Interested persons may request a hearing and proof of service on the Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should be sent to shareholders of record as of the Valuation Date. The Applicant will take all steps necessary to notify the persons contesting the issues.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549; Applicant, 777 Mariners Island Boulevard, San Mateo, California 94404.

FOR FURTHER INFORMATION CONTACT: Patricia Copeland, Legal Technician, (202) 272–3009 or Karen Skidmore, Branch Chief, (202) 272–3023 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application: the complete application is available for a fee from either the SEC’s Public Reference Branch in person, or the SEC’s commercial copier (800) 231–3282 (in Maryland (301) 258–4300).

Applicants’ Representations

1. Applicant (or the “Fund”), a California corporation and open-end diversified management company, filed a Notification of Registration on Form N-8A on November 16, 1983, Applicant registered an indefinite number of shares on Form N-1 which was declared effective on January 24, 1984.

2. Pursuant to an Agreement and Plan of Reorganization (the “Reorganization”) between the Fund and the Franklin Corporate Cash Portfolio of Franklin Managed Trust (File Nos. 811–4894; 33–9994) (the “Portfolio”), substantially all the assets of the Fund were transferred to the Portfolio in exchange solely for shares of beneficial interest of the Portfolio (the “Portfolio Shares”). The number of Portfolio Shares issued was calculated on the basis of the relative net asset values of the Fund and the Portfolio immediately prior to the transfer of assets on December 31, 1988. The Fund distributed the Portfolio Shares pro rata to its shareholders of record as of December 31, 1988. No brokerage commissions were paid in connection with such exchange.

3. On August 23, 1988, the Board of Directors of the Fund unanimously approved the Reorganization for the Fund and the transfer of the Fund’s assets in exchange for shares of the Portfolio. On or about November 10, 1988 a proxy statement and proxy were sent to shareholders of the Fund. On December 31, 1988 a special meeting of shareholders of the Fund was held wherein the proposed Reorganization and subsequent liquidation of the Fund was approved. The proxy material which was sent to shareholders of the Fund was filed with the Commission as part of Form N-14 on October 7, 1988.

4. The Fund incurred expenses of $24,456 in connection with the reorganization and liquidation of the Fund. The Fund paid for $20,000 of expenses incurred by the Fund in connection therewith. The Adviser paid $4,456 of expenses.

5. The Fund has filed a Form N-SAR for its fiscal year ended December 31, 1988 reflecting the winding up of its operations. The Fund is presently inactive under California state law and intends to file an application for a certificate of dissolution with the State of California. The Fund will take all action required by state law, including filing an application for a certificate of dissolution with the State of California.

6. Applicant has no shareholders, debts or liabilities as of the time of filing the application. 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 to wind up its affairs. Applicant intends to file the appropriate Certificate of Dissolution or similar document in accordance with state law after the relief requested has been granted.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz, Secretary.

[FR Doc. 89–12774 Filed 5–26–89; 8:45 am]

BILLING CODE 5010–01–M

Rel. No. IC–16964; (811–3908)
Interact Portfolios Series; Notice of Application


AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Deregistration under the Investment Company Act of 1940 (the "1940 Act").

Applicant: Interact Portfolios Series.

Relevant 1940 Act Sections: Section 8(f) and Rule 8f-1 thereunder.

Summary of Application: Applicant seeks an order declaring that it has ceased to be an investment company.

Filing Dates: The application was filed on January 9, 1989, and amended on May 8, 1989.

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, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on June 16, 1989, and should be accompanied by proof of service on the Applicant.

Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549; Applicant, One Financial Center, Boston, MA 02111.

FOR FURTHER INFORMATION CONTACT: Paul J. Heaney, Financial Analyst (202) 272-3420, or Brian R. Thompson, Branch Chief (202) 272-3016 (Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application; the complete application is available for a fee from the SEC's Public Reference Branch in person, or the SEC's commercial copier (800) 231-3282 (in Maryland (301) 283-4300).

Applicant's Representations

1. On December 24, 1987, Applicant filed Form N-8A to register under the 1940 Act as an open-end, diversified management investment company. On December 24, 1987, Applicant also filed Form N-1A pursuant to the Securities Act of 1933, which registration statement became effective on April 29, 1988. The initial public offering of Applicant's securities commenced on May 2, 1988. Applicant was organized as a Massachusetts business trust.

2. The public offering of Applicant's securities ceased on November 14, 1988, and letters were sent to all shareholders on December 1, 1988, informing them of the impending liquidation of Applicant and offering shareholders the option to transfer at no cost to another fund within the Colonial Group of Mutual Funds, which has investment management, distribution and services provided by affiliates of Applicant's investment adviser and principal underwriter, or to redeem their shares and receive a refund of all sales loads paid, or for shareholders who purchased shares on or after October 15, 1988, to accept rescission of their trade and a refund of all sales loads paid. On that date, Applicant consisted of seven separate portfolios with an aggregate net value of $4,619,870. All shareholders exercised one of the three options and the voluntary transfer program was completed by January 1, 1989.

3. No expenses were incurred by Applicant's shareholders during the implementation of the liquidation. Applicant and its affiliates, through leasing their investment remaining in the fund until all non-affiliated shareholders had transferred or redeemed, absorbed the expense of the unamortized organization costs and additional expenses. Applicant has no debts or other liabilities which remain outstanding.

4. Applicant has no shareholders and no assets. 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 to wind up its affairs. Applicant intends to dissolve under Massachusetts law.

For the SEC, by the Division of Investment Management, pursuant to delegated authority.

Jonathan C. Katz,
Secretary.

[FR Do. 68-12-776 Filed 5-26-89; 8:45 am]

BILLING CODE 6010-01-M

[Rel No. IC-15973; (811-5424)]

ML Venture Partners II, L.P., et al; Application

May 18, 1989.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 ("1940 Act").

Applicants: ML Venture Partners II, L.P. ("MLVP II"), Merrill Lynch Venture Capital Inc. ("Management Company"), ML Technology Ventures, L.P. ("ML Technology"), Merrill Lynch KECALP L.P. ("KECALP") and KECALP Inc. ("KECALP General Partner").

Relevant 1940 Act Sections: Order requested under section 17(b) and 57(e) exempting certain transactions from the provisions of sections 17(a) and 57(a)(10) and under section 57(i) and 17(d) and Rule 17d-1 authorizing certain transactions which are otherwise prohibited by sections 17(d) and 57(a)(4).

Summary of Application: Applicants seek an order relating to the acquisition of certain securities (i) deemed "joint transactions" under the 1940 Act or (ii) from an "affiliated person," as defined in the 1940 Act.

Filing Date: The application was filed on July 20, 1988, and amended on April 21, 1989. The Applicants will file an amendment during the notice period clarifying certain determinations under section 17(d) and Rule 17d-1.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing.

Interested persons may request a hearing by writing to the SEC's Secretary and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on June 12, 1989, and should state the nature of the requester's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549; Applicant's ML VP and Management Company, 717 Fifth Avenue, New York, New York 10022 and KECALP, the KECALP General Partner, and ML Technology, World Financial Center, North Tower, New York, New York 10261.
FOR FURTHER INFORMATION CONTACT:
Staff Attorney Cathey Baker (202) 272-3033 or Branch Chief Karen L. Skidmore (202) 272-3023 (Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee. One may obtain a copy by going to the SEC's Public Reference Branch or by telephoning the SEC's commercial copier (800) 231-3262 (in Maryland (301) 258-4300).

Applicants’ Representations
1. MLVP II, a Delaware limited partnership, is a business development company under the 1940 Act. The investment objective of MLVP II is to seek long-term capital appreciation by making venture capital investments.

2. The General Partners of MLVP II consist of the MLVP II Individual General Partners and the MLVP II Co., L.P. ("MLVP II General Partner"). The MLVP II Individual General Partners include the three MLVP II Independent General Partners (defined to be individuals who are not "interested persons" of MLVP II) and one General Partner who is an individual and an affiliated person of the MLVP II Managing General Partner. The MLVP II Managing General Partner is the managing general partner of MLVP II and is responsible for its venture capital investments. The MLVP II Managing General Partner is a limited partnership controlled by its general partner, Management Company, which performs the management and administrative services necessary for the operation of MLVP II. Both the MLVP II Managing General Partner and the Management Company are registered under the Investment Advisers Act of 1940. The Management Company is an indirect subsidiary of Merrill Lynch & Co., Inc. ("ML & Co.").

3. KECALP, a Delaware limited partnership, is registered under the 1940 Act as a non-diversified, closed-end management investment company. It is an "employees' securities company," within the meaning of Section 2(a)(13) of the 1940 Act, and operates in accordance with the terms of an exemptive order issued pursuant to section 6(b) of the 1940 Act in Investment Company Act Release No. 12363 (April 8, 1982) ("KECALP Exemptive Order"). The investment objective of KECALP is to seek long-term capital appreciation. Under the terms of KECALP's offering, as set forth in its registration statement, Units were offered exclusively to employees of ML & Co. and its subsidiaries and to non-employee directors of ML & Co. Employees of ML & Co. and its subsidiaries were permitted to purchase Units of KECALP only if they received annualized compensation in respect of 1986 equal to at least $75,000. The general partner for KECALP is KECALP Inc. ("KECALP General Partner"), a Delaware corporation and an indirect wholly-owned subsidiary of ML & Co. The KECALP General Partner is responsible for managing and making investment decisions for KECALP.

4. ML Technology is a Delaware limited partnership which has the investment objective of seeking cash flow from, among other things, the commercialization of new technology through development and manufacturing agreements with companies conducting research and development for it or with other third parties, through licenses or sales of technology, and from returns on investments in portfolio limited partnerships or warrants to purchase common stock of companies that sponsor portfolio limited partnerships. ML Technology is not registered as an investment company under the 1940 Act. See the no action letter in ML Research and Development Partners I, L.P. (pub. avail. September 24, 1984), ML R&D Co., L.P. ("ML Technology General Partner") is the general partner of ML Technology and is responsible for selecting, structuring and monitoring its research and development ventures. ("Merrill Lynch R&D"), the general partner of the ML Technology General Partner, is an indirect wholly-owned subsidiary of ML & Co.

5. ML/MS Associates is a California limited partnership organized on February 17, 1988 pursuant to a Limited Partnership Agreement among ML Research Ventures, L.P. ("ML Research Partnerships"), the Management Company, the KECALP General Partner and Morgan Stanley Research Ventures, L.P. ("Morgan Stanley Research") as the Initial Limited Partners. MLMS Cancer is a California corporation founded in 1986, is a privately-held biotechnology company with proprietary therapeutic products and diagnostic services for a broad range of immune disorders. The contractual arrangements between ML/MS Associates and IDEC are the following. IDEC has licensed to ML/MS Associates the background technology necessary to perform the project and to manufacture the products for sale, license or other disposition. Under the Development Agreement, IDEC will use its best efforts to carry out the research and development and clinical testing for the project in accordance with the Development Plan and Development Budget. ML/MS Associates has agreed to make certain payments to IDEC ("Development Funds"), as discussed further below, as consideration for the services performed under the Development Agreement. ML/MS Associates has also granted IDEC (i) an option to enter into a commercial joint venture with ML/MS Associates to produce, market, sell and commercialize the products and (ii) a further option to purchase, if the option referred to in (i) above is exercised. ML/MS Associates’ interest in the joint venture.

6. The investment opportunity in the research and development project with IDEC was brought to the attention of the ML Technology General Partner during July 1987. It was subsequently brought to the attention of MLVP II and KECALP by a member of the Board of Directors of Merrill Lynch R&D, the management company of ML Technology. The MLVP II Managing General Partner, the ML
Technology General Partner and the KECALP General Partner separately evaluated the proposed investments in MLMS Cancer and ML/MS Associates and independently determined to approve aggregate investments of approximately $4,500,000, $4,000,000 and $300,000 for MLVP II, ML Technology and KECALP, respectively. The investment decisions were made solely on the basis of the respective investment objectives and policies of MLVP II, ML Technology and KECALP. On approximately January 14, 1988, the KECALP General Partner separately approved additional investments of $36,000, $33,000, respectively, in MLMS Cancer (including $400,000, $370,000 and $300,000, respectively, in the form of a non-interest-bearing demand note which will roll over every six months); investments of $3,960,000, $3,663,000 and $297,000, respectively, in ML/MS Associates; and investments of $217,391, $201,087 and $16,304, respectively, in IDEC.

9. On February 17, 1988, ML Technology acquired 370,000 shares of common stock, no par value, of MLMS Cancer ("MLMS Cancer Common Stock") for a purchase price of $.10 per share or $37,000, paid in cash. ML Technology also delivered a demand note payable to MLMS Cancer in the aggregate principal amount of $370,000. Lastly, ML Technology acquired a limited partnership interest in ML/MS Associates for a capital contribution of $3,960,000 and made an initial capital contribution of $180,000.

10. The order issued in ML Venture Partners I, L.P., et al., Investment Company Act Release No. 48525 (September 7, 1988), permits MLVP II to co-invest on a prospective basis with KECALP in transactions otherwise prohibited by Sections 17(d) and 57 of the 1940 Act. The order does not grant prospective relief, however, in connection with co-investment by ML Technology and MLVP II, nor does it prohibit by Sections 17(d) and 57 of the 1940 Act. The order does not grant prospective relief to the Additional Limited Partner until September 30, 1988. Upon admission, the Additional Limited Partner was to purchase 50,000 shares of MLMS Cancer Common Stock for an aggregate purchase price of $5,000 and to deliver a demand note payable to MLMS Cancer in the amount of $50,000. The Additional Limited Partner was also to make a $495,000 capital contribution to ML/MS Associates and to deliver a demand note payable to MLMS Cancer in the amount of $50,000. The Additional Limited Partner would make a cash contribution of $27,174 to ML/MS Associates in full payment for the IDEC Warrants. On September 16, 1988, the ML Technology General Partner approved additional investments of $35,000, $495,000 and $27,174 by ML Technology and KECALP, respectively, to the Additional Limited Partner at a date no later than September 30, 1988. The Limited Partnership Agreement authorized the issuance of warrants to purchase 138,750 IDEC Warrant Shares to the Additional Limited Partner at a $2.51 per share, at a price per share of $2.90 (subject to adjustment for reorganization, merger, consolidation or sale of assets) on or before February 17, 1995 (such shares hereinafter, "IDEC Warrant Shares"). The IDEC Warrants were issued directly to the limited partners of ML/MS Associates based on their pro rata interest in MLMS Cancer and ML/MS Associates as follows: ML Technology, one warrant to purchase 878,750 IDEC Warrant Shares; Management Company, one warrant to purchase 950,000 IDEC Warrant Shares; the KECALP General Partner, one warrant to purchase 71,250 IDEC Warrant Shares; and Morgan Stanley Research, one warrant to purchase 712,500 IDEC Warrant Shares. On February 17, 1988, ML Technology, the Management Company, the KECALP General Partner and Morgan Stanley Research made cash contributions of $201,087, $217,391, $163,304 and $163,043, respectively, to the Additional Limited Partner in full payment for the IDEC Warrants.
Acquisition date of the respective purchases by the KECALP General Partner, which was subsequent to the authorization of the investment by the Board of Directors of the KECALP General Partner. MLVP II will not pay any carrying costs in respect of the period prior to May 4, 1988, the date on which the Independent General Partners of MLVP II were notified of the investment and given the opportunity to object to the acquisition. The carrying costs will be assessed only with respect to (i) the cash payments made by the Management Company and the KECALP General Partner to MLMS Cancer, ML/MS Associates and IDEC, respectively, plus the $40,000 payable on demand by the Management Company to MLMS Cancer, plus carrying costs related to such investments and (b) the original purchase price of $3,000, $297,000 and $19,304 paid by the KECALP General Partner on February 17, 1988 for the investments in MLMS Cancer, ML/MS Associates and IDEC, respectively, plus the $30,000 payable on demand by the KECALP General Partner to MLMS Cancer, plus carrying costs related to such investments. The cost shall therefore equal all cash payments made by the Management Company and the KECALP General Partner, respectively, to MLMS Cancer and ML/MS Associates and the balance due under the demand note delivered to MLMS Cancer. If the Value is greater than the obligation remaining to make any additional capital contributions to ML/MS Associates and the balance due under the demand note (“Outstanding Obligations”), MLVP II and KECALP will issue the Outstanding Obligations and will simultaneously make a cash payment to the Management Company and the KECALP General Partner, respectively, equal to the difference between the lesser of the Cost or Value and the Outstanding Obligations. If the Value is less than the Outstanding Obligations, MLVP II and KECALP will still assume the Outstanding Obligations; however, the Management Company and the KECALP General Partner will simultaneously make a cash payment to MLVP II and KECALP, respectively, equal to the difference between the Outstanding Obligations and the Value. If the Value is equal to the Outstanding Obligations, MLVP II and KECALP will assume the Outstanding Obligations and neither MLVP II or KECALP nor the Management Company or the KECALP General Partner, respectively, will make a cash payment. KECALP will pay no carrying costs in respect of the period prior to February 17, 1989, the deemed relevant, including the nature of the investments, the nature of the investments by affiliates of ML & Co. in MLMS Cancer, ML/MS Associates and IDEC, and the fairness of the purchase prices proposed to be paid by MLVP II and KECALP. The MLVP II Managing General Partner and the KECALP General Partner determined that the proposed investments by MLVP II and KECALP will not directly or indirectly benefit entities affiliated with ML & Co.

2. At a meeting of the Board of Directors of the KECALP General Partner held on December 3, 1987, KECALP’s investments were approved after consideration of each of the factors set forth in section 17(b). At a meeting of the Independent General Partners of MLVP II held on May 4, 1988, MLVP II's investments were approved after consideration of each of the factors set forth in section 57(c). MLVP II incurred no contractual obligation to make the investments prior to the meeting of the Independent General Partners on May 4, 1988. The MLVP II Independent General Partners have such knowledge in financial and business matters as to be capable of determining whether the investment is appropriate for MLVP II. As stated above, the purchase will not be consummated unless the Independent General Partners of MLVP II make an additional determination that the investment continues to be appropriate for MLVP II.

3. The Independent General Partners of MLVP II and the KECALP General Partner considered the fact that the proposed purchase price to be paid by MLVP II and KECALP will include carrying costs incurred by an affiliated person (i.e., the Management Company and the KECALP General Partner) if the fair value of the investments at the time of the acquisition is determined to be more than the sum of the purchase price plus the affiliate’s carrying costs. MLVP II and KECALP believe that it is appropriate for the purchase price paid for a portfolio investment to reflect carrying costs, provided that the value of the investment at the time of acquisition exceeds the amount of the purchase price plus carrying costs. The Applicants submit that to deny reimbursement for carrying costs would result in a further and unwarranted loss to the Management Company or the KECALP General Partner and would provide a disincentive to act on behalf of MLVP II and KECALP in the future.

4. With respect to the investment by MLVP II, the MLVP II Managing General Partner will render its written opinion as to the fair value of the investments in MLMS Cancer, ML/MS Associates and
IDEc on the date the investments are proposed to be acquired by MLVP II. The opinion shall discuss each of the factors, assumptions, estimates and projections (collectively, "Factors") considered in determining fair value. The MLVP II Managing General Partner will make a presentation to the Independent General Partners of MLVP II as to the basis for its opinion. The presentation will include detailed information as to each Factor considered. The Independent General Partners of MLVP II will independently review the opinion of the MLVP II Managing General Partner and each Factor considered. On the basis of this review and such other information as they deem necessary or appropriate, the Independent General Partners of MLVP II shall determine the fair value of the investments in MLMS Cancer, ML/MS Associates and IDEC on the date the investments are proposed to be acquired by MLVP II. Detailed minutes, which shall at minimum specifically discuss each of the Factors considered and the basis for any action taken, shall be kept of the MLVP II Managing General Partner's opinion, and the determination of fair value by the Independent General Partners of MLVP II. All such minutes, the MLVP II Managing General Partner's opinion, and any documents considered or reviewed by the Independent General Partners of MLVP II, shall be available for inspection by the Commission or its staff.

5. With respect to the investment by KECALP, representatives of management of the KECALP General Partner responsible for monitoring the research and development project with IDEC will render their written opinion as to the fair value of the investments in MLMS Cancer, ML/MS Associates and IDEC on the date the investments are proposed to be acquired by KECALP. The opinion will discuss each of the Factors considered in determining fair value. Such individuals will make a presentation to the Board of Directors of the KECALP General Partner as to the basis for their opinion. The presentation will include detailed information as to each Factor considered. The Board of Directors of the KECALP General Partner will independently review the opinion of the representatives of management of the KECALP General Partner and each Factor considered. On the basis of this review and such other information as they deem necessary or appropriate, the Board of Directors of the KECALP General Partner shall determine the fair value of the investments in MLMS Cancer, ML/MS Associates and IDEC on the date the investments are proposed to be acquired by KECALP. Detailed minutes, which shall at minimum specifically discuss each of the Factors considered and the basis for any action taken, shall be kept of the presentation by the representatives of management of the KECALP General Partner, the review of their opinion, and the determination of fair value of the investments by the Board of Directors of the KECALP General Partner. All such minutes, the opinion of representatives of management of the KECALP General Partner, and any documents considered or reviewed by the Board of Directors of the KECALP General Partner, shall be available for inspection by the Commission or its staff.

6. The investments are not otherwise available for purchase by MLVP II and KECALP. The MLVP II Managing General Partner and the KECALP General Partner have approved the investments after review of a considerable number of possible investments for MLVP II and KECALP.

7. The KECALP General Partner believes that the proposed investments are consistent with the rationale underlying the establishment of KECALP as an "employees' securities company." In the application for exemptive relief granted in the KECALP Exemptive Order, as well as in KECALP's prospectus, it was indicated that ML & Co. and its affiliates would be involved in structuring, identifying and investing in many of KECALP's portfolio investments. Similarly, the proposed investment of MLVP II is consistent with the investment objectives of MLVP II and the kinds of transactions in which it was contemplated MLVP II would participate.

8. With respect to the relief requested pursuant to Rule 17d-1, the MLVP II Managing General Partner, the ML Technology General Partner and the KECALP General Partner reviewed the proposed investments. The MLVP II Managing General Partner and the KECALP General Partner determined that such investments were consistent with MLVP II's and KECALP's investment objectives of seeking long-term capital appreciation. The ML Technology General Partner also determined that the investments were consistent with ML Technology's investment objectives. The MLVP II Managing General Partner, the ML Technology General Partner and the KECALP General Partner also determined that the investments would not disadvantage either of MLVP II, ML Technology or KECALP in making, maintaining or disposing of the investments. In reaching such determinations, the MLVP II Managing General Partner, the ML Technology General Partner and the KECALP General Partner considered several factors, including the difference in the amount proposed to be invested by MLVP II, ML Technology and KECALP. It was recognized that the terms of the purchases by MLVP II, ML Technology and KECALP are consistent with the rationale for the investments as set forth in the Exemptive Order, as well as in KECALP's prospectus, it was indicated that MLVP II may be a co-investor in portfolio companies with affiliates of management. Similarly, the prospectus of ML Technology indicated that ML Technology may co-invest in research and development partnerships with affiliates of management. MLVP II, ML Technology and KECALP thus submit that the relief requested is consistent with the purposes of MLVP II, ML Technology and KECALP, their stated policies and the disclosure made to prospective investors. Applicants also believe that the proposed investments are in the best interest of MLVP II, ML Technology and KECALP.

Applicants' Conditions

If the requested order is granted, Applicants agree to the following conditions:

1. The limited partnership interest in ML/MS Associates, the MLMS Cancer Common Stock and the IDEC Warrants will be acquired by KECALP and MLVP II, respectively, in the manner and on the terms described above.

2. In connection with the deliberations and determinations by the Board of Directors of the KECALP General Partner.
Partner regarding KECALP’s proposed investments in the limited partnership interest in MLMS Associates, MLMS Cancer Common Stock and IDEC Warrants, appropriate record-keeping will be maintained and made available for inspection by the Commission in accordance with the KECALP Exemptive Order and the 1940 Act. 3. In connection with the deliberations and determinations by the Independent General Partners of MLVP II regarding the valuation of MLVP’s proposed investments in MLMS Associates, MLMS Cancer Common Stock and IDEC Warrants, appropriate record-keeping will be maintained and made available for inspection by the Commission upon request.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 89-12777 Filed 5-26-89; 8:45 am]
BILLING CODE 9010-01-M

[Ref. No. IC—16970; 811-3000]

Nova Funds Group; Application for Deregistration

May 19, 1989.

AGENCY: Securities and Exchange Commission (“SEC”).

ACTION: Notice of application for deregistration under the Investment Company Act of 1940 (the “1940 Act”).

Applicant: Nova Funds Group (“Applicant”).

Relevant 1940 Act Section: Section 8(f).

Summary of Application: Applicant seeks an order declaring that it has ceased to be an investment company under the 1940 Act. Filing Dates: The application on Form N-8F was filed on March 15, 1989. An amendment clarifying and confirming certain points regarding expenses (summarized below) will be filed during the notice period.

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, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on June 12, 1989, and should be accompanied by proof of service on the 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 who wish to be notified of a hearing may request notification by writing to the SEC’s Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street NW., Washington, DC 20549; Applicant, Nova Funds Group, 260 Franklin Street, Boston, Massachusetts 02110.


SUPPLEMENTARY INFORMATION:
Following is a summary of the application; the complete application is available for a fee from either the SEC’s Public Reference Branch in person or the SEC’s commercial copier (800) 231-3282 (in Maryland (301) 287-4500).

Applicant’s Representations
1. Applicant is a business trust organized under the laws of the Commonwealth of Massachusetts. Applicant is registered under the Act as an open-end, diversified management investment company. On February 28, 1990, Applicant filed a Notification of Registration pursuant to section 8(a) of the 1940 Act on Form N-8A. On the same date, Applicant filed a registration statement under the Securities Act of 1933 on Form N-1 which was declared effective on May 27, 1990, and the initial public offering commenced immediately thereafter.

2. At a Special Meeting on November 18, 1988, Applicant’s Board of Trustees (“Trustees”) unanimously authorized the Merger of Applicant into National Telecommunications and Technology Fund, Inc. (“Teletech”) (811-3392), a registered open-end diversified investment company. Applicant filed a Proxy Statement on Form N-14 with the SEC on December 16, 1986. On February 17, 1989, Applicant’s shareholders approved the Merger by a 88% vote. In connection with such shareholder vote, the Applicant distributed proxies to shareholders on January 14, 1989.

3. The Trustees recommended the Merger after considering the following factors: (a) The performance of the Applicant in comparison to other comparable funds; (b) the decreasing assets of the Applicant; (c) the inability to obtain a large distributor of mutual funds to distribute the Applicant’s shares; and (d) the cost of operating a small mutual fund and the attendant risks associated therewith.

4. As of Monday, February 17, 1989 (“Valuation Date”), the Applicant had outstanding 555,623.110 shares of beneficial interest of Nova Fund, the net asset value of those shares combined was $7,274,567.94 and $13.09 per share. On Tuesday, February 21, 1989 (February 20 was a legal holiday), all of the portfolio securities of Applicant were transferred to Teletech in connection with the sale of assets. The Applicant merged into Teletech, in a share for share exchange whereby each Shareholder of the Applicant received a number of shares of Teletech stock equal to the number of shares of Applicant owned on the Valuation Date. No brokerage commissions or fees were paid.

5. Approximately $90,000 was allocated for the cost of the Merger of Applicant into Teletech of which the Applicant will be responsible for approximately $50,000. The Applicant retained $65,576 in cash for the purpose of liquidating the remaining liabilities of the Applicant. Applicant to date has paid out $56,252. This cash will not be invested in any securities. If the Applicant’s liabilities exceed this amount, Nova Advisors, Inc. (the Fund’s investment adviser) has undertaken to assume those liabilities. If instead there are funds remaining (which Applicant does not expect), either shares of Teletech will be purchased and distributed pro rata to former shareholders of the Fund or a cash dividend will be paid to those shareholders.

6. On February 21, 1989, Applicant filed a Termination of Declaration of Trust of Nova Funds Group with the Commonwealth of Massachusetts, which become effective on that date. Applicant has no shareholders, assets or liabilities. 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 to wind up its affairs.

7. Applicant is current on its required filings, including its N-SAR filing and will make all final filings required by the Act. For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 89-12778 Filed 5-26-89; 8:45 am]
BILLING CODE 8010-01-M

[Ref. No. IC—16965; 812-7245]

Oppenheimer Fund Management, Inc., et al.; Notice of Application

May 19, 1989.

AGENCY: Securities and Exchange Commission (“SEC”).
ACTION: Notice of application for approval of offers of exchange under the Investment Company Act of 1940 ("1940 Act").


Addressee: Secretary, SEC, 450 5th Street, Washington, DC 20549.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 89-12779 Filed 5-26-89; 8:45 am]
BILLING CODE 8010-01-M

The PNCG Money Market Fund, Inc., et al.; Application

May 19, 1989.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for approval under the Investment Company Act of 1940 ("1940 Act").


Relevant 1940 Act Section: Order requested under Section 11(a) of the 1940 Act.

Summary of Application: Applicants request an order approving offers of exchange, involving shares of registered open-end management investment companies, on a basis other than relative net asset value.

Filing Date: The application was filed on February 14, 1989 and was amended on April 11, 1989 and May 19, 1989.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing on the application, or ask to be notified if a hearing is ordered. Any request should be submitted in writing and should be received by the SEC by 5:30 p.m. on June 13, 1989. A request for a hearing should state the nature of the requestor's interest, the reason for the request, and the issues contested. Any person requesting a hearing should serve Applicants with a copy of the request, either personally or by mail.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 89-12779 Filed 5-26-89; 8:45 am]
BILLING CODE 8010-01-M

The PNCG Money Market Fund, Inc., et al; Application

May 19, 1989.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for approval under the Investment Company Act of 1940 ("1940 Act").


Relevant 1940 Act Section: Order requested under Section 11(a) of the 1940 Act.

Summary of Application: Applicants request an order approving offers of exchange, involving shares of registered open-end management investment companies, on a basis other than relative net asset value.

Filing Date: The application was filed on February 14, 1989 and was amended on April 11, 1989 and May 19, 1989.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing on the application, or ask to be notified if a hearing is ordered. Any request should be submitted in writing and should be received by the SEC by 5:30 p.m. on June 13, 1989. A request for a hearing should state the nature of the requestor's interest, the reason for the request, and the issues contested. Any person requesting a hearing should serve Applicants with a copy of the request, either personally or by mail.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 89-12779 Filed 5-26-89; 8:45 am]
BILLING CODE 8010-01-M

The PNCG Money Market Fund, Inc., et al; Application

May 19, 1989.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for approval under the Investment Company Act of 1940 ("1940 Act").


Relevant 1940 Act Section: Order requested under Section 11(a) of the 1940 Act.

Summary of Application: Applicants request an order approving offers of exchange, involving shares of registered open-end management investment companies, on a basis other than relative net asset value.

Filing Date: The application was filed on February 14, 1989 and was amended on April 11, 1989 and May 19, 1989.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing on the application, or ask to be notified if a hearing is ordered. Any request should be submitted in writing and should be received by the SEC by 5:30 p.m. on June 13, 1989. A request for a hearing should state the nature of the requestor's interest, the reason for the request, and the issues contested. Any person requesting a hearing should serve Applicants with a copy of the request, either personally or by mail.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 89-12779 Filed 5-26-89; 8:45 am]
BILLING CODE 8010-01-M
Applicant's Condition

1. Each Fund is registered under the 1940 Act as an open-end management investment company, and together they constitute a "group of investment companies" as that term is defined in the 1940 Act as an open-end management investment company and together they constitute a "group of investment companies" as that term is defined in the 1940 Act, Investment Company Act of 1940 (the "1940 Act").

2. Applicants will obtain an amended order granted their request, subject to compliance with all of the representations and conditions in the application.

3. Applicants request that any order granted to exchange offers in a manner inconsistent with the provisions of revised proposed Rule 11a-3, as it is currently proposed, and as it may be reproposed, adopted or amended. Applicants submit that granting their request is appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

4. Applicants seek an order to permit the exchange offers to continue and as it may be reproposed, adopted or amended.

SUMMARY OF APPLICATION: Applicants seek an order approving certain offers of exchange under the Investment Company Act of 1940 (the "1940 Act").

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for approval of offers of exchange under the Investment Company Act of 1940 (the "1940 Act").

Applicants: Quest For Value Family of Funds et al.; Application

May 19, 1989.

Summary of Application: Applicants seek an order approving certain offers of exchange among Funds and Additional Funds on a basis other than relative net asset value.

Filing Dates: The application was filed on November 21, 1988, and amended on March 13 and May 19, 1989.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing the SEC's Secretary, 450 5th Street NW., Washington, DC 20549. Applicants, c/o John W. Belash, Esq., Gordon Hurwitz Butowsky Weitzen, Shalov & Wein, 101 Park Avenue, New York, New York 10178.

FOR FURTHER INFORMATION CONTACT:
Jeremy N. Rubenstein, Staff Attorney, at (202) 272-2847, or Stephanie M. Monaco, Staff Attorney Regina Hamilton (202) 272-3024, or Branch Chief Karen L. Skidmore (202) 272-3023 (Office of Investment Company Regulation).

FOR FURTHER INFORMATION CONTACT:
Staff Attorney Regina Hamilton (202) 272-2847, or Branch Chief Karen L. Skidmore (202) 272-3024 (Office of Investment Company Regulation).

Additional Funds will comply with the provisions of the revised proposed Rule 11a-3, Investment Company Act Release No. 16504 (July 20, 1988), 53 FR 30299 (Aug. 11, 1988), as currently proposed and as further revised and/or adopted.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,
Secretary.

[F] [0x-0 to 583x802]

THE THORNTON GROUP, INC.; APPLICATION FOR Deregistration

May 19, 1989.

AGENCY: Securities and Exchange Commission (“SEC”).

ACTION: Notice of application for deregistration under the Investment Company Act of 1940 (the “1940 Act”).

Applicant: The Thornton Group, Inc. (“Applicant”).

Relevant 1940 Act Section: Section 8(f).

Summary of Application: Applicant seeks an order declaring that it has ceased to be an investment company under the 1940 Act.

Filing Dates: The application on Form N-8F was filed on April 8, 1989.

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 Applicants with a copy of the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC’s Secretary.

FOR FURTHER INFORMATION CONTACT:
For further information contact: Staff Attorney Bibb L. Strench (202) 272-2856 or Branch Chief Karen L. Skidmore (202) 272-3023 (Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee. One may obtain a copy by going to the SEC’s Public Reference Branch or by telephoning the SEC’s commercial copier (800) 231-3282 (in Maryland (301) 258-3290).

Applicants: U.S.T. Master Funds, Inc., et al.; Application

May 19, 1989.

AGENCY: Securities and Exchange Commission (“SEC”).

ACTION: Notice of Application for approval of offers of exchange under the Investment Company Act of 1940 (“1940 Act”).


Relevant 1940 Act Sections: Order requested under Section 11(a) of the 1940 Act.

Summary of Application: Applicants seek an order approving certain offers of exchange, involving securities or registered open-end investment companies, on a basis other than relative net asset value.

The application was filed on February 21, 1989, and amended on May 19, 1989.

Hearing or Notification of Hearing:
An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the SEC’s Secretary and serving Applicants with a copy of the request, personally or by mail.

Hearing requests should be received by the SEC by 5:30 p.m. on June 12, 1989, and should state the nature of the requestor's interest, the reason for the request, and the issues contested.

Hearing requests also should be accompanied by proof of service on the Applicants on the form of affidavits or, for lawyers, certificates of service. Requests for notification of a hearing may be made by writing to the SEC’s Secretary.

ADDRESSES: SEC, 450 5th Street, Washington, DC 20549. Applicants, 126 High Street, Boston, MA 02110.


SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee. One may obtain a copy by going to the SEC’s Public Reference Branch or by telephoning the SEC’s commercial copier (800) 231-3282 (in Maryland (301) 258-3290).

Applicants' Representations

1. Applicants consists of two open-end management investment companies registered under the 1940 Act and their distributor, U.S.T. Master Funds, Inc. currently consists of the Money Fund and the Government Money Fund, both no-load portfolios, and the Equity Fund, the Income and Growth Fund, the Managed Income Fund, and the International Fund, all load portfolios. U.S.T. Master Tax-Exempt Funds, Inc. currently consists of the Short-Term Fund, a no-load portfolio, and the Intermediate-Term Fund and the Long-Term Fund, both load portfolios.

Exemption is sought on behalf of the Distributor and each present and future portfolio of U.S.T. Master Funds, Inc. and U.S.T. Master Tax-Exempt Funds, Inc. distributed by the Distributor (such present and future no-load and load portfolios collectively referred to as the "Portfolios").

2. Shares of the no-load Portfolios are sold at net asset value without a sales charge. Shares of the load Portfolios are offered at net asset value plus a front-
end sales load. None of the Portfolios currently charge a contingent deferred sales load or a redemption fee.

3. The Applicants seek an order to allow the exchange of shares of a Portfolio, whether load or no-load, for shares of a load Portfolio on a basis other than their relative net asset values per share at the time of the exchange.

Applicants' Condition

The Applicants agree to the following condition:

The Applicants will comply with the provisions of proposed rule 11a-3, Investment Company Act Release No. 16594 [July 20, 1988], 53 FR 30299 [August 11, 1988] as currently proposed and as further revised and/or adopted.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz
Secretary.

[FR Doc. 89-12783 Filed 5-26-89; 8:45 am]
BILLING CODE 8010-01-M

II. Self-Regulatory Organization's Statement Regarding the Proposed Rule Change

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The CSE, through [NSTS], guarantees the execution of public agency market orders up to 2,000 shares at the national best bid or offer. Because NSTS is a multiple market maker system, the obligation to guarantee agency orders rotates daily among Designated Dealers ("DDs") in issues for which there is more than one such dealer.

In order to improve the quality of its markets and to achieve broader coverage of issues in NSTS, the Exchange determined that it was necessary to provide an incentive for prospective market makers to become DDs in issues not yet traded in NSTS. Therefore, the Exchange adopted a policy which permits its Securities Committee to authorize a requesting member to become the "primary" DD in any issue which was not traded in NSTS as of September 9, 1988. Primary DD status in an issue entitles a member to receive all of the guaranteed portion of all public agency market orders and marketable limit orders even if other DDs subsequently become registered in that issue. The guaranteed portion of an order is equal to 2,000 shares minus the number of shares executed in NSTS against any agency or principal interest, including interest of the DD of the day, priced at the ITS best bid or offer when the order enters the system.

Before he/she can be registered as a primary DD, a member must agree to maintain "competitive" quotations throughout the trading day. Competitive is defined by compliance with the following spread and size parameters:

<table>
<thead>
<tr>
<th>Spread and Size Parameters</th>
<th>Point and Percent Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>$80-$500</td>
<td>No more than 1/2 point</td>
</tr>
<tr>
<td>$50-$100</td>
<td>No more than 3/4 point</td>
</tr>
<tr>
<td>$100-$200</td>
<td>No more than 1 point</td>
</tr>
<tr>
<td>Greater than $200</td>
<td>No more than 2 point</td>
</tr>
</tbody>
</table>

"Active" stocks (defined as stocks which trade more than 5 million shares per month on a consolidated basis).

"Inactive" stocks (defined as stocks which have less than 5 million shares per month on a consolidated basis).

Exceptions to the above spread and size parameters will be permitted only during unusual market conditions or as otherwise allowed by an Exchange official.

The purpose of the proposed rule change is to implement the above-described modification to the Exchange's stock allocation and order execution procedures.

The proposed rule change is consistent with section 6(b)(5) of the Act in that it is designed to facilitate transactions in securities and to perfect the mechanism of a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition.

The Exchange believes that the proposed rule change will not impose any burden on competition which is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others.

The Exchange solicited comments on the proposed rule change from other Intermarket Trading System Participants and received comments from the Midwest Stock Exchange.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the Federal Register or within such longer period as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC, 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission and all written communications relating to the proposed rule change between the Commission and any persons, other than those that...
Self-Regulatory Organizations; Depository Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Fees

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on May 9, 1989, the Depository Trust Company ("DTC") filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

DTC is filing herewith the following changes in the fee schedule for DTC services:

<table>
<thead>
<tr>
<th>Service</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional Delivery (ID) System</td>
<td></td>
</tr>
<tr>
<td>For each On-Line and CCF Cumulative Eligible Trade Report 1</td>
<td>$0.07 per line to broker and clearing agent.</td>
</tr>
<tr>
<td>For each CCF T+3 and T+4 Unaffirmed Report</td>
<td>$0.07 per line to broker.</td>
</tr>
</tbody>
</table>

1 CCF, an acronym, refers to "computer to computer facility," a mechanism for high volume DTC participants. CCF permits participants to send instructions to DTC directly from participants' computers to DTC's computer.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change, which will be effective for services provided after April 30, 1989, is to recover DTC's costs for producing the subject ID reports which have been provided free-of-charge since they were first developed in the later part of 1988.

DTC has adopted the proposed rule change pursuant to section 17A(b)(6)(D) which requires clearing agency rules to provide for the equitable allocation of dues, fees, and other charges among its participants. DTC believes that the proposed rule change is consistent with the requirements of the Securities Exchange Act of 1934 and the rules and regulations thereunder applicable to participants. DTC believes that the fees will be allocated more equitably among DTC Participants.

(B) Self-Regulatory Organization's Statement on Burden on Competition

DTC does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Comments have not been solicited or received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3) of the Securities Exchange Act of 1934 and subparagraph (e) of Securities Exchange Act Rule 19b-4. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 450 Fifth Street NW., Washington, DC.

Copies of such filing will also be available for inspection and copying by any person, at the principal office of the CSE. All submissions should refer to File No. SR-DTC-89-10 and should be submitted by June 20, 1989.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,
Secretary.


[FR Doc. 89-12769 Filed 5-26-89; 8:45 am]
BILLING CODE 8010-01-M

Self-Regulatory Organizations; Options Clearing Corporation; Order Approving Proposed Rule Change

On March 1, 1989, the Options Clearing Corporation ("OCC") filed a proposed rule change (SR-OCC-89-03) under section 19(b) of the Securities Exchange Act of 1934 ("Act"). The proposal increases initial and minimum net capital requirements imposed by OCC on its members. To reflect these increases, the proposal also amends OCC's early warning notice requirement and expands OCC's authority to restrict member activities, transactions, and expands OCC's authority to restrict member activities, transactions,

positions, and distributions. The Commission published notice of the proposal in the Federal Register on March 22, 1989. No public comments were received. For the reasons discussed below, the Commission is approving the proposal.

I. Description of the Proposal

As noted above, the proposal increases OCC's initial and minimum net capital requirements. Currently, to become an OCC member, an applicant must have initial net capital equal to at least $150,000. That level must be maintained by the applicant for the lesser of three months after its admission as a clearing member or twelve months after it commenced doing business as a broker-dealer. After which, the member must maintain minimum net capital equal to at least $100,000. Under the proposal, a member's initial net capital requirement would be increased to $1 million, and its minimum net capital requirement would be increased to $750,000. OCC represents that nine of its approximately 170 clearing members have net capital less than $1 million. Of those, seven have net capital below $750,000. Under the proposal, members having net capital below $750,000 would have 12 months from the date of this Order to bring their net capital level to at least $750,000.

The proposal also increases minimum net capital requirements for OCC's managing clearing members. Currently, managing clearing members must maintain net capital equal to the greater of (1) the minimum net capital requirement applicable to other clearing members or (2) the sum of (A) $300,000 plus (B) $50,000 times the number of managed clearing members in excess of four. Under the proposal, managing clearing members would be required to maintain net capital equal to the greater of (1) the proposed minimum net capital requirement applicable to other clearing members or (2) the sum of (A) $2 million plus (B) $100,000 times the number of managed clearing members in excess of four. OCC represents that all seven of its managing clearing members maintain net capital meeting or exceeding these increased levels.

OCC's early warning notice provision would be amended to reflect increased net capital requirements. Currently, a member must notify OCC prior to 3:00 p.m. (Central Time) the following business day if its net capital falls below $150,000. Under the proposal, a member would be required to give notice if its net capital falls below $1 million.

The proposal would revise OCC's authority to restrict member activities, transactions, positions, and distributions to reflect increased net capital requirements. Currently, OCC can restrict a member's facilities management activities, transactions, and positions if that member's net capital falls below $150,000. OCC also may exercise such authority if a member's net capital falls below 11 percent of the sum of (i) the equity required by Rule 15c3-l(c)(2)(A)(i) and (ii) the equity required by Rule 15c3-l(a)(6)(iii), or 11 percent of the sum of the deductions required by Rule 15c3-l(a)(6)(ii). The proposal is designed to achieve that goal without inhibiting broad market participant access to OCC services.

II. OCC's Rationale for the Proposed Rule Change

OCC believes the proposal is consistent with the purposes and requirements of section 17A of the Act. OCC notes that its current net capital requirements do not reflect dramatic increases in the size, complexity, and volatility of the options markets, or the effects of inflation. OCC believes the proposal reflects those developments and enhances the creditworthiness of its members without inhibiting broad market participant access to OCC services.

III. Discussion

The Commission believes the proposal is consistent with Section 17A of the Act and therefore is approving the proposal. Specifically, the Commission believes the proposal is designed to implement post-October 1987 market break suggestions that clearing agencies update their capital requirements to reflect current market conditions, particularly increased market volatility. The proposal is designed to achieve that goal without inhibiting broad market participant access to OCC services.

In its market break report, the Commission's Division of Market Regulation ("Division") encouraged clearing agencies to consider increasing member net capital requirements. Specifically, the Division noted:

18 See OCC Rule 306 Interpretations and Policies. OCC also may exercise such authority if a member's net capital falls below 11 percent of the sum of (i) the deductions from such clearing member's net worth required by Rule 15c3-l(c)(2)(A)(i) and (ii) the equity required by Rule 15c3-l(a)(6)(ii), or 11 percent of the sum of the deductions required by Rule 15c3-l(a)(6)(ii).
The Division believes re-examination and possible strengthening of clearing agency rules establishing member net capital requirement would serve as a further layer of protection against members default.

The Interim Report of the Working Group on Financial Markets ("Working Group Report") made a similar recommendation. The Working Group Report noted clearing agency progress in evaluating the adequacy of broker-dealer capital and specifically cited OCC plans to increase member net capital requirements. The Working Group also noted the Commission, clearing agencies, and other self-regulatory organizations to continue evaluating the adequacy of broker-dealer capital and finding ways to improve existing practices and requirements.

Post market break studies also suggest that clearing agencies analyze negative aspects of increased member net capital requirements. For example, the Division cautions:

Although increased capital requirements for clearing members could strengthen clearing member financial positions and decrease default risk, especially during periods of high market volatility, such requirements also would have other effects. Increased clearing agency requirements could decrease the number of broker-dealers eligible for clearing agency membership and increase costs for broker-dealers that cannot maintain membership.

The Division believes clearing agencies, in adopting increased net capital requirements, should strike a prudent balance between their need to ensure member creditworthiness and their responsibility to provide broad market participant access to clearing services.

The Commission believes the proposal, consistent with post market break recommendations, is designed to update OCC net capital requirements to reflect current market conditions. OCC net capital requirements are designed to ensure that members initially and throughout their membership have sufficient liquid assets to meet their obligations to OCC. OCC has never increased these requirements despite inflation and increased market volume, complexity, and volatility. The Commission believes proposed initial and minimum net capital requirement increases are designed to reflect market developments and ensure member creditworthiness in the current market environment. The Commission further believes proposed increases in net capital levels triggers OCC's early warning notice requirement and OCC's authority to impose restrictions on members are commensurate with proposed initial and minimum net capital requirement increases and thereby are designed to reflect current market conditions and facilitate effective risk management.

The Commission also believes the proposal would not inhibit broad market participant access to OCC services. Few OCC members have net capital below proposed levels. Given the small number of OCC members currently affected by the proposed increases and the amount of time provided to meet increased levels, the Commission believes the proposal does not limit current member access to OCC services.

OCC represents that from 1973 to 1987, inflation has reduced the value $150,000 of OCC's current initial net capital requirement to the point that $420,000 in current dollars equals $150,000 in 1973 dollars. See Backup Study, supra note 3, at 21.

OCC believes members would achieve the proposed minimum net capital level via capital infusions from affiliates or reorganization. See Securities Exchange Act Release No. 25677 (March 16, 1989), 54 FR 11853. The Commission notes that OCC believes proposed increases in net capital requirements to reflect current market conditions. OCC represents as necessary to avoid "serious disruptions" to the affairs of those members. Given the small number of OCC members currently affected by the proposed increases and the amount of time provided to meet increased levels, the Commission believes the proposal does not limit current member access to OCC services.

Statistics reveal that most potential OCC applicants also would not be prohibited access by the increased net capital levels.

IV Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the Act and, in particular, with section 17A. The Commission believes the proposal is designed to implement post-October 1987 market break suggestions that clearing agencies update their net capital requirements to reflect current market conditions. The Commission also believes the proposal is designed to achieve that goal without inhibiting broad market participant access to OCC services.

It is therefore ordered, pursuant to Section 19(b) of the Act, that the proposed rule change (SR-OCC-88-03) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority. 17 CFR 200.30-3.

Jonathan G. Katz.

Secretary.

[FR Doc. 89-12770 Filed 5-26-89; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-26861; File No. SR-PHLX-89-18]

Self-Regulatory Organizations; Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Relating to Authorization of Foreign Currency Options Participants To Be Elected to the Exchange's Board Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"). 15 U.S.C. 78q(b)(1), notice is hereby given that on March 31, 1989, the Philadelphia Stock Exchange, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Philadelphia Stock Exchange, Inc., pursuant to Rule 19b-4, hereby proposes to amend sections 3-6, 3-7, and 4-1 of its By-Laws to permit a foreign currency options participant to...
be nominated for election and, if elected, to serve as a member of the Phlx Board of Governors.

The text of the proposed rule change is available for inspection and copying at the Commission’s Public Reference Section, 450 Fifth Street NW., Washington, DC and at the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the public reference room of the Commission, 450 Fifth Street NW., Washington, DC. The self-regulatory organization has prepared summaries, set forth in these statements, which may be examined at the public reference room of the Commission.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the rule change is to permit a foreign currency options program to the Phlx. It should be noted that at present fourteen of twenty-six Governors shall be members or participants associated with member or participant organizations which conduct such public customer business to include participant organizations which conduct such public customer business. The proposed By-law amendments are designed to provide an opportunity for representation on the Phlx Board of Governors of a person associated solely with a foreign currency options participant organization. The proposed amended By-Laws are consistent with section 6(b)(3) of the Act in that they will provide an opportunity for a balanced representation of all constituencies of the Exchange’s diverse membership and participants.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Phlx does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization’s Statements on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 90 days of the date of publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organizations consents, the Commission will:

(A) By order approve such proposed rule change, or,

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

If the purpose of the rule change is to permit a foreign currency options program to the Phlx, it should be noted that at present fourteen of twenty-six Governors shall be members or participants associated with member or participant organizations which conduct such public customer business to include participant organizations which conduct such public customer business.

Floor or general partners, executive officers or members or participants associated with member or participant organizations primarily engaged in business on the Exchange floor. Similarly, the Exchange proposes to amend the provisions of this Section that require that at least 9 of the 26 Governors shall be general partners, executive officers or members associated with member organizations which conduct a non-member public customer business to include participant organizations which conduct such public customer business.

Section 4—6(f) requires a governor to resign if the minimum number of governors required in the categories of on-floor or off-floor governor is not maintained because of a governor’s change in participant organization association.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission’s Public Reference Section, 450 Fifth Street NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by June 20, 1989.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,
Secretary.


[FR Doc. 89-12771 Filed 5-28-89; 8:45 am]
BILLING CODE 8010-01-M

[Release No. 34-26858; File No. SR-PHLX-89-36]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Order Approving Proposed Rule Change Relating to the Creation of an Emergency Committee

On November 10, 1988, the Philadelphia Stock Exchange, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b) of the Securities Exchange Act of 1934 ("Act") and Rule 19b-4 thereunder, a proposed rule change to adopt new Rule 98 establishing an Emergency Committee ("Committee") to determine the existence of, and make decisions during, extraordinary market conditions or other emergencies. The Phlx has represented to the Commission that "extraordinary market or emergency conditions" include, among other conditions, a...
proposed rule authorizes the Committee to take any action, in the event of such an emergency, regarding: (1) the operation of PACE, AUTOM, CENTRAL, or any other Exchange quotation, transaction reporting, execution, order routing or other system or facility; (2) operation of, and trading on, any Exchange floor; (3) trading in any securities traded on the Exchange; and (4) the operation of members' or member organizations' offices or systems. If the Committee determines that an emergency exists and takes action, a report on the matter will be submitted to the Commission and to the Phlx Board of Governors.

The proposed rule change was noticed in Securities Exchange Act Release No. 26672 (March 28, 1989), 54 FR 13737 (April 5, 1989). No comments were received on this proposal.

The Exchange stated that the purpose of proposed rule change is to establish a regular procedure for Phlx to take the necessary and appropriate action to respond to extraordinary market conditions or other emergencies.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of section 6(b)(5) and the rules and regulations thereunder. The exchange's proposal, which provides the Phlx with the necessary flexibility to deal with extraordinary market conditions, is designed to foster cooperation and coordination with persons engaged in regulating transactions in securities and to protect investors and the public interest. More specifically, in the event that extraordinary market conditions necessitate the exercise of the Committee's emergency powers, the Exchange has represented to the Commission that it will coordinate any exercise of its emergency authority with all self-regulatory organizations that might be impacted by such actions. In addition, the Committee will prepare a report of the emergency condition and the Committee action taken and submit it promptly to the Phlx Board of Governors and the Commission. Furthermore, the Exchange has committed to consulting with the Commission or its staff prior to taking any such action, and will promptly file notice of any consummated actions with the Commission pursuant to section 19(b)(3)(A) of the Exchange Act. These requirements should assure that the Committee will give careful consideration to all appropriate factors before using its authority granted under proposed new Rule 98.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change is approved.

For the Commission, by the Division of the Market Regulation, pursuant to delegated authority. 10

Jonathan G. Katz,
Secretary.

DEPARTMENT OF TRANSPORTATION

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ended May 19, 1989

The following applications for certificates of public convenience and necessity and foreign air carrier permits were filed under Subpart Q of the

Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 et seq.). The due date for answers, conforming application, or motion to modify scope is set forth for each application. Following the answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket No. 46300
Date Filed: May 18, 1989
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: June 15, 1989
Description: Application of Northwest Airlines, Inc. pursuant to Section 401 of the Act and Subpart Q of the Rules of Practice applies for an amendment of its certificate of public convenience and necessity for Route 179 or a new certificate authorizing it to provide non-stop service between the United States and Italy.

Docket No. 46301
Date Filed: May 18, 1989
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: June 1, 1989
Description: Application of American Airlines, Inc. pursuant to Section 401 of the Act and Subpart Q of the Rules of Practice applies for a certificate of public convenience and necessity authorizing service between Chicago, Illinois, and Tokyo, Japan.

Docket No. 46303
Date Filed: May 18, 1989
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: June 15, 1989
Description: Joint Application of American Airlines, Inc. and Continental Airlines, Inc. pursuant to Section 401 of the Act and Subpart Q of the Rules of Practice applies for the transfer to American's certificate of public convenience and necessity for Route 470 (Houston/Dallas/Ft. Worth, Texas-Calgary/Edmonton, Alberta, Canada-Anchorage/Fairbanks, Alaska).

Docket No. 46306
Date Filed: May 19, 1989
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: June 16, 1989
Description: Application of Tempus Air

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Federal Highway Administration

Environmental Impact Statement; Berks County, Pennsylvania

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement will be prepared for a proposed highway project in Berks County, Pennsylvania.

FOR FURTHER INFORMATION CONTACT: Mr. Philibert A. Ouellet, District Engineer, Federal Highway Administration, 228 Walnut Street, P.O. Box 1086, Harrisburg, Pennsylvania 17105; Telephone: (717) 782-3461

or

Mr. Jack Porter, Project Manager, Pennsylvania Department of Transportation, District 5-0, 1713 Lehigh Street, Allentown, Pennsylvania 18105; Telephone: (717) 821-4100.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Pennsylvania Department of Transportation (PennDOT) and Berks County, will prepare an Environmental Impact Statement (EIS) on a proposal to extend Park Road (SR 3019) from its current terminus at the Warren Street Bypass (US 422) in Wyomissing Borough, one-half mile west of Reading, one and one-half miles in a northwesterly direction to the current (southwestern) terminus of the Outer Bypass (SR 3055) in Spring Township.

The proposed study for the 1.5 mile project includes an engineering and environmental evaluation of a limited access and controlled access facility design, as well as various interchange configurations at the project termini. The project will complete a missing link in the regional transportation system and will provide needed access to a rapidly developing area of Berks County.

Initially four corridor alternatives will be evaluated in addition to the No-Build Alternative in a preliminary alternatives analysis. Other corridors, if any, that are recommended by the review agencies will also be studied. The most feasible alternative(s) will then be evaluated for being carried into the EIS Study phase.

These alternatives will be studied in detail, and their impacts to the environment will be assessed as they relate to the areas of air quality, noise, historical and archaeological resources, traffic/transportation/energy, water resources, socioeconomic, land use, terrestrial ecology, water quality and aquatic biota, farmlands evaluation, floodplain and flood hazard, wetlands, visual resources, soils and erosion analysis, municipal, industrial and hazardous waste facilities, and construction impacts. In addition, the EIS will contain a cost analysis of the various alternatives, preliminary engineering information and documentation of the public and agency consultation and coordination process.

Letters describing the proposed action and the Scope of Studies soliciting comments will be sent to appropriate Federal, State and local agencies, and to private organizations and citizens who express interest in the proposal. Scoping meetings are planned with the agencies during the spring of 1989 and public meetings will be held in the project area during the spring and summer of 1989. Public notices of the date, time and place of these meetings, and also of any required public hearings, will be provided in the local newspapers. Public involvement and interagency coordination will be maintained throughout the development of the EIS.

To ensure that the full range of issues related to this proposed action are addressed and that all significant issues are identified, comments or questions concerning this action and the EIS should be directed to the FHWA or PennDOT at the address provided above.

(Catalog of Federal Domestic Assistance Program No. 20.208, Highway Research, Planning and Construction and the provisions of Executive Order 12372. Intergovernmental Review of Federal Programs, regarding State and Local Review of Federal and Federally Assisted Programs and Projects to this Program)

Issued on May 9, 1989

George L. Hannon,
Assistant Division Administrator, Federal Highway Administration.
sidewall. We believe the likelihood of incorrect inflation to be insignificant. Should a person refer to the tire label, or owners manual, which references the tire label, for inflation pressures, it is remotely possible the person might inflate the normal tire to 40 PSI.

However, if the normal tire is inflated to 40 PSI, the load rating for the tire would not be exceeded.

Interested persons are invited to submit written data, views and arguments on the petition of Volvo Cars of North America described above. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5109, 400 Seventh Street SW., Washington, DC 20590. It is requested but not required that five copies be submitted.

All comments received before the close of business on the closing date indicated below will be considered. The application and supporting materials, and all comments received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, the Notice will be published in the Federal Register pursuant to the authority indicated below.

May 24, 1999.

Barry Felrice,
Associate Administrator, for Rulemaking.
[FR Doc. 89-12726 Filed 5-28-89; 8:45 am]
BILLING CODE 4910-59-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Date: May 16, 1989.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed.

Internal Revenue Service

OMB Number: 1545-0115.

Form Number: 1099-MISC.

Type of Review: Extension.

Title: Statement for Recipients of Miscellaneous Income.

Description: Form 1099-MISC is used by payers to report payments of $600 or more of rents, prizes and awards, fishing boat proceeds, medical and health care payments, nonemployee compensation, and crop insurance proceeds, $10 or more of royalties, any amount of certain substitute payments, golden parachute payments, and an indication of direct sales of $5,000 or more.

Respondents: Individuals or households, State or local governments, Farms, Businesses or other for-profit, Federal agencies or employees, Non-profit institutions, Small businesses or organizations.

Estimated Number of Respondents: 3,677,937.

Estimated Burden Hours Per Response: 13 minutes.

Frequency of Response: Annually.

Estimated Total Reporting Burden: 10,511,570 hours.

Clearance Officer: Garrick Shear (202) 535-4297, Internal Revenue Service, Room 5571, 1111 Constitution Avenue NW, Washington, DC 20224.

OMB Reviewer: Milo Sunderhauf (202) 395-6800, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,
Departmental Reports Management Officer.
[FR Doc. 89-12727 Filed 5-29-89; 8:45 am]
BILLING CODE 4810-25-M

Public Information Collection Requirements Submitted to OMB for Review.

Date: May 23, 1989.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub.L. 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2224, 1500 Pennsylvania Avenue NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545-0991.

Form Number: 1099.

Type of Review: Revision.


Description: Form 8633 will be filled in by tax preparers and submitted to IRS as an application to file individual income tax returns electronically; and by software firms, service bureaus, electronic transmitters, to develop auxiliary services.

Respondents: Businesses or other for-profit.

Estimated Number of Respondents: 20,000.

Estimated Burden Hours Per Response: 30 minutes.

Frequency of Response: Annually.

Estimated Total Reporting Burden: 10,000 hours.

Clearance Officer: Garrick Shear (202) 535-4297, Internal Revenue Service, Room 5571, 1111 Constitution Avenue NW, Washington, DC 20224.

OMB Reviewer: Milo Sunderhauf (202) 395-6800, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,
Departmental Reports Management Officer.
[FR Doc. 89-12728 Filed 5-29-89; 8:45 am]
BILLING CODE 4810-25-M

Establishment of the Office of Assistant Commissioner (Taxpayer Services)

Date: May 8, 1989.

By the authority vested in me as Secretary of the Treasury by 31 U.S.C. § 321(b); section 7801(a), 7802 and 7803 of the Internal Revenue Code of 1986; and Reorganization Plan No. 1 of 1952, pursuant to section 7804(a) of the Internal Revenue Code, all those offices in the National Office of the Internal Revenue Service which are designated in Treasury Order 150-02, dated July 2, 1987, continue uninterrupted except as follows: The position of Assistant Commissioner (Taxpayer Services) is hereby established. This position shall be under the Deputy Commissioner (Operations). The Assistant Commissioner (Taxpayer Services) shall be responsible for taxpayer service functions such as telephone, walk-in, and taxpayer educational services, and the design and production of tax and informational forms.

Nicholas F. Brady,
Secretary of the Treasury.
[FR Doc. 89-12670 Filed 5-29-89; 8:45 am]
BILLING CODE 4810-25-M

Office of Inspector General

Date: May 16, 1989.

By virtue of my authority as Secretary of the Treasury, including the authority
1. The Office of Inspector General (OIG)

a. There is within the Department of the Treasury an Office of Inspector General (OIG). The OIG shall be headed by an Inspector General (IG) who is appointed by the President and who shall report to and be under the general supervision of the Secretary and the Deputy Secretary. The IG shall provide policy direction for and shall conduct, supervise, and coordinate audits and investigations relating to the programs and operations of the Department.

b. The Office of Inspector General shall include the former administratively established Office of the Inspector General and all internal audit functions of the following offices:

(1) Office of Internal Affairs, Bureau of Alcohol, Tobacco and Firearms;
(2) Office of Internal Affairs, United States Customs Service; and
(3) Office of Inspection, United States Secret Service.

c. (1) The Office of Inspector General shall be placed organizationally within the Departmental Offices, but shall be independent of the Departmental Offices and all other offices and bureaus within the Department. Each fiscal year, the Inspector General shall submit to the Secretary a request for a separate appropriation account as contemplated by 31 U.S.C. 1105(a)(25). The staffing and funding level transmitted to OMB for the Inspector General shall subject to final determination by the Secretary or the Deputy Secretary.

(2) The Office of Inspector General shall be provided by the Department, and/or the bureaus, with adequate and appropriate office space at central and field office locations together with such equipment, office supplies, communications facilities and services necessary for the effective operation of such offices, and shall be provided with necessary maintenance services for such offices, equipment, and facilities located therein. For Fiscal Year 1991 and thereafter, the Office of Inspector General shall reimburse the providing entity for the costs of providing such space, equipment, supplies, communications facilities and services, and maintenance thereof. In addition, this paragraph is not to be construed to affect the extent of the Inspector General’s obligation to reimburse providing entities for the costs of providing space, equipment, supplies, communications facilities and services, and maintenance thereof in Fiscal Year 1989 or 1990.

d. All employees and officials of the Department of the Treasury shall report to the Inspector General any complaints or information concerning the possible existence of any activity constituting a violation of law, rules, or regulations, or mismanagement, gross waste of funds, abuse of authority, or a substantial and specific danger to the public health and safety relating to the Department, except that law enforcement bureau employees, i.e., employees of the Internal Revenue Service; United States Customs Service; Bureau of Alcohol, Tobacco and Firearms; and the United States Secret Service, shall report such matters either to the heads of the Internal Affairs or Inspection Offices of the bureau in which they work, or to the Inspector General.

e. (1) No officer or employee of the Department shall prevent the Inspector General from initiating, carrying out, or completing any audit or investigation, or from issuing any subpoena during the course of an audit or investigation, except that the Inspector General shall be under the authority, direction, and control of the Secretary and the Deputy Secretary of the Treasury with respect to matters set forth in section 8C(a) of the Inspector General Act, as amended.

(2) No officer or employee of the Department shall prevent or prohibit any duly appointed officer or employee of the Office of Inspector General from obtaining access to any information or documentation which the Inspector General has determined is necessary to the execution of an audit, investigation or other inquiry, except that the Inspector General shall be under the authority, direction, and control of the Secretary and the Deputy Secretary of the Treasury with respect to matters set forth in section 8C(a) of the Inspector General Act, as amended.

(3) Whenever information or assistance requested by the OIG is unreasonably refused or not provided, the Inspector General shall report the circumstances to the Secretary or Deputy Secretary without delay.

f. (1) The Inspector General shall have access to returns and return information, as defined in section 6103(b) of the Internal Revenue Code of 1986, only in accordance with the provisions of section 6103 of such Code and the Inspector General Act Amendments of 1988.

(2) Access by the Inspector General to returns and return information under section 6103(h)(1) of such Code shall be subject to the following additional requirements:

(a) In order to maintain internal controls over access to returns and return information, the Inspector General (or in the absence of the Inspector General, the Acting Inspector General, the Deputy Inspector General, the Assistant Inspector General for Audit, or the Assistant Inspector General for Investigations) shall provide the Assistant Commissioner (Inspection) of the Internal Revenue Service (IRS) written notice of the Inspector General’s intent to access returns and return information;

(b) If the Inspector General determines that the Assistant Commissioner (Inspection) of the IRS should not be made aware of a notice of access to returns and return information, such notice shall be provided to the Senior Deputy Commissioner of the IRS; and

(c) Such notice shall clearly indicate the specific returns or return information being accessed and shall contain a certification by the Inspector General (or in the absence of the Inspector General, the Acting Inspector General, the Deputy Inspector General, the Assistant Inspector General for Audit, or the Assistant Inspector General for Investigations) that the returns or return information being accessed are needed for a purpose described under section 6103(h)(1) of the Internal Revenue Code of 1986.

The notice shall also identify those employees of the Office of Inspector General who may receive such returns or return information.

2. Duties and Responsibilities of the Inspector General

a. In General. (1) The Inspector General shall recommend policies for and shall conduct, supervise, and coordinate audits and investigations relating to the programs and operations of the Department;

(2) The Inspector General shall recommend policies for and shall conduct, supervise, and coordinate other activities for the purpose of promoting economy and efficiency in the administration of, and for preventing and detecting fraud and abuse in, the Department’s programs and operations;

(3) The Inspector General shall recommend policies for and shall coordinate relationships between the Department and other Federal, State and local governmental agencies and nongovernmental entities with respect to:

(a) All matters relating to the promotion of economy and efficiency in the administration of, or the prevention and detection of fraud and abuse in, programs and operations administered or financed by the Department; and

(b) The identification, investigation, and prosecution of participants in such...
fraud and abuse. Provided, however, that the responsibilities and authorities of the Inspector General under this paragraph shall not be construed to impair or reduce the responsibilities of program managers to ensure that their programs are administered in an economic and efficient manner and that such programs are protected against waste, fraud and abuse. Similarly, this paragraph shall not be construed to prevent program managers from coordinating with other agencies in fulfilling their responsibilities for proper administration of their programs; (4) The Inspector General shall keep the Secretary and Deputy Secretary fully and currently informed concerning fraud and other serious problems, abuses, and deficiencies relating to the administration of programs and operations of the Department. The IG shall recommend corrective action concerning such problems, abuses, and deficiencies and shall report on the progress made in implementing such corrective action; (5) In the event that the Inspector General becomes aware of a particularly serious or flagrant problem, abuse, or deficiency, relating to the administration of programs and operations of the Department, the IG shall report immediately to the Secretary who shall transmit such report to the appropriate committees or subcommittees of Congress within seven calendar days, together with a report from the Secretary containing any comments he deems appropriate. (6) The Inspector General shall prepare semiannually, not later than April 30 and October 31 of each year, a report to the Secretary for transmission to Congress within thirty days after receipt, pursuant to section 5(a) of the Inspector General Act, as amended; summarizing the activities of the OIG and the Internal Affairs and Inspector Offices during the immediately preceding six-month period. (7) The Inspector General shall institute Departmentwide policies for resolving disagreements between the OIG and auditees related to findings and recommendations included in OIG audit reports. To the extent practicable and appropriate, such policies shall provide for resolving such disagreements prior to the issuance of the audit reports in final form; (8) The Inspector General shall review existing and proposed legislation and regulations relating to programs and operations of the Department and shall make recommendations in the semiannual reports to Congress concerning the impact of such legislation or regulations on the economy and efficiency in the administration of programs and operations administered or financed by the Department or the prevention and detection of fraud and abuse in such programs and operations; (9) The Inspector General may require by subpoena the production of information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence necessary for the performance of IG functions under the Inspector General Act, as amended, and under the Program Fraud Civil Remedies Act, except that the Inspector General shall be under the authority, direction, and control of the Secretary and the Deputy Secretary of the Treasury with respect to matters set forth in section 6(a) of the Inspector General Act, as amended; Such subpoenas, in the case of continuance or refusal to obey, shall be enforceable by order of any appropriate United States district court: Provided, the Inspector General shall use procedures other than subpoenas to obtain documents and information from Federal agencies when exercising authority under the IG Act, as amended; and (10) The Inspector General and the IG's designee(s) shall have the authority to administer to or take from any person an oath, affirmation, or affidavit, whenever necessary for the performance of IG functions.

b. For Audits. (1) The Inspector General shall routinely perform internal audits for all Treasury bureaus and offices, with the exception of the IRS. The Inspector General shall use procedures other than subpoenas to obtain documents and information from Federal agencies when exercising authority under the IG Act, as amended; and (2) The Inspector General and the IG's designee(s) shall have the authority to administer to or take from any person an oath, affirmation, or affidavit, whenever necessary for the performance of IG functions.

(3) The Inspector General shall provide the head of the law enforcement bureau, as the IG deems necessary or desirable; (4) The Inspector General may provide the head of the law enforcement bureau with written notice that the IG has initiated an investigation. If the IG issues such a notice, no other investigation shall be initiated into the matter and any other pending investigation into the matter within the Department shall cease; (5) The Inspector General shall require, receive, review, and analyze all reports informing the Secretary or Deputy Secretary of any significant problems, abuses, or deficiencies disclosed in any bureau or office investigation and the actions taken to correct them; (6) The Inspector General shall receive and monitor all requests submitted by IG's from other government departments and agencies for investigative services within the Department; (7) The Inspector General shall receive all matters referred to the Department of the Treasury by the Secretary and Deputy Secretary informed of any significant problems, abuses, or deficiencies disclosed in audits and the actions taken to correct them; and (8) The Inspector General may require by subpoena the production of information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence necessary for the performance of IG functions under the Inspector General Act, as amended, and under the Program Fraud Civil Remedies Act, except that the Inspector General shall be under the authority, direction, and control of the Secretary and the Deputy Secretary of the Treasury with respect to matters set forth in section 6(a) of the Inspector General Act, as amended; Such subpoenas, in the case of continuance or refusal to obey, shall be enforceable by order of any appropriate United States district court: Provided, the Inspector General shall use procedures other than subpoenas to obtain documents and information from Federal agencies when exercising authority under the IG Act, as amended; and (9) The Inspector General may require by subpoena the production of information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence necessary for the performance of IG functions under the Inspector General Act, as amended; Such subpoenas, in the case of continuance or refusal to obey, shall be enforceable by order of any appropriate United States district court: Provided, the Inspector General shall use procedures other than subpoenas to obtain documents and information from Federal agencies when exercising authority under the IG Act, as amended; and (10) The Inspector General and the IG’s designee(s) shall have the authority to administer to or take from any person an oath, affirmation, or affidavit, whenever necessary for the performance of IG functions.

For Investigations. (1) The Inspector General shall conduct investigations and shall prepare reports relating to the programs and operations of the Department, including those of the law enforcement bureaus, as the IG deems necessary or desirable; (2) The Inspector General may provide the head of the law enforcement bureau with written notice that the IG has initiated an investigation. If the IG issues such a notice, no other investigation shall be initiated into the matter and any other pending investigation into the matter within the Department shall cease; (3) The Inspector General shall routinely perform internal audits for all Treasury bureaus and offices, with the exception of the IRS. The Inspector General shall use procedures other than subpoenas to obtain documents and information from Federal agencies when exercising authority under the IG Act, as amended; and (4) The Inspector General shall require, receive, review, and analyze all reports informing the Secretary or Deputy Secretary of any significant problems, abuses, or deficiencies disclosed in any bureau or office investigation and the actions taken to correct them; (5) The Inspector General shall report the results of any significant investigation of any high official to the Secretary or the Deputy Secretary or other appropriate management official for action, and may so report the results of other investigations; (6) The Inspector General shall receive and monitor all requests submitted by IG’s from other government departments and agencies for investigative services within the Department; (7) The Inspector General shall receive all matters referred to the Department of the Treasury by the Secretary and Deputy Secretary informed of any significant problems, abuses, or deficiencies disclosed in audits and the actions taken to correct them; and (8) The Inspector General may require by subpoena the production of information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence necessary for the performance of IG functions under the Inspector General Act, as amended; Such subpoenas, in the case of continuance or refusal to obey, shall be enforceable by order of any appropriate United States district court: Provided, the Inspector General shall use procedures other than subpoenas to obtain documents and information from Federal agencies when exercising authority under the IG Act, as amended; and (9) The Inspector General may require by subpoena the production of information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence necessary for the performance of IG functions under the Inspector General Act, as amended; Such subpoenas, in the case of continuance or refusal to obey, shall be enforceable by order of any appropriate United States district court: Provided, the Inspector General shall use procedures other than subpoenas to obtain documents and information from Federal agencies when exercising authority under the IG Act, as amended; and
Special Counsel of the Merit Systems Protection Board (MSPB) regarding allegations of prohibited personnel practices, may investigate such matters, or may refer such matters for investigation to a law enforcement bureau Internal Affairs or Inspection Office;

(8) Bureaus or offices conducting investigations under 5 U.S.C. 1206[b][3] for the Special Counsel of the MSPB shall forward to the Inspector General all investigative reports prepared for such investigations. The IG may prepare, or delegate to the appropriate bureau or office for preparation, final reports to the Special Counsel for review and signature of the Secretary or the Deputy Secretary; and

(9) The Inspector General shall report expeditiously to the Attorney General whenever the IG has reasonable grounds to believe there has been a violation of Federal criminal law. However, in matters involving chapter 75 of the Internal Revenue Code of 1986, the Inspector General shall report expeditiously to the Attorney General only offenses under section 7214 of such Code, unless the Inspector General obtains the consent of the Commissioner of Internal Revenue to exercise additional reporting authority with respect to such chapter.

d. For Oversight. (1) The Inspector General shall have oversight responsibility for the Office of Internal Affairs of the Bureau of Alcohol, Tobacco and Firearms; the Office of Internal Affairs of the United States Customs Service; the Office of Inspection of the United States Secret Service; and the Office of the Assistant Commissioner (Inspection) of the IRS:

(2) The Inspector General shall require from the head of each office of Internal Affairs and Office of Inspection, monthly or more frequent reports of the significant activities being performed by such offices;

(3) Heads of Offices of Inspection or Internal Affairs shall routinely provide to the Inspector General timely information regarding any matter which could have a material effect on their office operations; and

(4) The Inspector General shall review, evaluate, and approve all Departmental and bureau programs, plans, policies and operations for referring allegations of criminal civil rights violations against Treasury law enforcement personnel and may make recommendations for changes.

c. For Intelligence Activities: (1) Pursuant to section 4 of Executive Order 12334, the Inspector General together with the General Counsel, to the extent permitted by law, shall report to the President's Intelligence Oversight Board concerning intelligence activities that the IG has reason to believe may be unlawful or contrary to Executive Order or Presidential directive; and

(2) All Treasury employees shall report to either the Inspector General, the General Counsel, or the head of an Inspector or Internal Affairs Office any matters which raise questions of propriety or legality under Executive Order 12333.

3. Miscellaneous Matters. (1) The Inspector General has the authority to select, appoint, and employ such officers and employees, including members of the Senior Executive Service (SES) and excepted service employees, as may be necessary for performing the functions and duties of the Office, subject to FTE ceilings and to the provisions of Title 5, United States Code:

(2) The Inspector General may exercise any and all administrative functions attendant upon this personnel authority except for those functions assigned by law to the Secretary, which may not be delegated;

(3) The Inspector General is authorized to exercise all authorities granted to an “appointing authority” pursuant to Title 5, United States Code as those authorities pertain to SES members or positions which are or would be within the OIG. With regard to any other authority accorded by law to the agency or the Secretary which pertains to SES members or positions within the OIG, the IG shall be under the direct supervision of the Secretary or the Deputy Secretary and no other Departmental official:

(4) The Inspector General has the authority to obtain services as authorized by 5 U.S.C. 3109 at daily rates not to exceed the equivalent rate prescribed for grade GS-18 of the General Schedule by 5 U.S.C. 5332, and to enter into contracts and other arrangements for audits, studies and other services and to make such payments as may be necessary to carry out the IG's mission:

(5) The Inspector General, under procedures the IG develops, may obtain by detail investigative, audit, and support personnel from law enforcement bureaus' Internal Affairs and Inspection Offices for conducting investigations or audits under the IG's direct supervision; provided that, the Office of Inspector General shall reimburse the providing entity for the costs of employing a detailed employee for the period of the detail.

At the Inspector General's discretion, personnel so detailed shall remain on the rolls of the service or office from which they were detailed but will report exclusively to the Inspector General regarding the matter being investigated or audited;

(6) Bureau heads shall consult with the Inspector General in recruiting and selecting candidates to head Internal Affairs or Inspection Offices of the law enforcement bureaus; and prior to completing performance evaluations for individuals encumbering those positions;

(7) The Inspector General is hereby delegated the authority to issue final decisions on administrative appeals under 5 U.S.C. 552 and 552a with respect to records which are within the custody of the OIG; and

(8) The Inspector General may issue additional directives or regulations regarding the OIG as the Inspector General deems appropriate.

3. Cancellation.

This Order supersedes Treasury Orders (TO):

a. TO 100-02, "The Office of the Inspector General and Delegation of Authority to the Inspector General," dated May 3, 1988; and


Nicholas F. Brady,
Secretary of the Treasury.

[FR Doc. 89-12669 Filed 5-26-89; 8:45 am]
BILLING CODE 4810-25-M

UNITED STATES INFORMATION AGENCY

Voice of America Broadcast Advisory Committee Meeting

A meeting of the Voice of America Broadcast Advisory Committee is scheduled for Friday, June 16, 1989, 301 4th St., SW., Room 800, from 10:00 a.m. to 1:00 p.m.

Please contact Louise Wheeler on 202-485-8889 for further information.


Ledra L. Dildy,
Management Analyst, Federal Register Liaison.

[FR Doc. 89-12706 Filed 5-26-89; 8:45 am]
BILLING CODE 8220-01-M

Culturally Significant Objects Imported for Exhibition; Determination

Notice is hereby given of the following determination: Pursuant to the authority
vested in me by the act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 FR 13339, March 29, 1978), and Delegation Order No. 85-5 of June 27, 1985 (50 FR 27393, July 2, 1985). I hereby determine that the object to be included in the exhibit, ‘‘The Scream by Edvard Munch’’ (see list 1) imported from abroad for the temporary exhibition without profit within the United States is of cultural significance. The object is imported pursuant to a loan agreement with the foreign lender. I also determine that the temporary exhibition or display of the listed exhibit object at the National Gallery of Art in Washington, DC, beginning on or about May 29, 1989, to on or about November 30, 1990, is in the national interest.

Public notice of this determination is ordered to be published in the Federal Register.

Date: May 25, 1989.
R. Wallace Stuart,
Acting General Counsel.

[FR Doc. 89-12957 Filed 5-26-89; 8:45 am]
BILLING CODE 8230-01-M

DEPARTMENT OF VETERANS AFFAIRS

Information Collection Under OMB Review

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document lists the following information: (1) The agency responsible for sponsoring the information collection; (2) the title of the information collection; (3) the Department form number(s), if applicable; (4) a description of the need and its use; (5) frequency of the information collection, if applicable; (6) who will be required or asked to respond; (7) an estimate of the number of responses; (8) an estimate of the total number of hours needed to complete the information collection; and (9) an indication of whether section 3504(h) of Public Law 96-511 applies.

ADDRESSES: Copies of the proposed information collection and supporting documents may be obtained by contacting Mr. R. Wallace Stuart of the Office of the General Counsel of USIA. The telephone number is 202/485-7979, and the address is Room 700, U.S. Information Agency, 301 4th Street SW., Washington, DC 20547.

Comments and questions about the items on the list should be directed to the VA’s OMB Desk Officer, Joseph Lackey, Office of Management and Budget, 720 Jackson Place, NW., Washington, DC 20503. (202) 395-7316.

DATES: Comments on the information collection should be directed to the OMB Desk Officer within 30 days of this notice.

Dated: May 19, 1989.
By direction of the Secretary
Frank E. Lalley,
Director, Office of Information Management and Statistics.

Extension
1. Office of Facilities.
3. VA Form 08-6298.
4. VA Form 08-6298 is the A/E’s proposed fee architect-engineer services based on the scope, complexity and nature of the project. The Office of Facilities uses the form in contract negotiations with A/E firms.
5. On occasion.
6. Business or other for-profit; small businesses or organizations.
7. 200 responses.
8. 4 hours.
9. Not applicable.

[FR Doc. 89-12713 Filed 5-25-89; 8:45 am]
BILLING CODE 8320-01-M
Sunshine Act Meetings

This section of the Federal Register contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL ENERGY REGULATORY COMMISSION

May 24, 1989.

The following notice of meeting is published pursuant to Section 3(a) of the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

DATE AND TIME:

MAY 31, 1989, 10:00 a.m.

PLACE:

825 North Capitol Street, NE., Room 9306, Washington, DC 20426.

STATUS:

Open.

MATTERS TO BE CONSIDERED:

Agenda.

Note.—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION:

Lois D. Cashell, Secretary, Telephone (202) 357-8400.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda; however, all public documents may be examined in the Public Reference Room.

Consent Power Agenda, 897th Meeting—May 31, 1989, Regular Meeting (10:00 a.m.)

CAP—1.

Project No. 2531-009, Central Maine Power Company

CAP—2.

Project No. 9249-003, Town of Telluride, Colorado

CAP—3.

Project No. 10727-001, Robert W. Shaw

CAP—4.

Docket No. EL88-25-001, Illiamna-Newhalen-Nondalton Electric Cooperative, Inc.

CAP—5.

Project No. 6783-005, BMB Enterprises, Inc.

CAP—6.

Project No. 6456-008, Village of Green Island, New York

CAP—7.

Project No. 5223-003, International Falls Power Company

CAP—8.

Project No. 3407-008, Magic Reservoir Hydroelectric, Inc.

Project No. 8000-002, Idaho Renewable Resources, Bonneville Pacific Corp., and Big Wood Canal Company


Project No. 4204-010, City of Batesville, Arkansas

Project Nos. 4659-0140 and 4668-011, Independence County, Arkansas

CAP—10.

Project No. 9812-001, Clifton Corporation

Project No. 9977-012, City of Augusta, Georgia

CAP—11.

Docket No. UI88-27-001, Consolidated Hydro, Inc.

CAP—12.

Docket Nos. EL86-44-001, 002, Project Nos. 10479-001 and 002, Island Power Company

CAP—13.

Project No. 8361-006, Olsen Power Partners

CAP—14.

Project No. 4939-001, Brownville Power Company

CAP—15.

Docket No. ER82-774-012, Tapoco, Inc.

CAP—16.

Docket No. ER88-142-002, Michigan Power Company

CAP—17.

Docket No. ER84-705-011, Boston Edison Company

CAP—18.

Docket No. ER89-106-001, Duke Power Company

CAP—19.

Docket Nos. EC87-19-000 and 001, Southwestern Public Service Company and Black Mesa Power Company

Docket No. ER87-394-002, Southwestern Public Service Company and Black Mesa Power Company

CAP—20.

Docket No. ER87-160-004, Cincinnati Gas & Electric Company

CAP—21.

Omitted

CAP—22.

Omitted

CAP—23.

Docket Nos. ER88-456-000 and ER88-629-000, Central Vermont Public Service Corporation

CAP—24.

Docket No. EL84-860-012, Union Electric Company

CAP—25.

Docket Nos. ER88-73-000 and ER89-74-000, Orange & Rockland Utilities, Inc.

Consent Miscellaneous Agenda

CAM—1.

Docket No. RM89-13-000, Revision of Formula for Computing Monthly Carrying Charges in PGA Filings

CAM—2.

Docket No. GP89-34-001, Columbia Gas Transmission Corporation

CAM—3.

Docket No. GP89-36-000, Utah Department of Natural Resources

CAM—4.

Docket No. GP89-28-000, Virginia Department of Mines, Minerals and Energy

CAM—5.


CAG—1.

Docket No. GP89-51-001, Northern Natural Gas Company, Division of Enron Corp. v. Cabot Pipeline Corporation and Texasco Producing Inc.

Consent Gas Agenda

CAG—1.

Docket No. RP89-163-000, Transcontinental Gas Pipe Line Corporation

CAG—2.

Docket Nos. RP89-165-000 and TM89-2-22-000, CNG Transmission Corporation

CAG—3.

Docket No. TA89-1-55-000, Questar Pipeline Company

CAG—4.

Docket Nos. TA89-1-56-000 and 001, Valero Interstate Transmission Company

CAG—5.

Docket No. TA89-1-25-000, Mississippi River Transmission Corporation

CAG—6.

Docket Nos. TM89-3-26-000 and TM89-3-26-000, Natural Gas Pipeline Company of America

CAG—7.

Docket Nos. TM89-3-25-000 and RP89-12-004, Mississippi River Transmission Corporation

CAG—8.

Docket No. TQ89-4-63-000, Carnegie Natural Gas Company

CAG—9.

Docket No. TQ89-6-4-000, Granite State Gas Transmission, Inc.

CAG—10.

Docket No. TQ89-4-49-000, Williston Basin Interstate Pipeline Company

CAG—11.

Docket Nos. RP89-184-002, 004, 005 and 006, El Paso Natural Gas Company

CAG—12.

Docket No. RP89-164-000, Eastern Shore Natural Gas Company

CAG—13.

Docket No. RP89-161-000, ANR Pipeline Company

CAG—14.

Docket No. RP89-160-000, Trunkline Gas Company

CAG—15.

Docket No. RP89-162-000, Ringwood Gas Company

CAG—16.

Docket No. RP82-55-041, Transcontinental Gas Pipe Line Corporation

CAG—17.

Docket Nos. RP82-114-015, 016 and 017, Williams Natural Gas Company

Federal Register

Vol. 54, No. 102

Tuesday, May 30, 1989

23015
I. Licensed Project Matters

II. Electric Rate Matters

III. Pipeline Rates Matters

II. Producer Matters

III. Pipeline Certificate Matters

Lois D. Cashell,
May 24, 1989.

FEDERAL COMMUNICATIONS COMMISSION

Wednesday, May 31, 1989, which is
Agenda, Item No., and Subject
on the subjects listed below on
Washington, DC.
Room 856, at 1919 M Street, NW.,
scheduled to commence at 9:30 a.m., in
Private Radio—1—Title: Reorganization of
Docket No. PR87—300, Electric Radio
Use of Radio Frequencies in a Mobile
Satellite Service for the Provision of
Various Common Carrier Services.
Summary: In this item the Commission
considers a request from certain aviation
Airline applications to reconsider the Commission's L-
band allocation in light of the 1987 Mobile
WARC.

Common Carrier—1—Title: Amendment of Parts 2, 22, and 25 of the Commission's
Rules to allocate spectrum for and to establish other rules and policies pertaining to the use of radio frequencies in a land mobile satellite service for the provision of various common carrier services, and applications of Global Land Mobile Satellite, Inc., et al. Summary: The Commission considers petitions for reconsideration and applications for review of the Second Report and Order and subsequent orders concerning the establishment of rules and applications for a mobile satellite services, General Docket No. 84-1234.

Common Carrier—2—Title: Amendment of Parts 2, 22, and 25 of the Commission's
Rules to allocate spectrum for and to establish other rules and policies pertaining to the use of radio frequencies in a land mobile satellite service for the provision of various common carrier services, and applications of Hughes Communications Mobile Satellite, Inc., et al. Summary: The Commission will consider applications seeking authority to construct, launch and operate a domestic mobile satellite system.

Common Carrier—3—Title: In the Matter of Aeronautical Radio, Inc. for authority to
construct and operate an aviation satellite system (CSS—87-015(F)), Summary: The Commission will consider the petition of Aeronautical Radio, Inc. for reconsideration and reinstatement of its application Nunc Pro Tunc.

Common Carrier—4—Title: Provision of Aeronautical Services via the INMARSAT System (CC Docket No. 87-76, CSS—86-005-M(2)), Summary: The Commission will consider whether to adopt a Report and Order regarding the establishment of a domestic structure by which U.S. entities may access INMARSAT space segment to provide aeronautical services.

Mass Media—1—Title: Amendment of Part 74 of the Commission's Rules and Regulations In Regard to the Instructional Television Fixed Service. Summary: The Commission will consider adopting rules in the comparative selection procedure for mutually exclusive ITFS applicants relating to the breaking ties among application that are indistinguishable under the primary selection criteria.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Sarah Lawrence, Office of Public Affairs telephone number (202) 632-5050.

Issued: May 24, 1989.
Donna R. Searcy,
Secretary

BILLING CODE 6717-01-M

NATIONAL MEDIATION BOARD

TIME AND DATE: 2:00 p.m., Wednesday, June 14, 1989.
PLACE: Board Hearing Room 8th Floor, 1425 K Street, NW., Washington, DC.
STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Ratification of the Board actions taken by notation voting during the month of May, 1989.

2. Other priority matters which may come before the Board for which notice will be given at the earliest practicable time.

SUPPLEMENTARY INFORMATION: Copies of the monthly report of the Board's notation voting actions will be available from the Executive Director's office following the meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Charles R. Barnes, Executive Director, Tel: (202) 523-5520.

Date of Notice: May 22, 1989.

Charles R. Barnes,
Executive Director, National Mediation Board

UNITED STATES INTERNATIONAL TRADE COMMISSION

[USTR 5E—89-21]
TIME AND DATE: Tuesday, June 6, 1989 at 11:30 a.m.
PLACE: Room 101, 500 E Street, SW., Washington, DC 20435.
STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda.

2. Minutes.

3. ratifications.

4. Petitions and Complaints.

5. Inv. No. 731-TA-433 (P) (Certain Residential Door Locks from Taiwan)—briefing and vote.

6. Any items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Deputy Secretary, (202) 252-1000.

Kenneth R. Mason,
Secretary

May 23, 1989.

BILLING CODE 7505-01-M

FEDERAL COMMUNICATIONS COMMISSION

May 24, 1989.

The Federal Communications
Commission will hold an Open Meeting on the subjects listed below on
Wednesday, May 31, 1989, which is
scheduled to commence at 9:30 a.m., in
Room 856, at 1919 M Street, NW.,
Washington, DC.

Agenda, Item No., and Subject

Private Radio—1—Title: Reorganization of
Docket of Part 97 of Rules Governing the Amateur Radio Services. Summary: The Commission will consider whether to adopt a Report and Order in PR Docket No. 88—
Corrections

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

Marine Mammals; Application for Permit; NMFS, Southwest Fisheries Center (P77 #33)

Correction
In notice document 89-10992 appearing on page 19934 in the issue of Tuesday, May 9, 1989, make the following corrections:
1. On page 19934, in the second column, in designated paragraph 5, in the second line, after "Tropical" insert "Pacific".
2. On the same page, in the same column, in the title appearing below the signature, in the second line, remove "Wildlife".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW-FRL-3555-1]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Proposed Exclusion

Correction
In proposed rule document 89-8999 beginning on page 14971 in the issue of Tuesday, May 9, 1989, make the following corrections:

1. On page 14973, in the third column, in Table 2, in the first column, the 11th entry should read "Bis(2-chloroethy1)ether".
2. On page 14974, in the first column, in Table 2, in the first column, the fifth entry should read "4-Nitrophenol".
3. On the same page, in the same column, in Table 3, in the second column, in the sixth entry, remove "<".
4. On the same page, in the third column, in Table 5, in the second column, the third entry should read "0.03".
5. On page 14975, in the 1st column, in the 1st complete paragraph, in the 10th line, "receive" was misspelled.
6. On the same page, in the same column, under "5. Conclusion", in the 12th line, "further" should read "future".
7. On the same page, in the second column, in the first complete paragraph, in the fourth line, "hazard" was misspelled.

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 416

[Regulations No. 16]
RIN 0960-AG54

Public Emergency Shelters for the Homeless, Exclusion of Underpayments, Increase in Benefit Rate for Individuals in Medical Care Facilities

Correction
In rule document 89-10715 beginning on page 19162 in the issue of Thursday, May 4, 1989, make the following corrections:

1. On page 19165, in the second column, in § 416.2097(d), in the fifth line, "payment" should read "payable".

2. On page 19165, in the second column, in § 416.2097(d), in the fifth line, "payment" should read "payable".

3. On the same page, in the same column, in § 416.2068(a), in the 11th line, "Statement" should read "State".

4. On the same page, in the same column, in the same paragraph, in the 16th line, "FRB" should read "FBR".

BILLING CODE 1505-01-D

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 531

Pay Under the General Schedule

Correction
In the proposed rule document beginning on page 13196 in the issue of Friday, March 31, 1989, make the following corrections:

1. On page 13197, in the 2nd column, in § 531.203(2)(i), in the 10th through 11th lines remove "the maximum rate for the grade in which pay is being fixed."

2. On page 13198, in the first column, in the file line, the docket number should read "89-7636".

BILLING CODE 1505-01-D

Federal Register
Vol. 54, No. 102
Tuesday, May 30, 1989
Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910
Occupational Exposure to Bloodborne Pathogens; Proposed Rule and Notice of Hearing
DEPARTMENT OF LABOR
Occupational Safety and Health Administration

29 CFR Part 1910
[Docket No. H-370]
RIN 1218-AB15

Occupational Exposure to Bloodborne Pathogens

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Proposed rule and notice of hearing

SUMMARY: The Occupational Safety and Health Administration proposes to reduce occupational exposure to Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV) and other bloodborne pathogens under section 6(b) of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 653. Based on a review of the available data, OSHA has made a preliminary determination that certain employees face a significant health risk as the result of occupational exposure to blood and other potentially infectious materials because they may contain bloodborne pathogens, including hepatitis B virus which causes Hepatitis B, a serious liver disease, and human immunodeficiency virus, which causes Acquired Immunodeficiency Syndrome (AIDS). The Agency preliminarily concludes that this significant health risk can be minimized or eliminated using a combination of engineering and work practice controls, personal protective clothing and equipment, training, medical follow-up of exposure incidents, and other provisions.

DATES: Written comments on the proposed standard and Notices of Intention to Appear at one of the informal rulemaking hearings must be postmarked on or before August 14, 1989.

Parties requesting more than 10 minutes for their presentation at the hearings and parties submitting documentary evidence at the hearing must submit the full text of their testimony and all documentary evidence no later than August 31, 1989 for the Washington, DC hearing and no later than September 29, 1989 for the Chicago, IL and San Francisco, CA hearings.

All informal public hearings will begin at 10:00 a.m. on the first day of the hearing and at 9:00 a.m. on each succeeding day. Three informal public rulemaking hearings are scheduled to begin on the following dates:

<table>
<thead>
<tr>
<th>Location</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Washington, DC</td>
<td>September 12, 1989</td>
</tr>
<tr>
<td>Chicago, IL</td>
<td>October 17, 1989</td>
</tr>
<tr>
<td>San Francisco, CA</td>
<td>October 24, 1989</td>
</tr>
</tbody>
</table>

ADDRESSES: Comments on the proposed standard are to be submitted to the Docket Officer, Docket No. H-370, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 523–7894. Comments limited to 10 pages or less in length also may be transmitted by facsimile to (202) 523–5046 or (for FTS) to 8–523–5046, provided the original and 4 copies of the comment are sent to the Docket Officer thereafter.

Notices of Intention to Appear at the informal rulemaking hearings, testimony, and documentary evidence for the public hearings are to be sent to Mr. Tom Hall, OSHA Division of Consumer Affairs, Docket No. H-370, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 523–8615. All informal public hearings will begin at 10:00 a.m. on the first day of the hearing and at 9:00 a.m. on each succeeding day. The locations of the informal public hearings are as follows:

- Chicago, IL: Parlor A, Palmer House, 17 East Monroe Street, Chicago, IL 60603.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, OSHA, U.S. Department of Labor, Office of Public Affairs, Room N–3647, 200 Constitution Avenue, NW., Washington, DC 20210; Telephone (202) 523–8151.

SUPPLEMENTARY INFORMATION:

Table of Contents
I. Introduction
II. Pertinent Legal Authority
III. Events Leading to the Proposed Standard
IV. Health Effects
V. Preliminary Quantitative Risk Assessment
VI. Significance of Risk
VII. Preliminary Regulatory Impact and Regulatory Flexibility Analysis
VIII. Environmental Impact
IX. Summary and Explanation of the Proposed Standard
X. Public Participation—Notice of Hearing
XI. Authority and Signature
XII. Standard

References to the rulemaking record are in the text of the preamble. References are given as “Ex.” followed by a number to designate the reference in the docket. For example, “Ex. 1” means exhibit 1 in Docket H–370. This document is the Advance Notice of Proposed Rulemaking that was published in the Federal Register on November 27, 1987 (52 FR 45438).

I. Introduction

The preamble to the proposed standard on bloodborne pathogens discusses the events leading to the proposal, the health effects of exposure, degree and significance of the risk, an analysis of the technological and economic feasibility of the proposal's implementation, regulatory impact and regulatory flexibility analysis, and the rationale behind the specific provisions set forth in the proposed standard.

Public comment on all matters discussed in this notice and all other relevant issues is requested for the purpose of assisting OSHA in the development of a new standard for occupational exposure to bloodborne pathogens. Persons need not resubmit information already submitted in response to the Advance Notice of Proposed Rulemaking entitled, "Occupational Exposure to Hepatitis B Virus and Human Immunodeficiency Virus" at 52 FR 45438 (November 27, 1987).

This proposed standard represents OSHA's first regulation of occupational exposure to biological hazards. The Agency recognizes the unique nature of both the healthcare industry and other operations covered by this proposed standard. Adequate employee protection must be provided in a manner consistent with a high standard of patient care. OSHA seeks comments and information from interested parties on how this goal can be achieved.

On February 6, 1989 the Department of Health and Human Services forwarded a document entitled "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public Safety Workers" (Exhibit 15) in compliance with the requirements of the Health Omnibus Programs Extension of 1988. Pub. L. 100–607. OSHA has placed this document and a companion document, "A Curriculum Guide for Public-Safety and Emergency-Response Workers—Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus" (Exhibit 16) in the public docket for this rulemaking. The Agency invites comments relative to using the information in this rulemaking. In particular, comments should be addressed to issues where these guidelines differ with the proposed requirements, such as vaccination (e.g., which body fluids require the use of precautions in emergency situations).
On November 1, 1988 the President signed the "Medical Waste Tracking Act of 1988" into effect. The Act is an amendment to the Solid Waste Disposal Act and requires the Environmental Protection Agency (EPA) to promulgate regulations on the management of medical waste by establishing a two-year demonstration program to track medical waste. As part of the tracking program EPA will be investigating, among other things, areas such as segregation, containerization, and labeling of medical waste. These facets of infectious waste management are also dealt with in the proposed OSHA standard for occupational exposure to Bloodborne Pathogens. On March 24, 1989, the Environmental Protection Agency (EPA) published "Standards for the Tracking and Management of Medical Waste" in the Federal Register (FR 5412326). In general, this EPA document sets forth the criteria and procedures for State participation in the demonstration program, EPA's definition of "medical wastes" for use under the Act, and the regulations and standards to be used in the demonstration program. OSHA has placed a copy of EPA's interim final rule in the record for consideration in development of the final Bloodborne Pathogens Standard (Ex. 6-497).

OSHA requests comments on health effects, risk assessment, significance of risk determination, technological and economic feasibility and provisions which should be included in a final bloodborne pathogens standard. The following list of questions is provided to assist persons in formulating comments, but it is not intended to be all inclusive or to indicate that participants need to respond to all issues or follow this format.

Specific issues of concern to OSHA are the following:
1. Are there any bloodborne pathogens, in addition to the ones discussed in section IV Health Effects that present a risk to employees with occupational exposure to blood? If so, what are these pathogens, and what evidence is available that they present a potential or actual risk to employees?
2. Are there additional studies or case reports on HBV and HIV that should be included in the health effects analysis? If so, what are they? Has OSHA adequately represented the results of available epidemiologic and case studies?
3. For its significance of risk determination, OSHA considered clinical hepatitis B, HBV carrier status, hospitalization, and death to be material impairment of health. Because of the possibility of infecting others (sexual partners, newborns) and the possibility of becoming an HBV carrier, should OSHA consider HBV infection as a material impairment of health?
4. Has OSHA employed the correct methodology for determining the quantitative and qualitative risks of exposure? Are alternative risk assessments available? Are there demographic factors which should be controlled for in estimating the background risk for HBV?
5. OSHA has chosen to protect employees from bloodborne pathogens by requiring that they be protected from exposure to blood and other potentially infectious materials. Is this the correct approach and is it the most protective approach? If not, what other approach should be employed?
6. The scope of the proposed standard would be based on occupational exposure to blood and other potentially infectious materials, whether or not the individual is employed in the healthcare industry. Is this approach the most protective? Will another approach provide greater protection? Should the scope of the standard be limited to one (or a few) industries?
7. In addition to law enforcement personnel, firefighters, and corrections personnel, are there any other occupations with potential for exposure that are predominantly or entirely confined to the public (federal, state or local) sector? If so, do they perform tasks or procedures that are unique and require special protective measures that are not addressed by this standard? If so, what are these protective measures?
8. What circumstances unique to law enforcement and correction officers place these employees at risk of exposure to blood and other potentially infectious materials? What, if any, additional requirements are needed to minimize or eliminate these exposures? What, if any additional training should be required? What can be done to ensure that personal protective equipment is available when and where it is needed?
9. What circumstances unique to firefighters, emergency medical technicians and paramedics place these employees at risk of exposure to blood and other potentially infectious materials? What, if any, additional requirements are needed to minimize or eliminate these exposures? What, if any additional training should be required? What can be done to ensure that personal protective clothing and equipment is available when and where it is needed?
10. There is evidence that HIV may be transmitted through human breast milk. Are employees at risk of infection due to exposure to human breast milk? If so, what tasks or procedures do they perform that place them at risk? What special protective measures, if any, should be required for these employees?
11. Throughout the proposal, OSHA uses the terms "contaminated" and "decontaminated". Are these terms clearly understood? Should OSHA define these terms? If so, what are the appropriate definitions? Should laundry be considered "contaminated" only when blood or other potentially infectious materials are visible on the laundry? If not, what should indicate "contaminated" laundry?
12. The proposed standard includes a number of requirements including an infection control plan, engineering and work practice controls, personal protective clothing and equipment, training, signs and labels, provision of HBV vaccination, and medical follow-up for exposure incidents. Are these requirements appropriate? Do they provide adequate protection? Should other provisions be added?
13. The Agency has traditionally preferred engineering and work practice controls over the use of personal protective equipment. Do employees, in nearly every case, need to use a combination of methods that include personal protective equipment, or are there tasks or worksites where exposures can be adequately minimized or eliminated by adherence to engineering or work practice controls alone? How could OSHA best structure the methods of control requirements to reflect actual working conditions?
14. The available evidence indicates that an exposure incident that involves a percutaneous exposure, resulting from an injury with a needle or other sharp object, carries the highest risk of HIV or HBV infection. Many of these injuries result from the need to disassemble the device after use, poorly designed equipment, or other factors that relate to the basic design of the equipment. How can OSHA encourage the development of safer instruments and equipment to further reduce the likelihood of percutaneous exposure?
15. The proposed standard does not require the use of respirators. Do aerosols present a risk for transmission of bloodborne pathogens? Are there instances when these bloodborne pathogens may be transmitted in respirable particles generated during medical procedures such as laser surgery or the use of medical or surgical instruments such as a bone saw? Are there other instances where respirable particles containing (or potentially...
Commenters have indicated that some procedures with potential for exposure are performed in locations where handwashing facilities are not available or not located near the work area (e.g., crime scenes or mobile blood collection sites). Is there an acceptable substitute for handwashing that can be used under these circumstances? Does it provide protection that is equivalent to handwashing?

17. In paragraphs (d)(3)(vii) (B), (D), and (E) OSHA has proposed that fluid-resistant clothing be worn if there is a potential for splashing or spraying of blood or other potentially infectious materials while fluid-proof clothing must be worn if there is a potential for clothing becoming soaked with blood or other potentially infectious materials. Is the distinction between fluid-resistant and fluid-proof clothing appropriate? Should these terms be defined? Are the requirements for two types of protective clothing based on anticipated exposure appropriate? If not, what other approaches will assure employee protection?

18. Should OSHA specify that all non-intact skin be bandaged or otherwise covered before performing tasks or procedures with a potential for occupational exposure?

19. The proposed standard allows the utility gloves for housekeeping and laundry workers. Is the decontamination and reuse of these gloves appropriate? Should OSHA require that these gloves be puncture-resistant?

20. Are the requirements for HIV and HBV research laboratories adequate and appropriate? What additional requirements should be included? Is the definition for “research laboratories” clear? Does the definition clearly differentiate between research laboratories and clinical (diagnostic) laboratories?

21. Are the requirements for HIV and HBV production facilities adequate and appropriate? What additional requirements should be included? Is the definition for “production facilities” clear? Does the definition adequately differentiate between research laboratories and production facilities?

22. Some research laboratories use blood and blood components but do not propagate bloodborne pathogens. Are the requirements for clinical laboratories adequate for these research laboratories? If not, what additional provision should be required?

23. The proposal requires that the HBV vaccine be offered to employees exposed an average of one or more times per month. Should the administration of the HBV vaccine be contingent on the frequency of exposure? Is this frequency appropriate? If this approach is not appropriate, what justification can be provided for an alternative approach?

24. The proposed standard requires that the HBV vaccine be made available 90 days after the effective date of the standard. Are there sufficient quantities of the HBV vaccine available, will there be a problem with the distribution of the vaccine? If no, should there be a phase-in period?

25. In paragraph (f) Hepatitis B vaccine and post-exposure follow-up, the employer is required to administer the vaccine and provide effective post-exposure prophylaxis according to “standard recommendations for medical practice.” Does this approach give sufficient guidance to the employer on what must be done? For example, should the Agency be more specific about the meaning of “** * accepted safe effective * * prophylaxis * * *”? Should these recommendations be those of the U.S. Public Health Service?

26. Employees may be reluctant to report exposure incidents if they fear that coworkers or others may gain access to their test results. OSHA has attempted to reduce barriers to the reporting of exposure incidents by requiring that employee medical records, including test results, be kept confidential except as required by law. Has OSHA adequately addressed the issue of confidentiality? If not, what additional measures should be required?

27. The biohazard signs required in paragraph (g)(1)(i) do not require the use of the word “Danger.” Is it necessary to require the use of “Danger” or other additional warning words in order to warn individuals who may not understand the meaning of “Biohazard”?

28. OSHA requires that infectious wastes be labelled or “red bagged.” If infectious waste is decontaminated prior to disposal, should OSHA allow the label to be removed from the container?

29. OSHA requires that exposed employees be trained. Should OSHA specify the minimum qualifications required for the individual who conducts the training program?

30. The standard would require that all employees participate in the training program when they are hired and annually thereafter. Certain individuals, for example, infection control practitioners or some virologists, would be expected to be thoroughly familiar with some of the material in the training program. Is it appropriate to substitute some measure of competency in lieu of training for these individuals? If so, what criteria would be appropriate?

31. In all previous OSHA health standards, the Agency has required the employer to bear the cost for all provisions of the standard. This proposed standard would also require the employer to pay for all the provisions of the standard. OSHA seeks comments on this issue.

32. In order to perform an economic feasibility analysis, it is helpful to have a financial and economic profile of the industries affected by the standard. The following information is requested to aid in that effort. Data should be provided for the last five years. Data already submitted to OSHA or Jack Faucett Associates (JFA) need not be resubmitted.

a. What were total annual revenues for your facility and/or industry sector?

b. What were the total annual investments categorized as replacement, expansion, modernization, and environmental health and safety?

c. What were the retained earnings, after tax income, total assets, stockholders’ equity, net worth, depreciation charges, and debt-equity ratios?

d. What were the total annual employment levels and labor turnover for the affected industries for the last 5 years?

33. How would an OSHA standard for occupational exposure to bloodborne pathogens affect competition in the healthcare industry?

34. OSHA and JFA have performed detailed feasibility analyses for all industry sectors. Comments are requested with regard to any other industry segments on additional impacts which should be considered prior to issuing a final standard.

35. Comments are requested on OSHA’s Preliminary Regulatory Impact Analysis (PRIA), the report prepared by Jack Faucett Associates, the feasibility of the proposed standard and alternatives.

36. The following information is requested for small businesses in addition to the information OSHA has gathered.

a. What kinds of small businesses or organizations would be affected by regulating exposures to blood and other potentially infectious materials? How many such businesses are there?

b. Which if any, federal rules may duplicate, overlap, or conflict with an OSHA regulation concerning exposure to blood and other potentially infectious materials?
c. Will difficulties be encountered by small entities when attempting to comply with this standard? What requirements, if any, should be deleted or simplified for small entities, while still achieving comparable protection for the health of employees of small entities?

d. What timetable would be appropriate to allow small entities sufficient time to comply?

37. OSHA's PRIA contains estimates of the current level of compliance for various provisions. Are these estimates accurate? If not, by what means and to what extent are employers currently providing protection to their employees?

38. The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.) requires that each Federal agency consider the environmental impact of major actions significantly affecting the quality of the human environment. Any person having information, data, or comments pertaining to possible environmental impacts is invited to submit them along with supporting documentation to OSHA. Such impacts might include a positive or negative environmental effect that could result should a standard be adopted; as well as any irreversible commitments of natural resources. Also, estimates of the effect on the level of hazardous pathogens in the environment by the proposed OSHA standard and alternatives are requested.

39. As discussed in Section IX—Summary and Explanation of the Proposed Standard and Section X—Public Participation, OSHA plans to devote several days of the public hearing to a discussion of Hepatitis B vaccination. OSHA seeks written comments concerning the elements of a HBV vaccination program that will result in a high degree of compliance of eligible employees.

40. OSHA believes a hepatitis B vaccination program where employers bear the cost of the vaccine, make the vaccine available to employees at a reasonable time and place, and provide information about the benefits of the vaccine is the most appropriate way to assure that a large percentage of eligible employees are vaccinated. The Agency seeks comment on whether this voluntary approach is the correct approach.

In the past, the Agency has not mandated medical examinations or other medical procedures. For example, the final standards for benzene, asbestos, cotton dust, and formaldehyde require the employer to "provide" or "make available" medical procedures (29 CFR 1910.1035; 1910.1067; 1910.1043; and 1910.1048, respectively). In the preamble to the Lead Standard (43 FR 54450), OSHA specifically rejected mandating worker participation in medical surveillance. The Agency noted that medical surveillance was a sensitive area and that: "Attempting to compel workers to subject themselves to detailed medical examinations presents the possibility of clashes with legitimate privacy and religious concerns. Health in general is an intensely personal matter." "In lead, medical surveillance involved effects on male and female reproduction, while in this proposed standard a major concern is that a vaccination is an invasive procedure. Here, as in the lead standard, OSHA prefers to encourage rather than try to force by governmental coercion, employee cooperation in the vaccination program.

The HBV vaccination provision is a significant element in this rule with regard to saving lives from hepatitis B infection. Complete vaccination of the healthcare workers at significant risk would substantially reduce hepatitis B associated illness and death. In addition, once immunized, workers are protected from infection both on the job and off even should other precautions fail. Finally, the vaccine is safe and effective.

OSHA seeks comment on whether the HBV vaccination should be mandated for some or all exposed employees and on what legal, ethical, medical, or other issues would be raised by such a requirement.

Paperwork Reduction

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.) and the regulations issued pursuant thereto (5 CFR Part 1320), OSHA certifies that it has submitted the information collection requirements contained in this proposed standard to the Office of Management and Budget (OMB) for review under Section 3504(b) of that Act. Paragraph (c) Infection Control, paragraph (g)(2) Training, and paragraph (h) Recordkeeping are the provisions that make the major contribution to the information collection requirements in the proposed standard. Comments on these information collection requirements may be submitted by interested parties to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for the Occupational Safety and Health Administration, New Executive Office Building, Washington, DC 20503. OSHA requests that copies of such comments also be submitted to the OSHA rulemaking docket, at the following address: Docket Officer, Docket No. H-370, Room N 2626, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210.

Public Reporting Burden

Public reporting burden for this collection of information is estimated to range from 4 to 16 hours for the Infection Control Plan and an average of 7 hours per facility for the remaining information requirements. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the OSHA rulemaking docket, at the address previously set forth; and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

Federalism

This proposed standard has been reviewed in accordance with Executive Order 12612, 52 FR 41685 (October 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting state policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of State law only if there is a clear Congressional intent for the agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the Occupational Safety and Health Act (OSH Act), expresses Congress' clear intent to preempt State laws with respect to which Federal OSHA has promulgated occupational safety or health standards. Under the OSH Act a State can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such Plan-States must, among other things, be at least as effective as the Federal standards in providing safe and healthful employment and places of employment.

Bloodborne pathogens are present wherever blood or other potentially infectious materials are found. Since these potentially infectious materials are present in workplaces in every state of the Union, the occupational hazard of bloodborne pathogens is a national problem.

The Federally proposed bloodborne pathogen standard is drafted so that employees in every State would be protected by general, performance-oriented standards. To the extent that
there are any State or regional peculiarities. States with occupational safety and health plans approved under Section 18 of the OSH Act would be able to develop their own State standards to deal with any special problems. Moreover, the performance nature of this proposed standard, of and by itself, allows for flexibility by States and employers to provide as much safety as possible using varying methods consonant with conditions in each State.

In short, there is a clear national problem related to occupational safety and health for employees exposed to bloodborne pathogens. Those States which have elected to participate under Section 18 of the OSH Act would not be preempted by this proposed regulation and would be able to deal with special, local conditions within the framework provided by this performance-oriented standard while ensuring that their standards are at least as effective as the Federal standard. State comments are invited on this proposal and will be fully considered prior to promulgation of a final rule.

State Plans

The 23 States and 2 territories with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within 6 months after the publication of a final standard for occupational exposure to bloodborne pathogens or amend their existing standard if it is not "at least as effective" as the final Federal standard. OSHA anticipates that this proposed standard will have a substantial impact on state and local employees. The states and territories with occupational safety and health state plans are: Alaska, Arizona, California, Connecticut, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, the Virgin Islands, Washington, and Wyoming. (In Connecticut and New York, the plan covers only State and local government employees.)

II. Pertinent Legal Authority

The primary purpose of the Occupational Safety and Health Act (29 U.S.C. 651 et seq.) (the Act) is to assure, so far as possible, safe and healthful working conditions for every American worker over the period of his or her working lifetime. One means prescribed by the Congress to achieve this goal is the mandate given to, and concomitant authority vested in, the Secretary of Labor to set mandatory safety and health standards. The Congress specifically directed that:

"The Secretary, in promulgating standards dealing with toxic or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practical, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired. (Section 6(b)(5))."

Where appropriate, standards are required to include provisions for labels or other appropriate forms of warning to apprise employees of hazards, suitable protective equipment, exposure control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, and training and education. Standards may also prescribe recordkeeping requirements where necessary or appropriate for enforcement of the Act or for the development of information regarding occupational accidents and illnesses (Section 8(c)).

In vacating OSHA's 1978 revision to its benzene standard, the Supreme Court required in *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 601, 64 L. Ed. 2d 1010, 100 S. Ct. 2844 (1980), that before the issuance of a new or revised standard pursuant to section 6(b)(5) of the Act, OSHA must make two threshold findings: that a place of employment is unsafe in that significant risks are present; and that the risks can be reduced or eliminated by a change in practices (448 U.S. at 642).

The Court also stated "that the Act does limit the Secretary's power to requiring the elimination of significant risks" (448 U.S. at 644, n. 49). The Court indicated, however, that the significant risk determination is "not a mathematical straitjacket," and that "OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty." The Court ruled that "a reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge [and that] . . . the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risk, error on the side of overprotection rather than underprotection" (448 U.S. at 655, 656).

The Court also stated that "while the Agency must support its finding that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is "significant" will be based largely on policy considerations." (448 U.S. at 655, 656, n. 62).

After OSHA has determined that a significant risk exists and that such risk can be reduced or eliminated by the regulatory action, it must set the standard "which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employees will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." (448 U.S. at 655, 656, n. 62).

The Supreme Court has interpreted this section to mean that OSHA must enact the most protective standard possible to eliminate a significant risk of material health impairment, subject to the constraints of technological and economic feasibility *American Textile Manufacturers' Institute, Inc. v. Donovan*, 452 U.S. 490 (1981). The Court held that "cost-benefit analysis is not required by the statute because feasibility analysis is." (452 U.S. at 509).

The Court stated that the Agency could use cost-effectiveness analysis and choose the least costly of two equally effective standards. (452 U.S. 531, n. 32).

Authority for this action is also found in section 8(c)(3) of the Act. In general, this section empowers the Secretary to require employers to make, keep, and preserve records regarding activities related to the Act. In particular, section 8(c)(3) gives the Secretary authority to require employers to "maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6." The Secretary's authority to issue this proposed standard is further supported by the general rulemaking authority granted in section 8(g)(2) of the Act. This section empowers the Secretary "to prescribe such rules and regulations as [she] may deem necessary to carry out [her] responsibilities under the Act." In this case as part of a section 6(b) standard. The Secretary's responsibilities under the Act are defined largely by its enumerated purposes, which include:

- Encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new
and to perfect existing programs for providing safe and healthful working conditions [29 U.S.C. 651(b)(1)].

Authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce [29 U.S.C. 651(b)(4)];

Building upon advances already made through employer and employee initiative for providing safe and healthful working conditions [29 U.S.C. 651(b)(6)];

Providing for appropriate reporting procedures with respect to occupational safety and health which procedures will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health program [29 U.S.C. 651(b)(12)].

Exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions [29 U.S.C. 651(b)(9)];

Encouraging joint labor-management efforts to reduce injuries and disease arising out of employment [29 U.S.C. 651(b)(15)]; and developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems [29 U.S.C. 651(b)(6)].

The Agency's preliminary judgment is that the bloodborne pathogens standard is reasonably related to these statutory goals, and that the evidence satisfies the statutory requirements, and that the standard will reduce a significant risk of hepatitis B and other adverse health effects, including but not limited to AIDS and non-A/non-B hepatitis. Thus, the Secretary preliminarily finds that the proposed standard is necessary and appropriate to carry out her responsibilities under the Act.

III. Events Leading to the Proposed Standard

Hepatitis B virus (HBV) has long been recognized as a pathogen capable of causing serious illness and death. Because the virus is transmitted through blood and certain body fluids, persons who handle these as part of their jobs have been at increased risk of contracting HBV. The human immunodeficiency virus (HIV), the virus that causes AIDS, has only been recognized in the last decade. Because the transmission of HIV is considerably less efficient than HBV, the risk of HIV infection to employees who must handle blood and other potentially infectious materials is less than for HBV infection (i.e., HIV results in fewer seroconversions following exposure incidents.) The consequences of HIV infection are grave, however, because HIV causes the fatal disease AIDS. Although OSHA has no standard that was designed specifically to reduce occupational exposure to these viruses, the Agency has a number of existing regulations that apply to this hazard. For example, 29 CFR 1910.132 requires employers to provide personal protective equipment and 29 CFR 1910.145(f) requires accident prevention tags to warn of biological hazards. In addition, section 5(a)(1) the General Duty Clause of the Act requires that each employer:

furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.

In 1983, OSHA issued a set of voluntary guidelines designed to reduce the risk of occupational exposure to hepatitis B virus [Ex. 4-25]. The voluntary guidelines, which were sent to employers in the healthcare industry, included a description of the disease, recommended work practices, and recommendations for use of immune globulins and the hepatitis B vaccine.

On September 19, 1986, the American Federation of State, County and Municipal Employees (AFSCME) petitioned OSHA to take action to reduce the risk to employees from exposure to certain infectious agents (Ex. 2A). They requested that OSHA issue an emergency temporary standard (ETS) under section 6(c) of the Act. The petitioners also requested that OSHA immediately initiate a section 6(b) rulemaking that would require employers to provide the HBV vaccine at no cost to employees at risk for HBV infection and would require employers to follow work practice guidelines such as those issued by the Centers for Disease Control. AFSCME also requested that OSHA amend the Hazard Communication Standard (48 FR 53280) to require a training program for employees exposed to infectious diseases, require counseling for pregnant employees about diseases that have reproductive effects, and mandate posting of isolation precautions in patient areas and in contaminated areas.

On September 22, 1986, the Service Employees International Union, the National Union of Hospital and Healthcare Employees, and RWDSU Local 1999-Drug Free Facilities and Healthcare union petitioned the Agency to promulgate a standard to protect healthcare employees from the hazard posed by occupational exposure to hepatitis B virus (Ex. 3). They requested that, as a minimum, the standard should contain all of the provisions in OSHA's 1983 guidelines with special emphasis on making workers aware of the benefits of vaccination. In addition, they asked OSHA to immediately issue a directive stating that employers must provide the HBV vaccine free of charge to all high risk healthcare workers.

Having determined that the available data did not meet the criteria for an ETS as set forth in section 6(c) of the Act, Assistant Secretary John A. Pendergrass denied the petitions by letter dated October 22, 1987. OSHA further determined that the appropriate course of action was to publish an Advance Notice of Proposed Rulemaking (ANPR) to initiate rulemaking under section 6(b) of the Act and to collect further information. Concurrently with the collection of this information, the Agency committed to enforcing existing regulations and section 5(a)(1) of the Act in healthcare settings and to undertaking an educational program in cooperation with the Department of Health and Human Services.

On October 30, 1987, the Departments of Labor and Health and Human Services published a Joint Advisory Notice entitled, "Protection Against Occupational Exposure to Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV)" [52 FR 4181]. In the cover letter to employers, Secretaries Brock and Bowen urged the "... * * widest possible adherence to the appropriate precautions as exemplified by the CDC guidelines and the Joint Advisory Notice." The letter, notice and a pamphlet written by OSHA for healthcare workers were mailed to more than 600,000 employers, employee representatives and trade and professional associations.

On November 27, 1987, OSHA published in the Federal Register an ANPR announcing the initiation of the rulemaking process [52 FR 45438]. The Agency requested information relevant to reducing occupational exposure to HBV and HIV under section 6(b) of the OSH Act. The public was asked to comment on the scope, the modes of controlling exposure, personal protective equipment, vaccination programs, management of exposure incidents, medical surveillance, training and education, generic standards, advances in hazard control, effectiveness of alternative approaches and the environmental effects. A sixty day period was set for comments, and these comments were to be submitted to the OSHA docket by January 26, 1988, as noted in a correction published in the Federal Register December 11, 1987 [52 FR 47097].

OSHA received an overwhelming response to the ANPR. Over 350 comments were filed by interested parties including employers, unions, health professionals, trade representatives, professional
associations, manufacturers, and federal, state and local government agencies. The comments have been analyzed and the data were used in preparing this proposal.

IV. Health Effects

A. Introduction

Certain pathogenic microorganisms can be found in the blood of infected individuals. For the purposes of this standard, OSHA is referring to these microorganisms as "bloodborne pathogens" and to the diseases that they cause as "bloodborne diseases." These bloodborne pathogens may be transmitted from the infected individual to other individuals when blood or certain other body fluids are exchanged, for example, when blood-contaminated needles are shared by intravenous drug users. Blood exposure is the exposure to the blood or body fluid that carries the risk of infection, individuals whose occupational duties place them at risk of blood exposure are at risk of becoming infected with these bloodborne pathogens, developing the disease and, in some cases, dying. Infected employees may also transmit the pathogens to others.

A complete discussion of two of the most significant bloodborne pathogens, hepatitis B virus and human immunodeficiency virus, follows. This includes a discussion of each of the viruses, the disease each causes, modes of transmission, and documented risk of infection resulting from occupational exposure. In addition, a discussion of other bloodborne diseases, including non-A, non-B hepatitis, delta hepatitis, syphilis, and malaria, are included. There is also a discussion of cytomegalovirus with a review of the literature concerning transmission of the virus and risks to pregnant women.

B. Hepatitis Viruses

Introduction

Hepatitis means "inflammation of the liver," and can be caused by a number of agents including drugs, toxins, autoimmune disease, and infectious agents including viruses. The most common causes of hepatitis are viruses. There are four types of viral hepatitis which are important in the U.S. ([Ex. 6-449, Ex. 6-430, Ex. 6-199]). Hepatitis A, formerly called "infectious" hepatitis, is spread by fecal contamination and is not generally considered to be a significant risk to healthcare workers, although episodes of transmission to healthcare workers in hospitals have been reported ([Ex. 6-430, Ex. 6-472; Ex. 6-449, Ex. 6-456]). Hepatitis B, formerly called "serum" hepatitis, is the major risk to healthcare workers and is extensively discussed in this document. Delta hepatitis affects persons already infected with HBV and can increase the severity of acute and chronic liver disease in these individuals ([Ex. 6-470]). Non-A, non-B hepatitis is the name given to a group of diseases caused by viral agents. The "post transfusion" type of non-A, non-B hepatitis is caused by a bloodborne virus that is inefficiently transmitted by blood transfusion and by needle sharing among IV drug users ([Ex. 6-430, Ex. 6-449]). There are occasional reports of transmission to healthcare workers ([Ex. 6-39, Ex. 6-455]). Although it is not thought to be a major occupational hazard to health workers, serological tests for this disease are not currently available, and the actual risk of transmission to health workers is unknown.

Hepatitis B virus (HBV) infection is the major infectious occupational hazard to healthcare workers. The Hepatitis Branch of the Centers for Disease Control (CDC) estimates that there are approximately 18,000 infections in healthcare workers each year in the United States. Approximately 12,000 of these infections occur in employees who have occupational exposure to blood, causing 2500-3000 cases of clinical acute hepatitis and 500-600 hospitalizations and over 200 deaths. Approximately 1000 health care workers annually become HBV carriers, at risk of long-term sequellae including disabling chronic liver disease, cirrhosis and liver cancer. Death may result from both acute and chronic hepatitis. Infected healthcare workers can spread the infection to family members or rarely, to their patients. [For a detailed discussion, see Section V, Preliminary Quantitative Risk Assessment.] The use of Hepatitis B (HB) vaccine and appropriate environmental controls will prevent almost all of these occupational infections. Efforts to reduce blood exposure and minimize puncture injuries in the healthcare setting will reduce the risk of transmission of all bloodborne hepatitis viruses.

Biology

Hepatitis B is caused by the hepatitis B virus (HBV), formerly called the Dane particle, that attacks and replicates in liver cells ([Ex. 6-430, Ex. 6-449]). The hepatitis B virus (HBV) is a spherical virus. It is composed of a lipoprotein called hepatitis B surface antigen (HBsAg). The viral capsid, which is serine protease resistant, contains a viral nucleic acid (HBV DNA) and the viral polymerase (HBV DNA polymerase). The virion has three distinct nucleocapsid proteins: the largest, called hepatitis B core antigen (HBCAg). The outer shell is composed of a lipoprotein called hepatitis B surface antigen (HBsAg), formerly called the Australia Antigen. The HBsAg is produced in great excess by body cells replicating the virus, and is found, along with complete virus, in the form of small spherical viruses and larger tubular particles in the blood of infected persons. The small spherical forms of HBsAg are important because the plasma derived hepatitis B vaccines are composed of a highly purified preparation of these particles. There is a readily available laboratory test for HBsAg, and its presence in blood indicates that an individual is currently infected with the HBV, and is potentially infectious to others.

Disease Outcomes

Infection with the hepatitis B virus in a susceptible person can produce two types of outcomes: self-limited acute hepatitis B and chronic hepatitis B infection ([Ex. 6-430, Ex. 6-449]). Similarily, the human body can mount two types of response to HBV infection. The most frequent response seen in healthy adults is development of self-limited acute hepatitis and the production of an antibody against HBsAg, called anti-HBs. The production of this antibody coincides with the destruction of liver cells containing the virus. Elimination of the virus from the body, and signifies lifetime immunity against reinfection. Persons having this response also develop an antibody against the core protein, call anti-HBc, and usually maintain both anti-HBc and anti-HBs in their blood for life.

Unfortunately, the destruction of liver cells in an attempt to rid the body of this infection often leads to clinically apparent acute hepatitis B. About one third of infected individuals have no symptoms when infected with the virus, one third have a relatively mild clinical course of a flu-like illness which is usually not diagnosed as hepatitis, and one third have a much more severe clinical course with jaundice (yellowing of the eyes and skin), dark urine, extreme fatigue, anorexia, nausea, abdominal pain, and sometimes joint pain, rash, and fever. These symptoms require hospitalization in about 20% of jaundiced cases, and often cause several weeks to months of work loss even in those cases that do not require hospitalization. Pulmonary hepatitis, which is about 85% fatal with even the most advanced medical care, develops in about 1-2% of reported acute hepatitis B cases, and an estimated 1 per 1000 HBV infections ([Ex. 6-217]).

The second type of response—development of chronic HBV infection—has more severe consequences ([Ex. 6-430, Ex. 6-449]). About 6% to 10% of newly-infected adults cannot clear the
From their liver cells and become chronic HBV carriers. These individuals continue to produce HBsAg for many years, usually for life. They do not develop anti-HBs, but do produce anti-HBc antibody. HBV carriers are at high risk of developing chronic persistent hepatitis, chronic active hepatitis, cirrhosis of the liver, and primary liver cancer. About 25% of carriers develop chronic persistent hepatitis, a relatively mild, non-progressive form of chronic liver disease, and 25% develop chronic active hepatitis. The latter is a progressive, debilitating disease that often leads to cirrhosis of the liver after 5-10 years (Ex. 5-8, Ex. 6-448). Patients with end-stage cirrhosis may develop ascites (fluid accumulation in the abdomen), esophageal bleeding from distended veins (causing patients to vomit large volumes of blood), coma, and death. Chronic HBV infection has been estimated to cause 10% of the 25,000-30,000 deaths that occur due to cirrhosis in the U.S. each year (Ex. 6-198).

The HBV in chronic carriers can integrate into the DNA of the host liver cell. This integration may lead to malignant transformation of the liver cell, and development of primary hepatocellular carcinoma (PHC) (Ex. 6-419, Ex. 6-443). PHC is almost uniformly fatal if diagnosed after symptoms appear. Patients with PHC usually die within four to six months after diagnosis. PHC usually develops in HBV carriers after a latency period of 20 to 60 years. In parts of the world where HBV infection is a common childhood infection, PHC is one of the leading causes of cancer death. In Taiwan, for example, Beasley and colleagues have found that 5 per 1000 adult male HBV carriers develop PHC each year, and estimate that approximately 25% of all HBV carriers, and 40% of male HBV carriers, will die from either PHC or cirrhosis (Ex. 6-419). The relative risk of developing PHC in an HBV carrier compared to a non-carrier in his studies is 100. Studies in the United States and in Great Britain, where HBV infection usually occurs in adulthood, have shown that 5 to 10 fold increased risk of developing PHC among HBV carriers (Ex. 6-460, Ex. 6-449). This may be compared to the relative risk of lung cancer in smokers vs. non-smokers of 10-20. Studies in many other populations worldwide have confirmed this extremely high relative risk.

The causal link between HBV carriage and PHC is not only based on epidemiologic studies, but is confirmed by both animal and molecular biological studies (Ex. 6-449, Ex. 6-443). Other animal species can become infected with HBV-like viruses (which belong to the same virus family—Hepadnaviruses) and develop primary liver cancers at very high rates. Molecular biological studies have shown that PHC tumor cells contain integrated HBV DNA in virtually all human and animal cases of PHC (Ex. 6-443).

There is likely a higher risk of developing PHC if infection occurs from perinatal (mother to child) transmission, or from infection during childhood than from infection in adulthood. Although persons who develop HBV carriage during adulthood are at increased risk of developing PHC, the exact risk of developing PHC following adult infection has not been established. The risk observed in blood donors in the United States is probably an underestimate, as PHC is most likely to occur in persons with chronic liver disease or cirrhosis who are excluded from such studies. In addition, many carriers will die of other causes before they develop PHC because of the long latency of this cancer. Nevertheless, it has been estimated that, in the U.S., about 25%-33% of all PCH cases, or 750-1000 PCH cases annually, result from HBV infection.

Modes of Transmission

Workplace. HBV is spread via several routes: parenteral (by direct inoculation through the skin), mucous membranes (blood contamination of the eye or mouth), sexual, and perinatal (from infected mother to newborn infant) (Ex. 6-430, Ex. 6-449). The most efficient mode of transmission is direct inoculation of infectious blood, such as might occur during blood transfusion, needle sharing by IV drug users, or needlestick injuries from a known infected patient (Ex. 6-427). The importance of this route of transmission in these less apparent ways should not be underestimated. Although gloving will not stop direct puncture injuries, it could prevent the virus from contacting preexisting lesions.

Infectious sera placed in both the eye and mouth of experimental animals has induced HBV infection (Ex. 6-430, Ex. 6-449). Splashes of blood or serum into the individual's eye or mouth in clinical settings or in the laboratory must be regarded as potentially serious exposures. While there has been concern about the potential infectivity of aerosols generated by dental, medical, and laboratory equipment, and although HBsAg may be found in large particles of “spatter” that travel short distances, OSHA is not aware of any data that link HBV transmission with the production of aerosols.

Secondary transmission in other settings. Sexual transmission of HBV infection is an efficient mode of viral spread as HBsAg has been found in both semen and vaginal secretions (Ex. 6-430, Ex. 6-445). Deposition of virus onto mucous membranes and trauma to tissue causing small lesions may both play roles in transmission. Approximately 30% of spouses or regular sexual partners of acutely infected HB patients become infected. Spouses of chronic carriers, who have a much longer duration of infectivity, escape infection less frequently.

Preventing secondary transmission of HBV infection to the spouse or sexual partners of infected healthcare workers is an additional benefit derived from and reason for controlling this disease (Ex. 6-423).

Non-sexual family contacts of HBV carriers are also at risk of infection.
Although the relative importance of various transmission modes has not been determined in families, in various studies about 40-60% of household contacts of carrier individuals infected by blood contact had markers of HBV infection (Exs. 6-420, 6-430). Daily exposure to the carrier for many years presents occasional for sharing razors or toothbrushes, exposure to blood and other events that could result in infection. Adopted carrier children have been shown to transmit infection to other family contacts.

Perinatal infection with the HBV is an efficient mode of transmission with particularly severe consequences. Highly infectious HBV carriers and persons with acute hepatitis B have an antigen present in their blood called the hepatitis B "e" antigen (HBeAg), in addition to the previously discussed HBsAg. Mothers positive for both HBsAg and HBeAg will infect 70% to 90% of their newborns, most of whom will become chronic HBV carriers (Exs. 6-199, 6-419). These carriers will have a 25% chance of dying from cirrhosis or PHC. They also remain infectious to others and can perpetuate the cycle of perinatal transmission. Fortunately, treatment of newborns at birth with Hepatitis B immune globulin (HBIG) and HBsAg during an early prenatal visit is effective in preventing these infants from becoming carriers (Ex. 6-419, Exs. 6-199). To be able to treat these infants at birth, their mothers must be recognized as carriers before delivery.

The Immunization Practices Advisory Committee of the CDC has recommended that all pregnant women in the U.S. be screened for HBsAg during an early prenatal visit (Ex. 6-424). Because pregnant healthcare workers may, if infected, transmit HBV to newborn infants, prevention of HBV infection is critical in women who work in occupations where they are at risk for exposure.

Epidemiology

HBV infection does not occur uniformly in the U.S. population. The infection is more prevalent in certain ethnic and racial groups, and is especially prevalent in certain "high risk" groups defined by occupation and lifestyle (Exs. 6-430, 6-449, 6-199). The prevalence of HBV antibodies in the general population, reflecting the percentage of the population ever infected, is 3% to 5% for whites and 13% to 14% for blacks (Ex. 6-390). Foreign born Asians have a prevalence of antibody of greater than 50%. The HBsAg prevalence, reflecting the percentage of the population who are HBV carriers, is 0.2% for whites, 0.7% for blacks, and up to 13% for foreign born Asians. The high prevalence in Asians is a reflection of the fact that most HBV infections in Asia occur in childhood. The ACIP has listed a number of groups who may be at higher risk for HBV infection and should receive the HBV vaccine (Ex. 6-199). Healthcare workers and staff of institutions for the mentally retarded are included on this list.

Transmission To Healthcare Workers

Although outbreaks of clinical hepatitis had been reported for many years (Ex. 6-438, Ex. 6-459), it was not until the 1970's that the risk to healthcare workers from HBV infection was well defined. The first studies noted that dentists were more likely than attorneys to have had clinical hepatitis (Ex. 6-441). When antibody testing became available, it was possible to show that the type of hepatitis that occurred in health workers was hepatitis B, that dentists and physicians were 4 to 10 times more likely to have serologic markers indicating previous HBV infection than first time blood donors (Ex. 4-15, Ex. 6-68), and that the prevalence of markers increased significantly with years in practice (Ex. 6-440, 6-55, Ex. 4-13, Ex. 4-16, Ex. 4-12).

During the next decade, dozens of studies were published measuring the prevalence of HBV markers in various healthcare occupational groups, and in various healthcare settings (Ex. 6-427, Ex. 6-88, Ex. 6-72, Ex. 4-54, Ex. 6-53, Ex. 6-440, Ex. 6-40, Ex. 4-14). The prevalence of markers was studied in hospitals of all sizes and types, in various sized communities, serving all types of populations. Studies were also done on a wide variety of individual occupational groups at meetings and through special studies. The most useful studies showed that risk of HBV infection in hospital personnel was increased several-fold over that in blood donors (Ex. 6-440), that risk was closely related to frequency of contact with blood and not related to contact with patients per se (Exs. 6-65; 4-13, Ex. 4-16), and that risk was directly related to duration in the healthcare setting (Ex. 4-15, Ex. 4-12, Ex. 4-16). Certain studies attempted to quantify the frequency of blood and needle exposure in various categories of healthcare workers, and relate this to risk of infection (Ex. 4-16). The following general observations can be made from these studies:

(1) These studies revealed that workers exposed to blood on the job had a prevalence of HBV markers several times that of non-exposed workers and the general population. The prevalence of markers increased with years on the job.

(2) The prevalence of HBV markers was related to the degree of blood exposure or frequency of needle exposure, and not to patient contact per se. Persons working in operating rooms, emergency rooms labs, and dialysis units had a higher marker prevalence than persons working on medical or pediatric wards, who in turn had a higher prevalence than clerical workers, social workers, and administrators.

(3) Groups shown to be at high risk include medical technologists, operating room staff, phlebotomists and intravenous therapy nurses, surgeons and pathologists, oncology and dialysis unit staff, emergency room staff, nursing personnel, staff physicians, dental professionals, laboratory and blood bank technicians, emergency medical technicians, and morticians (Ex. 6-199).

Most infected healthcare workers are unaware that they have been exposed to the HBV. Approximately 1% (or more) of hospitalized patients are HBV carriers; many HBV carrier patients seen in the healthcare setting are not symptomatic, are unaware that they are carriers, and their medical charts do not contain this information (Ex. 6-427). Health care workers may take extraordinary precautions when dealing with a known carrier, but are often unaware that they may treat five carriers for each one they recognize. This is a key point in understanding the rationale for the concept of "universal precautions," and for the use of HB vaccine in workers with exposure to blood. Although the risk of encountering HBV carriers may vary in the hospital setting, being highest in inner city referral hospitals dealing with high risk groups such as drug abusers and homosexual men, risk will be present in any work setting where human blood is encountered. The risk of HBV carriage in the general population is uniform (does not markedly vary with region of this country) (Ex. 6-390), and high risk groups such as Southeast Asian refugees, mentally retarded individuals, and occult drug abusers may be found in rural as well as urban settings.

Percutaneous exposure to blood through needlesticks and cuts with other sharp instruments are visible and efficient modes of transmission, but reported injuries do not account for the majority of infections in healthcare workers (Ex. 6-65, Ex. 6-427). This fact often goes unrecognized by worker's compensation boards, which sometimes deny coverage to infected workers unless they had reported a discrete needlestick or similar injury from a HBsAg positive patient. Some workers doing traumatic procedures get cuts, needlesticks or large blood exposures so frequently that they do not bother to
Transmission Via Environment

Transmission of HBV infection from exposure to contaminated environmental surfaces has been documented to be a major mode of HBV spread in certain settings, particularly hemodialysis units (Ex. 6-30, Ex. 6-449, Ex. 6-490, Ex. 6-481). The virus can survive for at least one week dried at room temperature on environmental surfaces, and medical procedures as well as disinfection and sterilization techniques must be adequate to prevent the spread of this virus (Ex. 6-422, Ex. 6-458). HBV contaminated blood from the surface of dialysis machines and carried on the hands of medical personnel to patients has been postulated as the mechanism of transmission in dialysis units. Unsterilized or improperly sterilized acupuncture needles have been implicated as the cause of large outbreaks of HBV infection (Ex. 6-439). Potential problems of environmental contamination in the dental operative environment have been discussed in the CDC guidelines for dental operations (Ex. 6-490).

HBV is thought to be far less resistant to sterilization and disinfection procedures than microbial endospores or mycobacteria used as reference criteria (Ex. 6-421). Any sterilization or disinfection procedure or product approved by the Environmental Protection Agency as a sterilizing agent or high level disinfectant will kill the virus if used as directed. Dilute solutions of sodium hypochlorite (household bleach) are particularly effective and inexpensive, although they may be corrosive or damaging to certain materials. Certain low-level "germicides" such as quaternary ammonium compounds are not considered to be effective against the virus (Ex. 6-422). Unfortunately, soaking medical and dental instruments in these solutions is a common and potentially dangerous procedure, since health workers may handle the sharp instruments soaked in these solutions with a false sense of security.

Methods Of Control

Hepatitis B Vaccine. In 1982 a safe, immunogenic and effective HB vaccine was licensed in the U.S. and was recommended for use in healthcare workers with blood or needle exposure in the workplace (Ex. 6-199). A second vaccine, produced in yeast by recombinant technology was licensed in 1987, and additional vaccine licenses are expected in the near future (Ex. 6-200). In 1988, CDC estimated that 1.4 million persons have received these vaccine in the U.S., and an estimated
a requirement of the proposed standard. This prescreening is often cost-effective, demonstrating that prior HBV infection and the costs of testing and vaccination. An algorithm to assist with this determination has been published by the ACIP (6-199).

Discussions on the issues surrounding the option of post-vaccination testing have also been published; and at this time post-vaccination testing is not considered necessary unless the response to vaccine is anticipated.

**Post-Exposure Prophylaxis**

Percutaneous and mucous membrane exposures to blood occur and will continue to occur in the healthcare setting (Ex. 6-431, 6-468). HBV infection is the major infectious risk that occurs from these exposures, and needlesticks from HBsAg-positive individuals will infect 7% to 30% of susceptible healthcare workers (Ex. 6-27, Ex. 4-28). Fortunately, effective post-exposure prophylaxis exists for HBV exposures if appropriate protocols are followed. Hepatitis B Immune Globulin given in two injections one month apart is about 75% effective in preventing clinical hepatitis B if it can be given within seven days of an HBsAg-positive needlestick. The addition of HB vaccine may substantially increase the post-exposure efficacy over that of HBIG alone and will also provide long-term protection (Ex. 6-199). HB vaccine is recommended for any previously unvaccinated healthcare worker who has a needlestick or other percutaneous accident with a sharp instrument.

**Non-A, non-B Hepatitis**

Non-A, non-B hepatitis in the United States is caused by more than one viral agent, and remains a diagnosis of exclusion (Ex. 6-437, Ex. 6-429, Ex. 6-449). Despite intensive research over the last decade, little progress was made in identifying the causative agents, and no serologic (blood) test is available to detect or study this infection directly. Nevertheless, in the past year, a candidate virus has been detected, and intensive work to verify this as the non-A, non-B virus(es), and an estimated 3-8% of healthy blood donors appear to chronically carry this virus (Ex. 6-429, Ex. 6-449). Non-A, non-B hepatitis viruses cause not only acute hepatitis, but also chronic hepatitis; 40-60% of infections lead to development of chronic hepatitis, with potential for progression to cirrhosis and for infectivity to others for the duration of life (Ex. 6-429, Ex. 6-446). The amount of virus present in the blood of acutely or chronically infected persons is modest, usually <1000 infectious doses per milliliter, although occasionally up to 1000 times higher (Ex. 6-423). Thus, relative infectivity of blood is 100 to 100,000 fold lower than with hepatitis B virus. Relative infectivity of other body fluids is not known.

The predominant mode of non-A, non-B transmission in the U.S. is, like that of HBV, bloodborne, and some evidence indicates that non-A, non-B hepatitis also presents an occupational risk to healthcare workers. About 5-9% of non-A, non-B cases occur in persons who work in healthcare professions, and in one study such persons were at significantly elevated risk of infection (Ex. 6-39, Ex. 6-47; Ex. 6-217). In addition, at least one episode of transmission of non-A, non-B hepatitis from an acutely infected patient to a nurse by needlestick has been reported (Ex. 6-455). Furthermore, non-A, non-B hepatitis transmission from infected patients to other patients and to staff has been reported from hemodialysis units; several outbreaks have been observed in this setting, and an incidence of 1.8% of non-A, non-B hepatitis among hemodialysis patients nationwide was observed in 1983 (Ex. 6-462, Ex. 6-386). While pathways of transmission in this setting have not been rigorously documented, bloodborne transmission by environmental contamination, similar to that of HBV, can be presumed to occur.

Given the facts that non-A, non-B hepatitis in the United States is largely due to a bloodborne virus, that between 3-8% of healthy persons likely are virus carriers, and that up to 50% of infections may progress to chronic liver disease, non-A, non-B hepatitis must be considered a potentially important risk in the workplace. The evidence of lower concentration of virus in blood of infected persons, and paucity of data clearly demonstrating this as an occupational illness of healthcare workers suggest it is likely to be less important than HBV; nevertheless, availability of specific tests in the next few years may better address the magnitude of risk.

Because the primary mode of transmission is bloodborne, and a large asymptomatic carrier reservoir exists, precautions to prevent non-A, non-B hepatitis transmission in the workplace are identical for those of other blood-borne viruses such as HBV (Ex. 6-461, Ex. 6-74, Ex. 6-426). Several studies have evaluated the efficacy of immunoglobulin (IG) prophylaxis following parenteral exposure, but results have been equivocal (Ex. 6-447, Ex. 6-436). Nevertheless, the CDC considers it reasonable to give IG as treatment to a healthcare worker after percutaneous exposure to blood from a known non-A, non-B infected patient (Ex. 6-199).

**C. Human Immunodeficiency Virus**

**Introduction**

In June of 1981, the first cases were reported in the United States of what was to become known as Acquired Immunodeficiency Syndrome (AIDS) (Ex. 6-362). Investigators described a new clinical entity characterized by Pneumocystis carinii pneumonia (PCP) and Kaposi's sarcoma (KS) that had developed in young, homosexual men without a known underlying disease or a history of immunosuppressive therapy (Ex. 6-350, Ex. 6-380).

By early 1982, 159 AIDS cases had been identified in 15 states, the District of Columbia and 2 foreign countries. All but 1 of these were men, over 92% of whom were homosexual or bisexual (Ex. 6-359). By the end of 1982, cases of AIDS were reported among children (Ex. 6-360), intravenous (IV) drug users (Ex. 6-360), blood transfusion recipients (Ex. 6-360), hemophilia patients treated with clotting factor concentrates (Ex. 6-360), and Haitians (Ex. 6-349). In 1983 the disease was also documented among female sexual partners of male IV drug users in the U.S. and among Africans (Ex. 6-349). By the close of 1985, all 50 states, the District of Columbia and three U.S. territories had reported AIDS cases (Ex. 6-350).

During 1983 and 1984, French and American scientists independently isolated a human virus associated with AIDS. Dr. Luc Montagnier and co-workers, of the Institut Pasteur in Paris, called it lymphadenopathy associated virus (LAV). Dr. Robert Gallo and co-workers at the National Cancer Institute identified this virus as human T-cell lymphotrophic virus type I (HTLV-I) (Ex. 6-380). Eventually human immunodeficiency virus type 1 (HIV-1) became the universally accepted term for the virus (Ex. 6-383). (In this
document, unless specifically noted. HIV refers to HIV-1.)

The Centers for Disease Control estimates that in the United States, between 1 million and 1.5 million persons are infected with HIV-1 (Ex. 6-356). As of February, 1989, 88,096 cases of AIDS had been reported to the CDC, at least 50,670 (57.5%) of whom had died (Ex. 6-478). Although the rate of spread of HIV-1 in the future is unknown, scientists with the U.S. Public Health Service (Ex. 6-356) have estimated that in the United States alone, a cumulative total of more than 365,000 cases of AIDS will have been reported by 1992 with 80,000 new cases diagnosed during that year. It is projected that there will be 68,000 deaths that year and 263,000 cumulative deaths. It is expected that a total of 172,000 AIDS patients will require hospital care in 1992. Of perhaps greater importance for healthcare workers is the 1 million-1.5 million persons who are infected with HIV, often unknowingly so, and who require medical treatment for unrelated conditions. For example, in a study examining 203 anonymous serum samples from a group of critically ill or severely injured patients treated at the Johns Hopkins University Hospital Department of Emergency Medicine (serving many indigent patients in an urban area), Baker and co-workers (Ex. 6-111) found HIV antibody in 3% as detected by both enzyme-linked immunoassay (ELISA) and Western blot. In a subgroup of this population, trauma victims between the ages of 25 and 34, 16% were seropositive for HIV. These individuals were bleeding and their treatment involved multiple invasive procedures. In a more recent study at an inner city emergency department, Kelen and co-workers tested blood samples from 2,302 consecutive adult patients for the presence of HIV antibodies. One hundred and nineteen patients (5.2%) were seropositive for HIV, 92 (4%) of whom had “unrecognized HIV infection” (Ex. 6-370).

There are published reports of 25 healthcare workers who apparently were infected with HIV through occupational exposure to blood or other potentially infectious materials. Some infections are likely to go unrecognized for several years until the HIV-infected individual develops AIDS. The number of documented HIV seroconversions among healthcare workers is low at present. However, if effective preventive procedures are not instituted, it is likely to increase as the number of infected individuals requiring healthcare increases.

The increasing number of individuals with AIDS, the large number of unidentified HIV infections, and the reports of occupational infection all indicate that healthcare workers are at risk for occupationally acquired HIV infection.

The Virus

HIV is a member of a group of viruses known as human retroviruses. Its genetic material is ribonucleic acid (RNA) rather than deoxyribonucleic acid (DNA), the genetic material found in most living organisms. The virus particle is comprised of a core containing the RNA and viral enzymes surrounded by an envelope consisting of lipids and proteins (Ex. 6-380, pp. 131-134).

Because they lack the cellular machinery necessary to reproduce, all viruses must reproduce intracellularly, that is, within the host cell. HIV replicates in human macrophages and T4 lymphocytes, two types of human cells that are vital components of the immune system. T4 lymphocytes and a few other cell types have protein molecules on their surfaces called CD4 antigens or receptors. HIV particles bind with the CD4 receptor sites of the host cells and then release their viral RNA. The RNA is then transcribed by viral enzymes into double-stranded DNA that is incorporated into the DNA of the host cell. The viral DNA then serves as a template to produce more virus particles. The transcription of RNA to DNA is the reverse of what occurs in most organisms and thus HIV is called a retrovirus. The process occurs with the aid of the viral enzyme reverse transcriptase, which is considered to be a marker for retrovirus production (Ex. 6-384; Ex. 6-178; Ex. 6-380, pp. 186-249).

HIV gradually depletes the number of cells which are essential for host immune function, rendering the infected individual increasingly susceptible to opportunistic infections (Ex. 6-345).

Circulating macrophages are also considered a reservoir as well as another target for HIV infection. Since some macrophages can circulate freely throughout the body, they may actually transport HIV to the brain which may lead to neurologic complications (Ex. 6-394).

Serologic Testing

Infection with HIV may be identified through testing the blood for the presence of HIV antibodies. Tests were first licensed for use in the United States in 1985 (Ex. 6-380, pp. 1-17) and have been used routinely to screen donated blood, blood components and blood products, and by physicians and clinics to diagnose HIV infection in patients.

The military also uses the antibody tests to screen recruit applicants and active duty personnel for HIV infection (Ex. 6-380, pp. 1-17). Although the antibodies do not appear to defend or protect the host against HIV, they serve as markers of viral infection. Most people infected with HIV have detectable antibodies within 8 months of infection, with the majority generating detectable antibodies between 6 and 12 weeks (Ex. 6-204). There have been a few reports of seroconversion as late as 14 months after infection (Ex. 6-183).

The enzyme-linked immunosorbent assay (ELISA or EIA) technique used to detect HIV antibodies is sensitive, economical and easy to perform. However, as with all laboratory determinations, this test can produce a false positive result, that is, the test gives a positive result when HIV antibody is not present. Therefore, current recommendations include repeating the ELISA test if the first test was positive. If the second test is also positive, a more specific test, usually employing the Western blot technique, is used to validate the ELISA results. A positive ELISA test and a positive Western blot result indicate the presence of HIV antibodies and HIV infection (Ex. 6-345).

Although many new tests are still in the experimental stages, one that is being developed uses the polymerase chain reaction (PCR) technique. This test detects integrated viral DNA rather than antibody and it may have the potential to detect the HIV infection earlier than currently available antibody tests (Ex. 6-329).

Transmission

HIV has been isolated from human blood, semen, breast milk, vaginal secretions, saliva, tears, urine, cerebrospinal fluid, and amniotic fluid; however, epidemiologic evidence implicates only blood, semen, vaginal secretions and breast milk in the transmission of the virus (Ex. 6-317).

Documented modes of HIV transmission include: engaging in sexual intercourse with an HIV-infected person; using needles contaminated with the virus; having parenteral, mucous membrane or non-intact skin contact with HIV-infected blood, blood components or blood products (Ex. 6-349); receiving transplants of HIV-infected organs and tissues including bone (Ex. 6-327, Ex. 6-310), or transfusions of HIV-infected blood (Ex. 6-349); and perinatal transmission (from mother to child around the time of birth) (Ex. 6-349).
HIV is not transmitted by casual contact. Studies evaluating nearly 500 household contacts of individuals diagnosed with AIDS reveal no cases of HIV infection of household members who had no other risk factors for the virus (including no sexual contact with or exposure to blood from the infected person) (Ex. 6-349). Friedland and Klein (Ex. 6-349) examined household members who lived with a person with AIDS for at least 3 months and within an 18-month period prior to the onset of symptoms in the infected person (during which time infection was presumably present). Other household members had been unaware of the infected individual's HIV status, and had not taken precautions during this time period. This study produced no evidence that HIV was transmitted by shaking hands or talking, by sharing food, eating utensils, plates, drinking glasses or towels, using the same household facilities or by "personal interactions expected of family members" including hugging and kissing on the cheek or lips. Other studies have shown that HIV is not transmitted by mosquitoes or other animals (Ex. 6-328).

The vast majority of people with AIDS in the United States can be placed in known transmission categories and the proportion of infected persons associated with each group has remained relatively stable since reporting began in this country in 1981. For adults and adolescents, the transmission categories are shown in Table 1.

### Table 1 — AIDS TRANSMISSION CATEGORIES

<table>
<thead>
<tr>
<th>Transmission Group</th>
<th>Percent of cumulative total AIDS cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homosexual/bisexual men</td>
<td>62%</td>
</tr>
<tr>
<td>Intravenous drug users</td>
<td>20%</td>
</tr>
<tr>
<td>Homosexual/bisexual men who are also IV drug users</td>
<td>7%</td>
</tr>
<tr>
<td>Heterosexual persons</td>
<td>4%</td>
</tr>
<tr>
<td>Transfusion recipients</td>
<td>2%</td>
</tr>
<tr>
<td>Persons with hemophilia/coagulation disorders</td>
<td>1%</td>
</tr>
<tr>
<td>Undetermined</td>
<td>3%</td>
</tr>
</tbody>
</table>

2 Includes persons who have had heterosexual contact with a person with AIDS or at risk for AIDS or who have no other identified risks but were born in countries in which heterosexual transmission is believed to play a major role although the precise means of transmission have not been fully defined.
3 Includes persons for whom risk information is incomplete due to death, refusal to be interviewed or loss to follow-up, patients still under investigation, or who reported only to have had heterosexual contact with a prostitute; interviewed patients for whom no specific risk was identified and one healthcare worker who seroconverted to HIV and developed AIDS after a documented needlestick exposure to blood.

In the U.S., more than 1,000 cases of AIDS have been reported in children (Ex. 6-364). Most (78%) of the cases are children born to mothers infected with the virus (Ex. 6-349, Ex. 6-350). These mothers transmitted the virus to their children prenatally, during birth or during infancy through breast-feeding although the latter is rare (Ex. 6-349). Other cases in children are in hemophiliacs (6%) and transfusion recipients (13%) (Ex. 6-349).

Although the efficiency for most routes of HIV transmission is unknown, some routes of transmission are clearly more efficient than others. The risk of infection from receipt of transfused blood from an HIV-infected donor is approximately 90% (Ex. 6-371). The risk of perinatal transmission from an HIV-infected mother is estimated to be 30-50% or higher (Ex. 6-384, Ex. 6-349).

Besides the particular route of transmission, other variables contributing to transmissibility may include susceptibility of the host, the virulence of the particular "HIV isolate" or strain, the stage of infection of the source, and the dose of virus and the size of inoculum transmitted (Ex. 6-348, Ex. 6-349). This last factor, the actual amount of virus, may be very important in the likelihood of transmission since it appears there is a greater probability of infection from HIV contaminated blood transfusions (890 infections per 1,000 persons transfused with contaminated blood) than from accidental needlesticks with needles that have been contaminated with HIV (3-5 infections per 1,000 persons injured with contaminated needles) (Ex. 6-384; Ex. 6-345; Ex. 6-371).

### Human Immunodeficiency Virus Type-2

A case of AIDS in a person from Africa, caused by another human retrovirus, human immunodeficiency virus type 2 (HIV-2), was diagnosed and reported in the United States in December, 1987 (Ex. 6-308). HIV-2 appears to be similar to HIV-1 in modes of transmission and natural history but has not yet been studied in as much detail. Although HIV-2 is unquestionably pathogenic, there is still much to be learned regarding its epidemiology, pathogenesis and efficiency of transmission. Although only one case of HIV-2 has been reported in the U.S., the infection is endemic in West Africa, where it was first linked with AIDS in 1986. There have also been cases of HIV-2 infection reported among West Africans living in Europe.

Serologic tests licensed for detecting HIV-1 can detect only 42-92% of HIV-2 infections, but HIV-2 surveillance is being conducted in the United States to monitor the frequency of occurrence using specific tests not yet available commercially (Ex. 6-306).

### Clinical Manifestations of Disease

HIV adversely affects the immune system, rendering the infected individual vulnerable to a wide range of clinical disorders. These conditions, some of which tend to recur, can be aggressive, rapidly progressive, difficult to treat, and less responsive to traditional modes of treatment. They usually lead to the death of the HIV-infected patient (Ex. 6-361). The CDC has divided the disease progression into several stages, depending on the type of signs or symptoms of infection. The order of groups appears to follow a basic pattern or chronology of disease regardless of mode of transmission (Ex. 6-370).

**Group I:** Within a month after exposure, an individual may experience acute retroviral syndrome, the first clinical evidence of HIV infection. This is a mononucleosis-like syndrome with signs and symptoms that can include fever, lymphadenopathy, myalgias, arthralgias, diarrhea, fatigue, and rash. Acute retroviral syndrome is usually self-limiting and followed or accompanied by the development of antibodies (Ex. 6-270).

**Group II:** Although most persons infected with HIV develop antibodies to the virus within 6-12 weeks after exposure, most of these individuals are asymptomatic for months to years following infection. However, they can transmit the virus to others throughout this time (Ex. 6-270).

**Group III:** Although no other signs or symptoms are experienced, some HIV-infected patients will develop a persistent, generalized lymphadenopathy (PGL) that lasts more than 3 months (Ex. 6-270).

**Group IV:** The clinical manifestations of patients in this group may vary extensively. Some of these HIV-infected patients may experience "constitutional disease," also known as HIV "wasting syndrome," which may be characterized by severe, involuntary weight loss, chronic diarrhea, constant or intermittent weakness, and fever for 30 days or longer (Ex. 6-270). This syndrome in and of itself may result in death.

Epidemiologic information indicates that most persons who are infected with HIV will eventually develop AIDS (Ex. 6-384). AIDS can result in severe opportunistic infections that an individual with a normal immune...
system would only rarely experience, as well as a wide range of neurologic and oncogenic or neoplastic processes (Ex. 6-270). Individuals with AIDS may develop HIV-related symptoms such as apathy, dementia, myelopathy or peripheral neuropathy. This may occur when HIV infects mononuclear cells present in the cerebrospinal fluid surrounding the brain and spinal cord or infects these cells within the brain or spinal cord. Persons with dementia experience varying degrees of cognitive disability or impairment of intellectual function and motor disability or dysfunction. Effects ranging from apathy and depression to memory loss and severe dementia may interfere with a person's occupation as well as activities of daily living and can ultimately be fatal (Ex. 6-380, pp. 548-573; Ex. 6-270). In addition, the virus is capable of affecting the peripheral nervous system causing severe pain and weakness or numbness in the limbs (peripheral neuropathy) (Ex. 6-270).

According to CDC's case definition (Ex. 6-157), there are specific diseases that are considered indicators of AIDS if laboratory tests for HIV were not performed or gave inconclusive results and no other known causes of immunodeficiency are present. Among these are parasitic diseases such as Pneumocystis carinii pneumonia, the most common opportunistic infection and cause of death in AIDS patients; fungal diseases such as candidiasis of the esophagus, trachea, bronchi or lungs; viral diseases such as cytomegalovirus disease of an organ other than the liver, spleen or lymph nodes; cancer/ neoplastic diseases such as Kaposi's sarcoma affecting persons under 60 years of age; and bacterial infections such as Mycobacterium avium complex (Ex. 6-157; Ex. 6-361).

In addition to the diseases listed above there are diseases caused by organisms such as disseminated or extra-pulmonary Mycobacterium tuberculosis (TB) which may be considered indicative of AIDS if substantiated by reactive HIV-antibody tests (Ex. 6-157).

Unlike adults, children under 13 years of age can be classified as having AIDS if they experience lymphoid interstitial pneumonia or pulmonary lymphoid hyperplasia (LIP-PLH complex). Children who are seropositive for HIV can be classified as having AIDS if they experience recurring serious bacterial infections such as septicemia, pneumonia, meningitis, bone or joint infections or abscess of an internal organ or body cavity caused by Haemophilus, Staphylococcus or other pyogenic bacteria (Ex. 6-157).

AIDS is primarily managed by treating clinical disease symptoms, but conventional therapy cannot reverse the immunodeficiency (Ex. 6-361). Currently, researchers are testing experimental drugs and conducting a number of treatment protocols on patients at various stages of infection or disease. At this time, only one antiviral drug, Zidovudine or Retrovir TM, (formerly known as azidothymidine or AZT) has been approved by the FDA for some patients, specifically those who have experienced Pneumocystis carinii pneumonia (PCP), or are symptomatic for AIDS-related illness and have less than 200 T4 cells/ml (Ex. 6-479).

Although some patients have had to discontinue the drug due to serious side effects, clinical trials have shown the drug to prolong the life of AIDS patients (Ex. 6-364). There is no vaccine to prevent HIV infection (Ex. 6-361).

Occupational Exposure And HIV Infections

Occupational transmission of HIV has been documented in healthcare workers. Twenty-five cases of HIV infection associated with occupational exposure are summarized below. These cases represent a spectrum of healthcare personnel including, among others, nurses, laboratory workers and a dentist. In 10 of these cases exposure to the blood of HIV infected individuals occurred by needlestick. Two infections were believed to have resulted from cuts with sharp, HIV-contaminated objects. In 7 cases, exposure occurred via mucous membrane or non-intact skin. Two workers were exposed to highly concentrated volumes of HIV: 1 by a cut with a sharp, HIV-contaminated object and 1 through skin exposure.

For the 25 cases, HIV status was determined by HIV-antibody testing. Baseline serologic data indicating a non-reactive HIV-antibody status post-exposure was available for at least 18 of the individuals, all of whom were later determined to have seroconverted to an HIV-antibody-positive status. All 25 denied other known risk factors for HIV infection, but in cases where the baseline serologic data were unknown, other modes of transmission cannot be ruled out. Nevertheless, all cases were investigated for risk factors and none were identified. In addition to these cases, as of September 1988 there were at least 44 healthcare workers with AIDS for whom no risk factors have been identified after thorough investigation (Ex. 6-378), providing further, though not as strong, evidence of occupational transmission.

Case Reports

Case 1: A hospital healthcare worker sustained an accidental self-inflicted injection of "several milliliters of blood while obtaining blood in a vacuum collection tube from an AIDS patient" (Ex. 6-365). The healthcare worker subsequently seroconverted to an HIV-antibody-positive status and has since developed AIDS. Having determined there were no other HIV risk factors for this individual, investigators concluded the worker acquired the infection occupationally.

Case 2: In November 1983, a previously healthy, 33 year old United States Navy hospital corpsman punctured his fingertip while disposing of a phlebotomy needle used to draw blood from a patient who was later diagnosed with Pneumocystis carinii pneumonia and serologically tested HIV-positive (Ex. 6-337). Upon learning of his diagnosis two weeks after the incident, the corpsman submitted to HIV serology testing on a monthly basis and was HIV-negative for 3 months. Five months after the incident, he experienced a characteristic acute retroviral syndrome, which was self-limiting. Six months after the incident he tested HIV-positive. He reported a negative history of other risk factors for HIV, and his wife was seronegative.

Case 3: Weiss and co-workers (Ex. 6-187) reported that a laboratory worker, who worked with concentrated HIV-1, tested seropositive for the virus (See EPIDEMIOLOGIC STUDIES). Clinical evaluation revealed no signs of symptoms of HIV-related illness. As part of routine laboratory duties, this individual was involved in several possible exposure circumstances such as decontaminating equipment, cleaning up spills or touching potentially contaminated surfaces with gloved hands. Virus-positive culture fluid had occasionally leaked from equipment and contaminated centrifuge rotors. Although reportedly using Biosafety level 3 precautions, the subject was not fully knowledgeable with and did not strictly follow these practices all of the time.

The subject did not recall any direct skin exposure but did report having had a nonspecific dermatitis on the arm, although the "affected area was always covered by a cloth laboratory gown." The individual also reported incidents where he had pinholes or tears in his gloves and had to change them immediately.

Strains of HIV-1 isolated from different individuals generally differ significantly, but strains of HIV-1 isolated from this subject was indistinguishable from 1 of the 2 predominant HIV genotypes this individual worked with in the laboratory.
Although no specific exposure incident had been identified, the investigators concluded that the subject acquired HIV in the laboratory, most likely through undetected skin contact with the concentrated virus.

Case 4: A female phlebotomist reported that blood splattered on her face and in her mouth when the top of a 10-ml vacuum blood collection tube flew off while she was collecting a patient's blood (which subsequently tested HIV-positive) (Ex. 6-108). The HCW was wearing gloves and glasses and reported that no blood got in her eyes. She reported no open wounds but did have facial acne. She washed off the blood immediately after exposure. Her blood tested HIV-negative one day post-exposure and 8 weeks later. However, when donating blood 9 months after exposure, she was HIV-antibody positive. She denied having other known risk factors for HIV.

Case 5: A female medical technologist was exposed to a blood spill that covered most of her hands and forearms while she was manipulating an apheresis machine (Ex. 6-109), a machine that separates blood components, retains some, and returns the remainder to the donor. Although she was not wearing gloves, she did not report any open wounds on her hands or any mucous membrane exposure. However, she did have dermatitis on her ear and may have touched that ear.

Eight weeks after the incident she experienced symptoms of acute retroviral syndrome. She was HIV-negative 5 days post-exposure; however, 3 months after exposure she was HIV-antibody positive. She denied having other known risk factors for AIDS. Her husband also denied any risk factors for AIDS and tested HIV-seronegative.

Case 6: Neison-Vernant and co-workers (Ex. 6-93) reported that a “24-year-old female student nurse pricked the fleshy part of her index finger with a needle used to draw blood from an AIDS patient.” She did not recall injecting blood. Two months later signs and symptoms of acute retroviral illness appeared, including fever and a macular eruption lasting 3 days. Although she tested HIV-negative 1 month after the incident, she tested positive 6 months after exposure. She denied all other risk factors for HIV and her husband tested HIV-antibody negative 62 days after his wife’s exposure incident.

Case 7: Michelet and co-workers (Ex. 6-369) reported a case of occupationally acquired HIV infection in a female nurse in France. Having drawn a blood sample in a vacuum tube from an individual with AIDS, she stuck her finger with the large-bore needle of the adapter, but reportedly did not inject any blood. Immediately after the incident, she placed her finger in 5% sodium hypochlorite solution in accordance with the hospital’s guidelines. Twenty-three days after exposure, she developed signs and symptoms of acute retroviral syndrome, including abdominal cramps, nausea, vomiting, and diarrhea. She later experienced anorexia, fatigue and facial palsy.

Clinical evaluation found generalized lymphadenopathy. Although she tested HIV-antibody negative 13 days after the incident she was HIV-antibody positive 71 days post-exposure. Investigators failed to identify any risk factor for HIV for the nurse or her husband, who tested HIV-antibody negative 62 days after his wife’s exposure incident.

Case 8: A nurse from England (Ex. 6-369) reported a case of occupationally acquired HIV infection in a female nurse in France stuck her finger superficially while resheathing a hypodermic needle (Ex. 6-369). A small amount of blood may have been injected as well. Signs and symptoms of acute retroviral syndrome developed. Although HIV-antibody negative 27 days post injury, she was determined to be HIV-positive on day 40. She denied all other known risk factors for HIV.

Case 9: Oksenhendler and co-workers (Ex. 6-18) reported that a female nurse in France stuck her finger superficially while recapping a needle contaminated by bloody pleural fluid from a patient positive for both HbsAg and HIV. Immediately post-exposure she received the HBV vaccine and specific immunoglobulins. She experienced acute retroviral syndrome including fever, fatigue and vomiting 25 days after the incident. Fifty-three days after exposure, she developed an acute “anicteric” hepatitis (possibly related to the primary HIV infection.) Although she tested HIV-negative after the exposure (days 1 and 13), she tested HIV-positive 16 days after her husband tested HIV-seronegative for HIV 110 days after the incident.

Case 10: A nurse from England received a needlestick injury to a finger while resheathing a hypodermic needle on a syringe containing an AIDS patient’s blood from an arterial line (Ex. 4-41). A small amount of blood may have been injected as well. Signs and symptoms of acute retroviral syndrome presented 13 days after exposure with a rash developing 17 days after the incident.

Although she tested HIV-negative 27 days post injury, she was determined to be HIV-positive on day 49. She denied all other known risk factors for HIV.

Case 11, 12 and 13: Marcus and co-workers (Ex. 6-372) reported 3 cases of healthcare workers who seroconverted to an HIV-antibody-positive status. One healthcare worker sustained a deep needlestick injury inflicted by another worker while attempting to resuscitate an AIDS patient. The healthcare worker was HIV-antibody and antigen negative the day after the exposure. Four weeks after the incident the worker experienced fever, “shaking chills,” night sweats, lymphadenopathy, and malaise which lasted about 4 days. One hundred twenty-one days after the exposure the worker tested HIV-seropositive. The healthcare worker denied other known risk factors for HIV and a recent sex partner tested HIV-seronegative.

A second healthcare worker accidentally stuck herself on two occasions with needles that had been used on HIV-infected patients. The first exposure occurred while recapping a needle that had been used on a patient with AIDS. Ten days later the worker stuck herself with a needle that had been used to draw blood from a symptomatic HIV-infected individual. “After removing the tube of blood from the plastic needle holder, the healthcare worker placed the needle holder upright on its base, such that the needle was pointed vertically into the air. The healthcare worker then turned away and subsequently injured herself on the exposed needle.” The worker tested positive for HIV-antibody and antigen 21 after the first exposure (11 days after the second.) She developed an acute viral illness four weeks after the first incident, characterized by shaking chills, dehydration, nausea, malaise, bilateral lymphadenopathy and a weight loss of more than 10 pounds. During this illness she was HIV-antibody negative; however, lymphocyte cultures were positive for HIV-antigen and reverse transcriptase, an enzyme which serves as a marker for HIV. The healthcare worker tested HIV-antibody positive on day 121 after the first exposure (111 days after the second exposure.) Four months after 1st exposure incidents, the worker’s spouse tested HIV-antibody negative (See EPIDEMIOLOGIC STUDIES).

A third case, a healthcare worker, received a deep intramuscular needlestick injury with a large bore needle and syringe unit visibly contaminated with blood from an AIDS patient (Ex. 4-39, Ex. 6-367). Fourteen months after the first exposure, acute retroviral syndrome developed. Although HIV-antibody negative 9 days post-exposure, the healthcare worker was determined HIV-antibody positive on day 184. The worker and the worker’s spouse denied
any other risk factors for AIDS and the spouse tested HIV-antibody negative 239 days after the incident (See EPIDEMIOLOGIC STUDIES).

Case 14: Marcus and co-workers (Ex. 6-377) reported a case where a female nurse received a puncture wound from a colonic biopsy needle (visibly contaminated with blood and feces) used in an AIDS patient. She tested HIV-positive approximately 10 months after exposure although there were no serologic baseline data before or immediately after the incident. She denied other risk factors for AIDS; however, her sexual partner also tested HIV-positive approximately 10 months after exposure. She did not report having open wounds or exudative dermatitis on her hands. One month after the child tested HIV-positive, the mother was determined to be seronegative for HIV. However, 4 months later she was determined to be HIV-antibody-positive. She reported a negative history for other risk factors for HIV for herself and the child. The child's father was seronegative for HIV. Investigators concluded the mother most probably acquired the infection by providing her infected child healthcare that involved extensive exposure to blood and body fluids without using infection control practices.

Case 15: Applebaum (Ex. 6-378) reported a case of a 32-year-old mother tested HIV-positive subsequent to providing care to her infected hemophiliac. Beginning 11 days, hands, eyes and mouth heavily splashed" with blood from an HIV-infected patient with AIDS, he had treated blood donated 16 weeks after the second exposure and was found HIV-positive. Although he did not recall treating a patient with AIDS, he had treated patients at high risk for HIV infection after sustaining a deep needlestick injury with an HIV-contaminated needle (See EPIDEMIOLOGIC STUDIES).

Case 16: Marcus and co-workers (Ex. 6-379) reported a case of a healthcare worker who acquired HIV infection after sustaining a deep needlestick injury with an HIV-contaminated needle. The worker had been followed for at least 90 days after the exposure incident and had not reported any signs or symptoms of acute-retroviral illness.

Case 17: Groopman and co-workers (Ex. 6-334) reported that a 37-year-old intensive care nurse in Italy “had her hands, eyes and mouth heavily splashed” with blood from an HIV-infected hemophiliac. Beginning 11 days post-exposure, the nurse developed signs and symptoms of acute retroviral illness including fever, fatigue, chills, arthralgias, cervical and axillary lymphadenopathy and arthritis. She was hospitalized 18 days after the incident due to the severity of her symptoms plus progressive increases of aminotransferase levels. During her 55-day hospital stay the worker developed an acute, anicteric non-A non-B hepatitis, which may have been associated with HIV infection. HIV antigen was detected in her blood on day 21 and by day 43 she had seroconverted to an HIV-antibody-positive status.

Case 18: A 32-year-old mother tested HIV-antibody positive at 24 months of age. Although the mother did not report any needlestick or other parenteral exposure to the child’s blood, she recalled having had frequent hand contact with the child’s blood and body fluids. She did not wear gloves and did not wash her hands immediately after exposure. She did not report having open wounds or exudative dermatitis on her hands. One month after the child tested HIV-positive, the mother was determined to be seronegative for HIV. However, 4 months later she was determined to be HIV-antibody-positive. She reported a negative history for other risk factors for HIV for herself and the child. The child’s father was seronegative for HIV. Investigators concluded the mother most probably acquired the infection by providing her infected child healthcare that involved extensive exposure to blood and body fluids without using infection control practices.

Case 19: A laboratory worker apparently became infected in a laboratory accident (Ex. 6-187, Ex. 6-386, Ex. 6-312). He handled large volumes of HIV in a high containment laboratory under contract with NIH, performed techniques to concentrate the virus as part of a commercial process and reportedly followed biosafety guidelines. He was tested and found to be HIV-seropositive. The lab worker was not informed of his HIV status until 18 weeks after he tested HIV-positive. At that time, he recalled having cut his finger with a blunt stainless steel needle while cleaning a piece of contaminated equipment. He had tested HIV-negative 4 to 9 months prior to the laboratory incident but tested HIV-positive 6 to 9 months post exposure. Biosafety officials were of the opinion that the incident probably caused the infection. The laboratory worker has not participated in any studies that could determine whether he is infected with a laboratory strain of HIV.

Case 20: Klein and co-workers (Ex. 6-386) reported a male dentist who had tested HIV-seropositive (See EPIDEMIOLOGIC STUDIES). He denied having other risk factors for the virus. Although he did not recall treating a patient with AIDS, he had treated patients at high risk for HIV infection. He reported having frequent open lesions or “obvious breaks in the skin” on his hands; however, he only intermittently used personal protective equipment. His wife, although refusing to be tested for HIV, denied other HIV-risk factors. There was no report of baseline or convalescent serology and exposure to HIV-positive blood cannot be documented (See EPIDEMIOLOGIC STUDIES).

Case 21: A healthcare worker applied pressure to an HIV-infected patient’s arterial catheter insertion site to stop bleeding (Ex. 6-109). During the procedure, she may have had a small amount of blood on her index finger for 20 minutes before washing her hand. She did not wear gloves during the procedure and although she reported no open wounds, her hands were chapped. Twenty days after exposure, she developed symptoms of acute retroviral syndrome lasting 3 weeks. Blood she had donated 8 months prior to the exposure was HIV-negative. However, blood donated 16 weeks after the incident was HIV-positive. She denied having other known risk factors for HIV. No baseline data or serologic testing results were obtained immediately following exposure for this case.

Case 22: A female healthcare worker received accidental needlestick injuries when drawing blood from AIDS patients in two incidents separated in time by 4 months (Ex. 6-258). She had her first blood test for HIV 6 months after the second exposure and was found HIV-positive. Although previously healthy, she developed a persistent mild lymphadenopathy 3 months after the second incident and intermittent diarrhea which started 5 months after that incident. She denied other HIV risk factors. Her long-term sex partner also denied any HIV risk factors, and he repeatedly tested HIV-antibody-negative over an 8-month period following the healthcare worker’s positive test result. HIV was obtained from the man’s peripheral lymphocytes within 13 months after the second incident but could not be obtained several months later. Heterosexual transmission could not be ruled out for the healthcare worker but seems less likely than parenteral transmission in this case.

Case 23: A male laboratory worker, was found to be HIV-positive when first tested (Ex. 6-258). The worker recalled having received 2 parenteral exposures to blood from persons of unknown HIV status. He sustained an accidental needlestick and a cut on the hand while processing blood 8 and 16 months respectively prior to being tested. Although asymptomatic when tested, he has experienced transient cervical lymphadenopathy. He denied all known risk factors for HIV, but heterosexual transmission could not be ruled out in this case as no serologic data were available immediately after the exposures.
Case 24: Grint and co-workers (Ex. 6-333) reported that a 44-year-old woman from England, although not a healthcare worker, developed AIDS after providing healthcare services for a Ghanaian man with a postmortem diagnosis of AIDS. She recalled having small cuts on her hands, an exacerbation of chronic eczema, and frequent skin contact with body secretions and excretions. There was no report of baseline or convalescent serology.

Case 25: Ponce de Leon and co-workers (Ex. 6-326) reported that a 39-year-old male laboratory technician in Mexico acquired AIDS occupationally and died as a consequence of this disease. From 1971 to 1986 he worked as a laboratory technician in a company that processed blood and blood products and where infection control procedures were not "customary." He reported experiencing many accidental punctures and blood contact with his "tendons and mucosa." The worker also recalled a laboratory accident "in late 1985 in which a deep cut in his right hand was grossly contaminated with plasma." Early in 1986 he experienced an acute illness characterized by fever and lymphadenopathy lasting several days. In 1987 the worker experienced a seven-month illness characterized by persistent diarrhea, weight loss, persistent oral thrush, intermittent fever, generalized lymphadenopathy, anisocoria and signs of meningitis. He eventually was hospitalized on December 11, 1987 two weeks after dizziness, mental confusion and vomiting ensued. Tests revealed the presence of the opportunistic infection cryptococcosis. The worker tested HIV-antibody-positive and was diagnosed as having AIDS. The patient died on December 26, 1987 and therefore, subjects were enrolled only if they had had parenteral, mucous membrane or non-intact skin exposure to the blood of an HIV-infected individual.

As of July 31, 1988, a cohort of 1201 healthcare workers with exposure to HIV-contaminated blood was being followed. Of these, 751 (63%) were nurses, 164 (14%) were physicians or medical students, 134 (11%) were technicians or laboratory workers, 90 (7%) were phlebotomists, 30 (3%) were respiratory workers and 26 (2%) were housekeeping or maintenance staff. Upon enrollment the subjects provided investigators with epidemiologic data including demographic information, medical history, details of the exposure circumstances, infection control precautions used and post-exposure treatment. Nine hundred sixty-two (80%) of the subjects had sustained needlestick injuries, 103 (8%) had been cut with a sharp object, 79 (7%) had contaminated an open wound and 57 (5%) had had a mucous membrane exposure. Seven hundred seventy-nine (68%) of the exposed healthcare workers were exposed in a patient room, on a ward or in an outpatient clinic; 161 (14%) in an intensive care unit; 87 (7%) in an operating room; 94 (7%) in a laboratory; 62 (5%) in an emergency room; and 28 (2%) in a morgue.

Each subject was asked to complete a confidential questionnaire to identify nonoccupational risk factors for HIV and his wife was seronegative for HIV-antibody.

Epidemiologic Studies

A number of prospective studies and surveys have been conducted to determine occupational risks for HIV infection.

Marcus and co-workers (Ex. 6-372) reported that the Centers for Disease Control has been conducting a national prospective study beginning in 1983, to assess initially the risk of Acquired Immunodeficiency Syndrome and later, with the advent of HIV-antibody testing, the risk of Human Immunodeficiency Virus among healthcare workers exposed to the blood or body fluids of persons with HIV infection. In 1988, data were reported on the first 451 healthcare workers who had entered the study and had been tested for HIV antibody. Initially the eligibility criteria for entering the study included having been exposed to the blood or body fluids of a patient with AIDS or AIDS-related illness. Nine hundred sixty-two (80%) were thus considered seroconversions, the risk of Human Immunodeficiency Virus among healthcare workers exposed to the blood or body fluids of persons with HIV infection. In 1988, data were reported on the first 451 healthcare workers who had entered the study and had been tested for HIV antibody. Originally the subjects were followed up at 6-month intervals for a period of 3 years to detect signs of clinical AIDS. When HIV-antibody testing became available during 1985 and 1986, exposed healthcare workers were followed up at 6 weeks, 3 months, 6 months, and 12 months after the exposure incident to determine if seroconversion had occurred. Seroconversions were defined as healthcare workers who were seronegative for HIV antibody within 30 days after occupational exposure and seropositive 90 days or more after the exposure incident.

Nine hundred sixty-three subjects had been followed for at least 6 months, 860 (89%) of whom had sustained either a needlestick injury or a cut with a sharp instrument. Of these, four were seropositive yielding a seroprevalence rate of 4/860 = 0.47%. One of the four was tested for HIV-antibody 10 months after sustaining a needlestick exposure to blood of an HIV-infected patient (see CASE 14). As there was no available acute blood specimen collected within 30 days after exposure this case cannot by definition be considered a seroconversion. The remaining 3 HIV-seropositive subjects (see CASES 12, 13 and 14) had HIV-seronegative acute blood specimens and were thus considered seroconversions, yielding a seroconversion rate of 3/860 = 0.35%.

Weiss and co-workers (Ex. 6-187), conducted a prospective study to assess the risk of Human Immunodeficiency Virus (HIV-1) in laboratory workers. Invitations to participate in the study were issued to workers with possible exposure risk in 15 laboratory facilities from 6 states.

Of the 265 subjects studied, 225 had laboratory exposure (including 99 who worked with concentrated HIV and 126 who worked with blood containing HIV, non-infectious viral proteins, or cloned viral DNA). 30 worked with AIDS patients in support of the laboratory and 10 were clerical staff working in the laboratory environment. Of the 225 laboratory workers, 10 reported one or more episodes of parenteral exposure to HIV, including needlesticks or cuts, and 55 reported one or more episodes of skin contact with HIV.

Participants completed a questionnaire focusing on workplace exposure to human retroviruses, biosafety precautions used at the facility and by the subject, accidents occurring in the laboratory or other areas and the risk factors of drug use, sexual activity, transfusion and country of origin. Eight (3%) of the 265 reported high risk factors for the virus. Of the 225 workers, ten
reported parenteral virus exposure, and 35 reported 1 or more skin contacts. This indicated that they did not wear gloves at all times when working with HIV-infected material. Blood samples from all subjects were analyzed for HIV antibodies by enzyme-linked immunosorbent assay and confirmed by tests such as immunoblot and radioimmunoassays. 

One individual who worked with concentrated HIV-1 was seropositive for the virus upon entering the study (See CASE REPORTS, CASE 3). However, HIV isolated from the subject's blood was shown to be genetically identical to a strain of HIV used in the laboratory, thus strongly implicating occupational exposure as the source of infection. The authors concluded that the most plausible source of exposure was contact of the worker's gloved hand with culture supernatant fluid containing concentrated virus, followed by inapparent exposure to skin. No HIV seroconversions were identified in the other study participants during the period of prospective follow-up. The authors calculated that the rate of HIV infection was 0.48 per 100 person-years during the period of prospective follow-up. The rate of HIV infection was 0.48 per 100 person-years during the period of prospective follow-up.

Gerberding and co-workers conducted a prospective cohort study to assess the risk of transmitting the human immunodeficiency virus to healthcare workers intensively and frequently exposed to the more than 1600 patients with AIDS and AIDS-related conditions at San Francisco General Hospital (Ex. 6-375, Ex. 6-353). After inviting the hospital healthcare workers to participate in the study, investigators recruited a cohort of 623 subjects between 1984 and 1988. At the time of enrollment blood samples were drawn from each subject and tested within six months for HIV antibody. Upon entering the study, each subject was asked to complete a confidential, self-administered questionnaire designed to elicit information regarding demographic characteristics; employment history; medical history; type, frequency, duration and intensity of exposures to HIV-infected patients or laboratory specimens from such patients; a description of infection-control procedures; and non-occupational risk factors for AIDS. Subjects who described non-occupational risk factors for AIDS on the questionnaire were excluded from this study, leaving 468 for prospective follow up. Forty-four percent were laboratory technicians. Of these, 11% worked solely in AIDS units or research labs and 26% worked in the operating room, emergency room, or intensive care unit. Two hundred twelve of the subjects reported having had accidental exposure (with some having had multiple exposures) to HIV-infected blood by needlestick or by splashes to mucous membranes or non-intact skin. Of the one hundred eighty subjects who received follow-up HIV antibody testing at least 6 months after exposure, Gerberding and co-workers reported that only one, a healthcare worker who had sustained a deep needlestick injury with an HIV-contaminated needle, seroconverted to the virus (See CASE REPORTS, CASE 15) yielding a seroconversion rate of 1/180=0.47%.

Klein and co-workers (Ex. 6-396), conducted a study to assess the occupational risk of HIV among individuals working in the dental profession. Dental professionals in the boroughs of Manhattan and the Bronx in New York City received a mailing requesting their participation in the study. Others were also recruited during dental meetings in the New York City metropolitan area (between October 1985 and May 1987), and during the annual meeting of the American Dental Association in Miami Beach (October 1986).

Written consent was given and questionnaires were completed by a cohort of 1,360 dental professionals. The questionnaires addressed the issues of demographics (including type, duration and location of practice), behavior or other risk factors related to AIDS, "precautions used when treating patients, type and estimated numbers of patients treated, estimated number of accidental parenteral inoculations," and HBV vaccination status. Blood samples were then obtained and analyzed for HIV antibodies by EIA and, if reactive, confirmed by Western blot assay. The blood samples of those subjects who had not received the HBV vaccine were analyzed for HBV antibodies as well.

Twenty-five participants who reported no or "uncertain" contact with patients and 13 subjects for whom blood samples were not obtained were excluded from the study. For 13 participants who reported other risk factors for HIV, including 10 homosexual or bisexual men, 2 heterosexual intravenous drug users and 1 homosexual or bisexual IV drug user, blood samples were analyzed separately.

The remaining cohort of 1,303 subjects consisted of 1,132 dentists, 131 dental hygienists and 40 dental assistants. Most of the dentists were male and 5% were oral surgeons. Nearly all of the dental hygienists and assistants were female. About half of the participants practiced in cities where a large number of AIDS cases have been reported.

Although the vast majority of subjects reported working with AIDS patients 15% or with patients at high risk for AIDS (72%), only 31% of the dentists and 8% of dental assistants reported always wearing gloves when performing dental treatment. Most of them did use gloves intermittently. Seventy three percent of the hygienists, reported always wearing gloves while working with patients. Most of the dentists and dental hygienists used masks, eye protection and disposable gowns intermittently, although the majority of dental assistants never used these infection control procedures. Nearly all subjects who used precautions reported they had increased their use of precautions since 1983 due to concern about AIDS.

Approximately 94% of the subjects reported sustaining accidental "parenteral inoculations with sharp instruments," ranging from one to as many as 7,500 within a 5-year period. Serologic test results revealed that at least 21% of the subjects who had not received the HBV vaccine had been infected with HBV; however, only 1 subject, a male dentist, was seropositive for HIV (See CASE REPORTS, CASE 20).

Klein and co-workers concluded that there is a risk of dental professionals acquiring HIV occupationally. Because the study represents a point prevalence survey, the HIV seroconversion rate among dental personnel cannot be estimated from it.

Henderson and co-workers are conducting a prospective study that began September, 1983, to assess the risk of nosocomial transmission of HIV to healthcare workers (Ex. 6-377, Ex. 6-353). Investigators invited healthcare workers with varying degrees of occupational exposure to more than 1,000 HIV-infected patients seen at the Clinical Center at the National Institutes of Health (NIH) to participate in the study. As of October 1988, the cohort being followed consists of healthcare workers, including clinical and research laboratory personnel as well as healthcare workers providing direct patient care. Blood was obtained from each subject at the time of enrollment and every 6 months thereafter. The samples were tested for the presence of HIV antibody by ELISA and if reactive, were then confirmed by Western blot. Questionnaires designed to obtain
demographic information, job description, type and frequency of procedures performed on HIV-infected patients, type and frequency of patient blood or body fluid exposure, and type and frequency of exposure to patient specimens were given to each subject at the time of enrollment and every 6 months thereafter. Questions regarding non-occupational risk factors were not included. Two categories of exposure were defined: "physical contact with either a patient or specimen container in routine work"; and "adverse exposure, either parenterally (by a needle, scalpel or other sharp object contaminated with blood or body fluids from HIV-infected patients) or by splash to the mouth, nasal or conjunctival membranes (by blood, urine, saliva, sputum or feces from an HIV-infected patient). Three hundred fifty-nine of the subjects in the cohort reported percutaneous or mucous membrane exposure to blood or body fluids from HIV-infected patients and were evaluated separately, given more comprehensive initial and follow-up questionnaires, and were requested to provide serologic baseline samples as close as possible to the time of exposure as well as yearly samples thereafter. All adverse exposures were followed for at least 6 months (ranging from 6 to 63 months.)

For 6 subjects, blood samples were positive for HIV antibody at the time of entry into the study. None of the 6 had reported an adverse exposure to blood or body fluids. However, upon reevaluation, all 6 described having at least one other risk factor for AIDS. As there were no baseline serologic data for these subjects, it could not be determined when seroconversion occurred. Henderson and co-workers have not published reports of any seroconversion.

Kuhl and co-workers at UCLA School of Medicine conducted a prospective study to assess the occupational risk of HIV to healthcare personnel caring for AIDS patients (Ex. 6-335). Investigators enrolled a cohort of 292 female healthcare workers consisting of physicians, nurses, nursing aids, and laboratory technicians. Upon entering the study, each subject was asked to complete a self-administered, confidential questionnaire designed to elicit information regarding the individual's demographic characteristics, sexual history, job description, medical history concerning immune system function, and frequency and intensity of exposure to biological specimens of AIDS patients. Blood was obtained from each subject and tested for the presence of HIV antibody by EIA. If the original and at least one of two repeat EIA tests were reactive, the subject was considered HIV-seropositive. "Reactive or nonreactive samples that were near the cutoff value were confirmed by Western blot analysis." All members of the cohort tested HIV-seronegative.

Two hundred forty-six (94%) of the subjects were followed up 9–12 months after enrollment. Of these, 102 reported at least 50 AIDS "specimen contacts" during the previous 3 years and were classified as the "high exposure group"; 111 subjects reported no exposure to AIDS patients or specimens from such patients during the previous 3 years and were classified as the "no exposure group." The 43 remaining subjects reported 1–49 AIDS specimens contacts and were classified as the "low exposure group." The subjects reported exposure to various body fluids including blood and blood products, urine, respiratory secretions, upper gastrointestinal secretions, pleural fluid, cerebrospinal fluid and semen. Ten of the high exposure subjects reported needlestick exposures and 15 reported mucous membrane exposures. Each completed an updated questionnaire and had serologic testing for HIV antibody. None of these subjects have seroconverted to an HIV-antibody-positive status.

Healthcare Workers With AIDS

Further evidence of occupational transmission is provided by reports of healthcare workers who have AIDS, but have no identifiable risk for infection (Ex. 6–378). As of September 19, 1988, there were 169 workers in this group. Information is not complete for 28 of these due to death or refusal to be interviewed. Investigations are in progress for 97 and case investigations have been completed for the remaining 44 persons. Among the latter there are 8 physicians, including 4 surgeons; 1 dentist; 8 nurses; 9 nursing assistants; 8 housekeeping or maintenance workers; 4 clinical laboratory technicians; 2 therapists; 1 mortician; 1 paramedic and 4 others who did not have contact with patients. Eighteen of these healthcare workers recalled having needlestick or other parenteral exposure to blood or "body fluids" from patients in the 10 years preceding their diagnosis of AIDS. However, none of the patients were known to be infected with HIV at the time of exposure. While data on these cases are less complete compared to the 25 case reports discussed above, it is reasonable to assume that at least some of them resulted from occupational exposure.

D. Other Bloodborne Pathogens

Several additional infectious diseases are characterized by a phase in which the causative agent may circulate in blood for a prolonged period of time. With the exception of syphilis and malaria, which are both treatable with chemotherapeutic agents, these diseases are rare in the United States and would therefore be unlikely to pose a measurable risk to healthcare workers.

Syphilis

Syphilis, a sexually transmitted infectious disease, is increasingly prevalent in the United States. 33,147 cases were reported in civilians in 1987 (Ex. 6–456). Marked increases occurred in 1987. The 25% increase over the 1986 rate was the largest single-year increase since 1960 (Ex. 6–453). Moreover the incidence of 14.6 cases per 100,000 persons in 1987, equal to that of 1982, is the highest rate since 1950 (Ex. 6–453). Syphilis is caused by infection with Treponema pallidum, a spirochete.

The natural history of syphilis is characterized by an incubation period of 10 to 90 days during which the patient is seronegative and asymptomatic (Ex. 6–495). Subsequent to this incubation period, a primary stage occurs, usually characterized by the appearance of a single lesion, or chancre, and normally accompanied by reactivity in serologic tests. Untreated, the primary lesion heals in weeks. Within weeks to months, a variable systemic illness, the secondary stage, characterized by rash, fever and widespread hematogenous and lymphatic dissemination of spirochetes occurs. All infected persons have reactive serologic tests in this stage (Ex. 6–495). Furthermore, the highest levels of spirochetalemia (spirochetes present in blood) are reached during this period. Over two-thirds of patients probably have a prolonged period of latency when they are asymptomatic: the rest, after a variable period of latency, progress to a tertiary stage with high morbidity and mortality including involvement of skin, bones, central nervous and cardiovascular system (Ex. 6–495).

During latency and tertiary syphilis, spirochetaemia is markedly reduced, as is infectivity. However during the course of untreated syphilis, spirochetes may be intermittently found in the bloodstream, and syphilis can probably be transmitted through the course of the illness, though not as readily as during the primary and secondary stages (Ex. 6–495). Although syphilis is primarily transmitted sexually and in utero, a few cases of transmission by needlestick, by
tattooing instruments, and by blood transfusion have been documented (Ex. 6-453, Ex. 6-496). A reported transmission has occurred by needlestick exposure to the blood of a patient with secondary syphilis, resulting in a chancre on the hand (Ex. 6-453). Preventive treatment of an exposed healthcare worker with an antibiotic during the incubation period would be expected to prevent seroconversion and the potential for permanent reactivity on treponemal testing, as well as preventing the manifestations of infection.

Malaria

Malaria is a potentially fatal mosquito-borne parasitic infection of the blood cells characterized by paroxysms of fever, chills, and anemia; 944 cases were reported in the United States in 1987 (Ex. 6-465). Malaria is an important health risk to immigrants from numerous malaria-endemic areas of the world and to Americans who travel to such areas. Moreover, transmission by mosquito vector has been documented in some areas of the United States. Malaria is characterized by a prolonged erythrocytic phase during which the causative agent, one of several species of the *Plasmodium* genus, will be present in the blood. In many nations, malaria is among the most common transfusion-related infectious diseases. In temperate countries, it is only occasionally reported (Ex. 498). Malaria has also been transmitted by needlestick injury; in one incident, a patient was transmitted to a child who received a unit of blood and to the recipient's physician, who stuck himself with a needle (Ex. 467).

Babesiosis

Babesiosis is a tick-borne, parasitic disease similar to malaria which is caused by the intraerythrocytic parasite *Babesia microti*. It is endemic in certain islands off the northeastern coast of the United States. Transmission by transfusion of fresh blood from asymptomatic donors has been reported (Ex. 454).

Brucellosis

Brucellosis is a febrile illness caused by members of the genus *Brucella*. It is typically associated with occupational exposure to livestock or with ingestion of unpasteurized dairy products; 129 cases were reported in 1987 (Ex. 6-465). It is characterized by fever and weakness, sweats and arthralgias. Transmission by blood transfusion has been reported; in one incident, brucellosis and syphilis were transmitted in the same unit of blood to one recipient (Ex. 6-496).

Leptospirosis

Leptospirosis, a prolonged illness characterized by fever, rash, and occasionally jaundice, is caused by strains of *Leptospira interrogans*, a spirochete. The septicemic phase, during which leptospirosa are present in the bloodstream of patients, usually resolves within 1-2 weeks. It is typically acquired by contact with urine of infected animals, including cattle, swine, dogs, and rats; 43 cases were reported in 1987 (Ex. 6-465). No cases of nosocomial transmission by blood have been reported.

Arboviral Infections

Arboviral infections generally do not lead to high or sustained levels of viremia in humans, therefore, there is little potential for person-to-person transmission of these infections through blood products or needlestick exposure. The exception is Colorado tick fever (CTF) caused by a tick-borne virus which infects red blood cells. Within 3-14 days following tick exposures, the patient experiences fever, chills, headache, muscle and back aches. Several hundred cases are reported annually and transmission by blood transfusion has been documented (Ex. 6-416).

Relapsing Fever

Relapsing fever is a rare disease, caused by pathogenic *Borreliae*, transmitted by lice or ticks and characterized by recurring febrile episodes separated by periods of relative well-being. In the United States, a few cases of tick-borne relapsing fever are reported in localized geographic areas (Western United States). Though very rare, occupational transmission as a result of patient care practices has been reported. Infections have been attributed to blood from the vein of a patient squirting into the nose of a technician and, in another incident, splashing into another HCW's eye from a placental specimen (Ex. 6-468).

Creutzfeldt-Jakob Disease

Creutzfeldt-Jakob disease, a rare disease with worldwide distribution, is a degenerative disease of the brain caused by a virus. It is believed to be transmitted by ingestion of or inoculation with infectious material, primarily neural tissue. No cases of nosocomial transmission by blood have been reported, although rare instances of transmission have occurred secondary to homologous dura mater implants, receipt of human growth hormone, and insertion of unsterilized stereotactic electrodes which had been inserted into the brains of Creutzfeldt-Jakob disease patients and then used on others (Ex. 6-492).

Meningococcal Infections

Meningococcal disease is a bacterial infection with worldwide distribution. Meningococcal meningitis is caused by the meningococcal organism, a Gram-negative diplococcus. The infection characteristically involves the nasopharynx, and transmission is thought to occur primarily by respiratory droplet. There have been no reports of nosocomial transmission of meningococci.

Human T-lymphotropic Virus Type 1

Human T-lymphotropic virus type 1 (HTLV-1), the first human retrovirus to be identified, is endemic in southern Japan, the Caribbean, and in some parts of Africa, but it is also found in the United States, mainly in intravenous drug users (Ex. 6-493). The virus can be transmitted by transfusion of cellular components of blood (whole blood, red blood cells, platelets) (Ex. 6-499). HTLV-I has been associated with a hematologic malignancy known a adult T-cell leukemia/lymphoma and with a degenerative neurologic disease known as tropical spastic paraparesis or HTLV-I-associated myopathy. There is some evidence that the neurologic disease may be associated in some cases with blood transfusion (Ex. 6-494).  No cases of occupational acquisition of HTLV-1 infection have been reported.

Viral Hemorrhagic Fever

The term viral hemorrhagic fever refers to a severe, often fatal illness caused by several viruses not indigenous to the United States, but very rarely introduced by travelers coming from abroad. These illnesses are characterized by fever, sore throat, cough, chest pain, vomiting, and in severe cases, hemorrhage, encephalopathy and death. Although a number of febrile viral infections may produce hemorrhage, only the agents of Lassa, Marburg, Ebola, and Crimean-Congo hemorrhagic fevers are known to have caused significant outbreaks of disease with person-to-person transmission, including nosocomial transmission (Ex. 6-417). Blood and other body fluids of patients with these illnesses are considered infectious. Any patient suspected of illness due to one of these agents should be reported immediately to the local and state health departments and to the Centers for Disease Control.

The bacterial and parasitic diseases listed above are treatable with antibacterial or antimalarial drugs. No specific therapy is available for the viral diseases, with the exception of Lassa fever. Precautions designed to minimize the more important bloodborne viral diseases, namely HIV, hepatitis B, and non A non B hepatitis, would be effective in minimizing occupational transmission of all the above agents in the clinical setting.
E. Cytomegalovirus Infection and Disease

Risk From Exposure to Blood
In contrast to some other viral agents, there have been no documented reports of cytomegalovirus (CMV) transmission by needlestick or other occupational exposure to blood. While infection can be transmitted via blood transfusion, the risk per unit of blood is low and infection is more likely to occur after multiple transfusions. Even in patients with active CMV infection, the titer of virus found in blood samples is extremely low.

Risk From Exposure to Patients Excreting CMV in Their Secretions
The medical community has become increasingly aware of cytomegalovirus and cytomegalic inclusion disease of newborns. This awareness has prompted the publication of guidelines for the prevention and control of CMV infection and disease, particularly in settings where women of childbearing age may be affected (Ex. 6-396, Ex. 6-483).

CMV is an ubiquitous, non-seasonal virus that infects most persons at some time during their lives (Ex. 6-397, Ex. 6-450). The virus persists in latent form, and reactivation may occur years later, particularly under conditions of immunosuppression. Transmission of CMV from person to person probably occurs most commonly as a result of contact with salivary secretions, but urine may also play a role. Although the virus is not highly contagious, spread of CMV in households and day care centers is well documented. Acquisition appears to require close or intimate contact with persons who are excreting CMV in their urine, saliva, seminal fluid or cervical secretions. Sexual spread also occurs as could be expected with seminal and cervical excretion of virus. The frequency with which sexual contact may cause transmission of CMV is not clear, but sexual transmission appears to be a major source of infection among some adult populations (i.e., homosexual men and patients attending a sexually transmitted disease clinic) (Ex. 6-398). Infants and children acquire CMV infection either from other infected children or from their mother in utero, at birth, or during the perinatal period (Ex. 6-396, Ex. 6-397). CMV can also be transmitted via blood transfusions, breast milk, and transplanted organs (Ex. 6-399, Ex. 6-400). Infection in normal children and adults is usually asymptomatic, although, in immunocompromised hosts, CMV may be an opportunistic pathogen, causing serious illness with high morbidity and mortality. CMV infection is the most common cause of all the intrauterine infections, occurring in an estimated 0.4% to 2.3% of all live births (Ex. 6-397). It can have a variable outcome and may result from either primary infection acquired during gestation or from a recurrent (reactivation or reinfection) maternal infection in a seropositive woman (Ex. 6-401). It is currently believed that most but not all symptomatic congenital CMV infections result from primary infection (Ex. 6-402).

In the United States, 10%–65% of women (the percentage is higher in the white race and those of upper socioeconomic status) entering their childbearing years are seronegative and susceptible to primary CMV infection (Ex. 6-401). The rate of primary infection as measured by seroconversion during normal pregnancy is estimated to be between 1% and 2% (Ex. 6-402, 6-482); however, only 40%–50% of pregnant women who develop primary CMV infection will transmit that infection to their fetuses. Of these infected infants, one study has shown that 5%–10% will be symptomatic at birth (Ex. 6-402). The most severely affected are those with cytomegalic inclusion disease (CID) manifested by hepatosplenomegaly, jaundice, petechial rash, chorioretinitis, cerebral calcifications, and microcephaly. These children with CID are one of the major long-term public health problems associated with CMV. Of congenitally infected infants, 90% to 95% are asymptomatic at birth; 10% of these will develop manifestations of infection later in childhood, usually as hearing loss which is sometimes progressive, or poor intellectual performances (Ex. 6-403, Ex. 6-404). Congenital or perinatal acquired infections are chronic in nature with viral excretion persisting for months or years (Ex. 6-450). It is unknown why some offspring are severely affected, while others remain asymptomatic.

Since CMV infection is endemic in the community and infection in childhood is common and usually asymptomatic, day-care centers, nurseries, hospitals, developmental centers, schools, and other group settings usually contain a number of children who are excreting CMV in urine or saliva. The prevalence of excretion of CMV in urine or saliva in day-care centers in one study has been reported as 59% of healthy children between 1 and 5 years of age and was highest, 83%, in the second year of life (Ex. 6-450). In another study, the prevalence was 22% (Ex. 6-481). Adults who have young children in the home, particularly children who attend day-care centers, are unknowingly exposed and frequently become infected with CMV (Ex. 6-409, Ex. 6-410).

The risk of spread of CMV infection to patient-care personnel who practice good personal hygiene appears to be no higher than that of their peers who are not engaged in patient care. In the largest study to date, Balfour and Balfour (Ex. 6-117) enrolled 943 subjects including renal transplant nurses, neonatal intensive care nurses, student nurses, and blood donor controls. The rate of seroconversion during the study, based on observing 519 seronegative subjects for a median period of two years, was 1.84% and did not differ significantly among the study groups. Another study by Demmler et al. (Ex. 6-159) investigated possible nosocomial transmission of CMV by detailed serologic and virologic isolation procedures in two different hospital areas for a two year period. One was a busy, crowded pediatric chronic care unit with high (16%) prevalence of CMV among its patients and another was a neonatal unit with low (0.7%) prevalence of CMV. None of the 56 seronegative personnel in the chronic care unit became infected and only 2 of 37 nurses in the neonatal unit seroconverted. The source of one infection was proved to be familial, and an occupational source in the second was unlikely because this nurse did not care for either of the two congenitally infected infants in the unit. Similar to the Balfour study (Ex. 6-117) the annual seroconversion rates among nurses from various areas of the hospital did not correlate with the average CMV prevalence of the patients housed within those areas. Three smaller epidemiologic studies suggested that pediatric nurses or nursing students may have acquired CMV in the workplace (Ex. 6-409, Ex. 6-410, Ex. 6-411) while five additional studies concluded that patient-to-staff transmission was not a risk (Ex. 6-412, Ex. 6-413, Ex. 6-414, Ex. 6-452, Ex. 6-414).

Yearly seroconversion rates in hospital personnel have varied from 0% to 12%. However, when controls are included, these rates have not been significantly different from those of age-matched adults of similar socioeconomic background in the same community who did not care for CMV-infected patients. The study of Friedman et al. (Ex. 6-411) appears to be the only exception. A significant difference was found only when a subset of pediatric personnel was compared with the rest of the study population. The overall seroconversion
rate for all patient-contact employees was not significantly different from non-contact personnel. Differences in patient care practices or infection control policies could also explain some of the variation between hospitals. Intimate exposure to infected infants could be responsible for transmission to staff in some instances. Heneberg et al (Ex. 6-410) in Norway found a high rate of seroconversion among student nurses on their first two-month pediatric rotation. They noted that "it is common to see personnel kiss drooling infants while feeding them." Rates of infection fell when more attention was given to hygiene. Therefore, the risk of infection in hospital workers who care for pediatric patients and who practice good personal hygiene is probably no greater than that of women in the general community. Screening programs to identify children or adults such as renal transplant recipients who are asymptomatic excretors of CMV are currently impractical and costly. The intermittent nature of CMV shedding, the days required for testing and the high cost of the tests create problems for such screening programs. Since a significant percentage of such patients may be present in any institutional setting, care for any infants and children should include routine hygienic measures such as thoroughly washing hands after each contact with urine, respiratory tract, or other potentially infectious secretions and careful handling and disposal of diapers and other articles known to be contaminated with urine or other secretions (Ex. 6-396), (Ex. 6-431), (Ex. 6-442), (Ex. 6-74). The most practical means by which pregnant women or women planning pregnancy can prevent acquiring CMV is rigorous, good personal hygiene while working in these settings and at home throughout their pregnancy (Ex. 6-394).

The petitioners specifically requested that the Agency address the risk of occupational exposure to cytomegalovirus from patients with AIDS. In order to respond to the request of the petitioners, we have included the above discussion in the proposed standard. As discussed above, CMV is most often transmitted by saliva and urine and not by blood. The infection control procedures that would be employed to control the spread of pathogens transmitted by urine and saliva (except dental operations) are not required by this proposed standard and are not the focus of this rulemaking. The Agency seeks comments on this matter.

V. Preliminary Quantitative Risk Assessment

(A) Introduction

The United States Supreme Court, in the "benzene" decision, (Industrial Union Department, AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980)) has ruled that the OSHA Act requires that, prior to the issuance of a new standard, a determination must be made, based on substantial evidence in the record considered as a whole, that there is a significant risk of health impairment under existing exposure conditions and that issuance of a new standard will significantly reduce or eliminate that risk. The Court stated that "before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices" (448 U.S. 642). The Court also stated "that the Act does limit the Secretary's power to require the elimination of significant risks" (448 U.S. 644).

The Court in the Cotton Dust case, (American Textile Manufacturers Institute v. Donovan, 452 U.S. 490 (1981)), rejected the use of cost-benefit analysis in setting OSHA standards, it reaffirmed its previous position in "benzene" that a risk assessment is not only appropriate, but also required to identify significant health risk in workers and to determine if a proposed standard will achieve a reduction in that risk. Although the Court did not require OSHA to perform a quantitative risk assessment in every case, the Court implied, and OSHA as a matter of policy agrees, that assessments should be put into quantitative terms to the extent possible.

Quantifying the risk associated with exposure to bloodborne diseases such as HBV or HIV is different than quantifying the risk associated with exposure to toxic chemicals, the risks that OSHA has typically quantified. For most of these chemicals, response is associated with cumulative dose, and workers risk chronic health effects from long term exposure to airborne concentrations of the chemical. The response associated with exposure to bloodborne pathogens does not depend on cumulative dose acquired through years of exposure. With each exposure, either infection occurs or it does not occur. While repeated exposure increases the risk of infection, each exposure is associated with a unique risk which depends upon the virulence of the pathogen, the size of the delivered dose, the route of exposure, etc., and not upon any prior exposure. Thus, in the case of bloodborne diseases, it is necessary to reduce the risk of exposure. The use of a vaccine or other prophylactic treatment against a particular viral agent will further reduce the risk.

HBV is the only bloodborne pathogen for which there are sufficient data to quantify the risk of infection from occupational exposure to blood and other potentially infectious materials for an entire population of workers. A number of epidemiological studies demonstrate an increased prevalence of HB markers in the blood of health care workers with frequent blood exposure, and a brief review of some of these studies is presented below, followed by OSHA's estimates of risk. Finally, OSHA presents a qualitative risk assessment for infection from occupational exposure to HIV.

(B) Review of the Epidemiology of HBV Infection in Health Care Workers

Numerous epidemiological studies have measured the prevalence of HBV infection among health care workers. These studies determined what proportion of health care workers had ever been infected with HBV and measured prevalence as the proportion of workers with any serological marker of past or present HBV infection. Most of the studies relied upon the voluntary cooperation of the study population, so there is some chance for bias to be introduced into any estimate of HBV prevalence. Health care workers who know they are infected with HBV at the time of study or who know they are HBV carriers may decline to participate in a study in which they may feel could jeopardize their careers. This would lead to an underestimate of the prevalence of HBV infection among health care workers.

Jovanovich et al did not rely upon voluntary participation in their study of HBV prevalence among workers at a 1000-bed community hospital in Detroit (Ex. 4-14). The authors reported a high prevalence of HBV among employees in worksites where blood and other potentially infectious materials are frequently present. All new employees were screened for HBV markers at the time of hire, and the blood tests were repeated every six months thereafter for all employees designated as being at high risk for HBV infection. In the hemodialysis unit, these tests were repeated monthly. This design allowed investigators to determine not only the HBV prevalence but also the conversion
rate to HBV seropositivity per 100 employee-years.

Jovanovich et al reported the highest prevalence of HBV among the emergency room staff (27.9%), followed by the operating room staff (25.2%), the hemodialysis unit staff (17.2%), the dental staff (15.4%), and the staff of the intensive care unit (12.7%). The authors did not state what proportions of the study subjects were in specific occupations (e.g. physicians, nurses, etc.). The emergency room staff experienced the highest rate of conversion to HBV seropositivity with a conversion rate of 11.7 per 100 employee-years.

Like Jovanovich et al, Dienstag and Ryan found the highest prevalence of serological markers for HBV among the emergency room staff, (specifically nurses), in a study of workers at an 1100 bed urban teaching hospital in Boston (Ex. 4-13). This study relied upon voluntary participation, and of 830 staff at the hospital, 624 or 75% agreed to participate. Among workers with frequent blood contact, the prevalence of HBV serological markers was 21.2% versus 8.6% for workers with occasional, rare, or no blood contact (p<.001). The highest rates of seropositivity were found among emergency room nurses, pathology staff, blood bank staff, laboratory technicians, intravenous teams, and surgical house officers. The prevalence of HBV serological markers was 30% among emergency room nurses and was in excess of 15% in each of the other groups. Workers with less frequent blood contact had HBV serological markers at rates between 5% and 10%. Four of thirty-two administrators, (16%), were found to have serological markers of HBV infection, but the authors stated that the high observed prevalence among this group may have been related to the inclusion of two persons known to be members of a high risk group. All of these groups were compared to a population of 462 volunteer blood donors, which had a 5% prevalence of HBV.

Neither frequency of patient contact nor socioeconomic status (SES) as measured by years of education were found to be associated with the prevalence of HBV serological markers. SES is often associated with prevalence of HBV infection but not among this cohort. Indeed, as demonstrated in Table A, among workers with a comparable level of education, frequency of blood contact was statistically significantly associated with HBV prevalence. Prevalence increased with age for all employees regardless of degree of blood contact, but prevalence was observed to increase with years in occupation only for workers with frequent blood contact.

**TABLE A—CORRELATION BETWEEN FREQUENCY OF BLOOD CONTACT AND HBV PREVALENCE IN HOSPITAL WORKERS WITH UNIFORM SOCIOECONOMIC STATUS MEASURED BY YEARS OF EDUCATION**

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Exposure to blood</th>
<th>N</th>
<th>Number with HBV markers (percent)</th>
<th>Odds ratio</th>
<th>Chi-square (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians</td>
<td></td>
<td></td>
<td>Frequent</td>
<td>81 (17)</td>
<td>3.11</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Infrequent</td>
<td>89 (7)</td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td></td>
<td></td>
<td>Frequent</td>
<td>104 (22)</td>
<td>2.80</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Infrequent</td>
<td>126 (11)</td>
<td></td>
</tr>
</tbody>
</table>

* Data from Table 2 of Dienstag and Ryan (Ex. 4-13).

**Pattison et al.** reported similar findings of the relationship between frequency of blood contact and the prevalence of HBV in an earlier study conducted between 1972 and 1974 at a 495 bed urban hospital in Arizona (Ex. 6-65). The study population was selected from consecutive employees undergoing yearly physical examination on the anniversary of their initial employment examination. Except for physicians, study participants had been affiliated with the hospital for at least two years. Over 99% of the eligible employees who represented 40% of all hospital personnel participated in the study.

The overall prevalence of HBV serological markers was 14.4%. No association was observed between frequency of patient contact and prevalence of HBV, but the association between frequency of blood contact and prevalence of HBV was statistically significant (p<.05). Among workers with frequent blood contact, the seroprevalence of HBV markers was 18.9%; for workers with occasional blood contact, it was 13.4%; and for workers with no blood contact, it was 11.4%. Socioeconomic status, as measured by the Hollingshead Index derived from educational level attained and category of employment (highest socioeconomic level corresponding to Hollingshead Index 1; lowest socioeconomic level corresponding to Hollingshead Index 5), was statistically significantly associated with HBV prevalence but only when categories 1 through 4 were combined and compared to category 5. Among workers with similar Hollingshead indicies (i.e. controlling for socioeconomic status), workers with frequent or occasional blood contact were twice as likely to have serological markers for HBV as were workers with no blood contact. This is demonstrated in Table B.

**TABLE B— CORRELATION BETWEEN FREQUENCY OF BLOOD CONTACT AND HBV PREVALENCE IN HOSPITAL WORKERS WITH SIMILAR SOCIOECONOMIC STATUS MEASURED BY THE HOLLINGSHEAD INDEX**

<table>
<thead>
<tr>
<th>Hollingshead Index</th>
<th>Exposure to Blood</th>
<th>N</th>
<th>Number with HBV markers (percent)</th>
<th>Odds ratio</th>
<th>Chi-square (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 and 2</td>
<td></td>
<td>136</td>
<td>18 (13.2)</td>
<td>2.21</td>
<td>1.09 (p&lt;.25)</td>
</tr>
<tr>
<td>3 and 4</td>
<td></td>
<td>125</td>
<td>20 (16.0)</td>
<td>1.97</td>
<td>2.56 (p&lt;.05)</td>
</tr>
</tbody>
</table>
TABLE B.—CORRELATION BETWEEN FREQUENCY OF BLOOD CONTACT AND HBV PREVALENCE IN HOSPITAL WORKERS WITH SIMILAR SOCIOECONOMIC STATUS MEASURED BY THE HOLLINGSHEAD INDEX*—Continued

<table>
<thead>
<tr>
<th>Hollingshead Index</th>
<th>Exposure to Blood</th>
<th>N</th>
<th>Number with HBV markers (percent)</th>
<th>Odds ratio</th>
<th>Chi-square (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Never</td>
<td>102</td>
<td>9 (8.8)</td>
<td>2.55</td>
<td>(p &lt; .10)</td>
</tr>
<tr>
<td></td>
<td>Freq/Occ</td>
<td>41</td>
<td>13 (31.7)</td>
<td>4.34</td>
<td>(p &lt; .05)</td>
</tr>
<tr>
<td></td>
<td>Never</td>
<td>78</td>
<td>2 (2.6)</td>
<td>3.34</td>
<td>(p &lt; .05)</td>
</tr>
<tr>
<td></td>
<td>Freq/Occ</td>
<td>202</td>
<td>51 (16.9)</td>
<td>3.57</td>
<td>(p &lt; .10)</td>
</tr>
<tr>
<td></td>
<td>Never</td>
<td>211</td>
<td>23 (10.9)</td>
<td>3.57</td>
<td>(p &lt; .10)</td>
</tr>
</tbody>
</table>

*Data from Table 3 of Pattison et al. (Ex. 6–65).

(a) The Hollingshead Index is a measure of socioeconomic status derived from educational level attained and category of employment. The highest socioeconomic level corresponds to Hollingshead Index 1; the lowest socioeconomic level corresponds to Hollingshead Index 5.

In a more recent study by Hadler et al., frequency of blood contact but not frequency of patient contact was again shown to be strongly related to HBV prevalence (Ex. 4–16). Of all employees at three urban teaching hospitals and two midwest community hospitals, 5,697 (36%) participated in this study.

Sero logical markers of past or present HBV infection were found in 14.2% of the study population. For workers with frequent blood contact, the prevalence of HBV markers increased with duration in occupation at a rate of 1.05 infection per 100 person-years (R = .95; p < .01), and for workers with occasional blood contact, the prevalence increased at a rate of 0.71 infections per 100 person-years (R = .85; p < .01), and for workers with rare needle accidents, the increase in HBV infections per 100 person-years, and among workers with no blood contact, HBV prevalence was constant over duration of employment.

Hadler et al. also found that frequency of needle accidents was related to HBV prevalence. Among workers with frequent or occasional needle accidents, HBV prevalence increased with duration in occupation at a rate of .80 infections per 100 person-years (R = .95; p < .01), and for workers with rare needle accidents, prevalence increased at a rate of .72 infections per 100 person-years. Among workers who reported no needle accidents, the increase in HBV prevalence with duration in occupation was much lower (.24 infections per 100 person-years). When subjects were stratified into groups by degree of blood contact, frequency of needle contact was positively associated with HBV infection rates only in persons with frequent blood contact and not in persons having occasional or no blood contact.

Needlesticks and cuts with sharp objects are by no means the only way workers with exposure to blood or other potentially infectious materials can be exposed to the HB virus. In a study of the transmission of HBV in clinical laboratory areas, Lauer et al. found that 26 of 76 (34%) environmental surfaces sampled were positive for HBsAg (Ex. 6–56). Samples were taken in a dialysis room specifically used for patients who had HBV infections at the time of dialysis. In addition, samples were collected in the clinical laboratory where tests were done on blood samples drawn from HBV-infected dialysis patients.

The HB surface antigen was found on the outside of 6 of 11 (55%) of the sampled blood-specimen containers and 4 of 9 (44%) of the sampled serum-specimen containers. The gloves and bare hands of personnel who had contact with the blood- and serum-specimen containers were also sampled, and two of the three samples taken, including one from a bare hand, were positive for HBsAg. Other contaminated surfaces included the handle portion of pipetting aids, marking devices, and an assay instrument for complete determination of blood cell counts. The authors stated that their data "indicate that transmission of HBV in the clinical laboratory is subtle and mainly via hand contact with contaminated items during the various steps of blood processing. These data support the concept that the portal of entry of HBV is through inapparent breaks in skin and mucous membranes."

(C) QUANTITATIVE ASSESSMENT OF HBV RISK

OSHA’s quantitative risk assessment focuses on HBV infection in healthcare workers because healthcare workers with frequent exposure to blood or other potentially infectious materials constitute the only occupational group with such exposure for which OSHA has sufficient data to estimate the occupational risk of HBV infection. OSHA believes, however, that it is the exposure to blood and other potentially infectious materials that places these workers at risk for HBV and not some other factor unique to health care workers. This conclusion is borne out by the epidemiological studies reviewed in the previous section. Therefore, for this risk assessment, OSHA will use the data available for healthcare workers with frequent exposure to blood or other potentially infectious materials to predict the HBV infection risk to any worker with frequent occupational exposure to blood or other potentially infectious materials.

Estimates of the incidence of HBV infection in the U.S. population in general and among health care workers in particular come from the Hepatitis Branch of the Center for Infectious Disease of the U.S. Public Health Service’s Centers for Disease Control (CDC). There are two systems for collecting information on hepatitis: the CDC National Morbidity Reporting System and the Viral Hepatitis Surveillance Program (VHSP). The National Morbidity Reporting System collects data on the number and type of hepatitis infections as well as the patients’ ages in reported cases. The VHSP collects serological and epidemiological data pertaining to risk factors for the disease (Ex. 6–217). Based on data from these systems, the CDC estimates that there are over 300,000 HBV infections each year in the U.S. (Ex. 6–176). Only a fraction of all infections are actually reported to the CDC because most infections produce no symptoms and people are unaware that they are sick. Furthermore, even when people become ill enough to seek medical help, the disease is not always correctly diagnosed or faithfully reported. For its risk assessment, OSHA will assume that exactly 300,000 HBV infections occur each year, but the reader should bear in mind that CDC estimates the number to be higher (Ex. 6–176).

It is estimated that there are approximately 5.3 million health care workers who have frequent contact with blood or other potentially infectious materials but at high risk for bloodborne diseases including HBV (Ex.
6-13). This estimate includes staff at institutions for the developmentally disabled.

A portion of the 5.3 million workers with frequent blood contact or exposure to other potentially infectious materials are not at risk for HBV infection. CDC estimates that between 15% and 30% of these workers (795,000 to 1,590,000) have already been infected with HBV and are now immune to further infection (Ex. 6-190). In addition, it is estimated that approximately 1.2 million health care workers have received the plasma-derived HB vaccine since its introduction in 1982. CDC reports that 1.4 million persons have completed the three-dose series of vaccine injections. Although no precise figures are available, it is estimated that over 85% of the distributed vaccine has gone to health care workers with frequent blood contact, staff and clients of institutions for the developmentally disabled, and staff and patients in hemodialysis units (Ex. 6-176). The vaccine has been demonstrated to provide protective antibody levels in over 90% of healthy adults who have received the series (Ex. 6-383), so OSHA estimated that 1,080,000 workers, (1,200,000 X 0.9) are immune to HBV from vaccination. These factors, prior infection and vaccination, remove between 1,875,000 and 2,670,000 from the pool of 5.3 million health care workers with frequent exposure to blood or other potentially infectious materials, leaving between 2,630,000 and 3,425,000 workers at risk for HBV infection.

Of the 300,000 HBV infections each year, CDC estimates that 6% or 18,000 occur in all health care workers. Two-thirds of these 18,000 cases, or 12,000 cases, are believed to occur in health care workers who have frequent exposure to blood or other potentially infectious materials (Ex. 6-392). If between 2,630,000 and 3,425,000 workers are exposed, then the annual HBV infection rate for these workers is between 4.69 and 6.93 per 1,000 exposed workers. Clearly it is possible for workers with frequent blood exposure to become infected with HBV by means other than occupational exposure. Over 50% of all cases reported in 1985 had no known risk factors (Ex. 6-217). The risk attributable to occupational exposure is the difference between the risk faced by exposed workers and the background risk faced by the general population. Thus, to determine whether workers exposed to blood and other potentially infectious materials face a significant risk of infection due to their occupational exposure, OSHA has estimated the background risk of HBV infection.

OSHA's estimate of the background risk of HBV infection is probably much higher than the actual risk faced by most adults. Certain behaviors are known to substantially increase the risk of HBV infection, but not all adults engage in these behaviors with equal probability. For example, a recent General Social Survey conducted in early 1988 recorded homosexual activity among 3.2% of 504 sexually active men in the previous 12 months (Ex. 6-342), yet the proportion of HBV cases associated with homosexual activity in 1987 in the CDC's sentinel county study was 9%, nearly three times as large (Ex. 6-321). Intravenous drug users, who accounted for 28% of the HBV cases in 1987 in the same CDC study, are another group which are disproportionately represented in the number of HBV cases as compared to their number in the adult population. Removing the HBV cases associated with male homosexual activity and IV drug use from the annual number of cases and removing adult men who engage in homosexual activity and IV drug use from the population at risk would substantially reduce OSHA's estimate of the background risk of infection because a greater proportion of cases would be removed from the number of HBV cases (i.e., the numerator) than the proportion of people removed from the population at risk (i.e., the denominator). This

OSHA's estimate of the background risk of HBV infection in children, OSHA has assumed for this risk assessment that infections occur only in adults in order to arrive at an estimate of the HBV infection rate in the adult population. While this assumption may lead to an overestimate of the infection rate, any bias will be offset to some degree by the assumption that exactly 300,000 HBV infections occur each year, which is probably an underestimate.

There are approximately 180 million adults in the U.S. (Ex. 6-390; in 1985, there were 380,779,000 residents in the U.S. 15 years of age or older). Of these, it is estimated that 4.8% (approximately 8.8 million) are immune because they have already had the disease (Ex. 6-390). In addition, we will assume that all of the 1.4 million persons who have received the HB vaccine are adults and that 90% of them (1,500,000) are immune. Therefore, of the 180 million adults in the U.S., approximately 170 million are at risk of HBV infection. Given that there are 300,000 cases of infection each year, the annual infection rate is 1.76 infections per 1,000 adults. This estimated infection rate for the entire adult population constitutes the background risk for HBV. In other words, OSHA estimates that the probability that an adult in the U.S. will be infected with HBV this year is .00176. Estimates of the populations at risk and their HBV infection rates are given in Table C.

### Table C. Estimate of Populations at Risk for HBV Infection

<table>
<thead>
<tr>
<th>U.S. adults</th>
<th>High risk health care workers</th>
</tr>
</thead>
<tbody>
<tr>
<td>100,000,000</td>
<td>5,300,000</td>
</tr>
<tr>
<td>8,600,000</td>
<td>1,400,000</td>
</tr>
<tr>
<td>1,300,000</td>
<td>1,080,000</td>
</tr>
<tr>
<td>170,100,000</td>
<td>2,530,000</td>
</tr>
</tbody>
</table>

* Percent immune is the proportion of the population which has already been infected with the HB virus. Previous infection confers life-long immunity.

* This number has been rounded to the nearest hundred thousand.

* This assumes that vaccination confers immunity on 90% of those that receive it.

The vast majority of the 300,000 infections that occur each year in the U.S. are in young adults. In 1985, for example, 70% of all reported cases of acute infection occurred in the 20 to 39 year old age group. In contrast, only 1.4% of the reported cases of acute infection occurred in children under 15 years of age (Ex. 6-217). Because of the low incidence of HBV infection in children, OSHA has assumed for this risk assessment that infections occur only in adults in order to arrive at an estimate of the HBV infection rate in the adult population. While this assumption may lead to an overestimate of the infection rate, any bias will be offset to some degree by the assumption that exactly 300,000 HBV infections occur each year, which is probably an underestimate.

OSHA's estimate of the background risk of HBV infection in children, OSHA has assumed for this risk assessment that infections occur only in adults in order to arrive at an estimate of the HBV infection rate in the adult population. While this assumption may lead to an overestimate of the infection rate, any bias will be offset to some degree by the assumption that exactly 300,000 HBV infections occur each year, which is probably an underestimate.

There are approximately 180 million adults in the U.S. (Ex. 6-390; in 1985, there were 380,779,000 residents in the U.S. 15 years of age or older). Of these, it is estimated that 4.8% (approximately 8.8 million) are immune because they have already had the disease (Ex. 6-390). In addition, we will assume that all of the 1.4 million persons who have received the HB vaccine are adults and that 90% of them (1,500,000) are immune. Therefore, of the 180 million adults in the U.S., approximately 170 million are at risk of HBV infection. Given that there are 300,000 cases of infection each year, the annual infection rate is 1.76 infections per 1,000 adults. This estimated infection rate for the entire adult population constitutes the background risk for HBV. In other words, OSHA estimates that the probability that an adult in the U.S. will be infected with HBV this year is .00176. Estimates of the populations at risk and their HBV infection rates are given in Table C.

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</thead>
<tbody>
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<td>5,300,000</td>
</tr>
<tr>
<td>8,600,000</td>
<td>1,400,000</td>
</tr>
<tr>
<td>1,300,000</td>
<td>1,080,000</td>
</tr>
<tr>
<td>170,100,000</td>
<td>2,530,000</td>
</tr>
</tbody>
</table>

* Percent immune is the proportion of the population which has already been infected with the HB virus. Previous infection confers life-long immunity.

* This number has been rounded to the nearest hundred thousand.

* This assumes that vaccination confers immunity on 90% of those that receive it.

OSHA's estimate of the background risk of HBV infection is probably much higher than the actual risk faced by most adults. Certain behaviors are known to substantially increase the risk of HBV infection, but not all adults engage in these behaviors with equal probability. For example, a recent General Social Survey conducted in early 1988 recorded homosexual activity among 3.2% of 504 sexually active men in the previous 12 months (Ex. 6-342), yet the proportion of
approach would be reasonable because males represent only 25% of all healthcare workers, as opposed to 48% of the general population, and IV drug users most likely are underrepresented among the healthcare worker population.

Unfortunately, there are no reliable estimates of the number of people engaging in high risk behaviors such as homosexual activity or IV drug use. Therefore, OSHA must rely on its estimate of 1.76 HBV infections per 1000 adults as its estimate of the background risk. The true risk for most adults in the U.S., and therefore the background risk for healthcare workers, is probably much lower.

As outlined in the discussion of the health effects of HBV, there are a number of possible outcomes following infection. Between two thirds and three fourths of all infections result in either no symptoms of infection or a relatively mild flu-like illness. Between one quarter and one third of the infections, however, take a much more severe clinical course. As noted above, the symptoms include jaundice, dark urine, extreme fatigue, anorexia, nausea, abdominal pain, and sometimes joint pain, rash, and fever. Hospitalization is required in about 20% of these cases. For its risk assessment, OSHA will use the lower estimate of 25% as the proportion of HBV infections which take a more severe clinical course.

CDC estimates that 2.2% of HBV infections lead to death. Death from fulminant hepatitis occurs in 0.125% of cases. Death from cirrhosis of the liver is estimated to occur in 1.7% of cases, and death from primary hepatocellular carcinoma is estimated to occur in 0.4% of cases (Ex 6-392).

Between 5% and 10% of individuals infected with HBV become chronic carriers of the virus. These individuals represent a pool from which the disease may spread. About 25% of the chronic carriers suffer from chronic active hepatitis (Ex 6-392).

The estimated numbers of infections that result in any of these outcomes each year in both the adult population and in the population of high risk health care workers is presented in Table D. Recall that among the adult population, approximately 170 million persons are estimated to be at risk for HBV and among health care workers with frequent exposure to blood or other potentially infectious materials, there are between 2,630,000 and 3,425,000 workers estimated to be at risk for HBV infection. Using the numbers in Table D and these population estimates, the annual risk of HBV infection for the adult population and for any worker with frequent occupational exposure to blood or other potentially infectious materials have been calculated and are presented as rates per 1000 in Table E.

Table D.—Estimates of the Number of HBV Infections and Outcomes in the U.S. Adult Population and Among Health Care Workers Exposed to Blood and Other Potentially Infectious Material

<table>
<thead>
<tr>
<th>Category</th>
<th>U.S. adults</th>
<th>Health care workers</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV Infections</td>
<td>300,000</td>
<td>12,000</td>
</tr>
<tr>
<td>Clinical Illness (25%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalized (5%)</td>
<td>75,000</td>
<td>3000</td>
</tr>
<tr>
<td>HBV Carrier (5% to 10%)</td>
<td>15,000</td>
<td>600</td>
</tr>
<tr>
<td>Chronic HB (25% Carriers)</td>
<td>15,000-30,000</td>
<td>600-1200</td>
</tr>
<tr>
<td>Fulminant Death (1.25%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death—Cirrhosis (1.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death—HCC (0.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deaths (2.225%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Data from Ex. 6-392.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Primary hepatocellular carcinoma.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table E.—Estimates of the Annual Risk HBV Infection and its Outcomes in the U.S. Adult Population and Among Workers Exposed to Blood and Other Potentially Infectious Material

<table>
<thead>
<tr>
<th>Category</th>
<th>U.S. adults</th>
<th>Exposed workers</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV Infections</td>
<td>1.76</td>
<td>3.50-4.56</td>
</tr>
<tr>
<td>Clinical Illness (25%)</td>
<td>0.44</td>
<td>0.86-1.14</td>
</tr>
<tr>
<td>Hospitalized (5%)</td>
<td>0.09</td>
<td>0.18-0.23</td>
</tr>
<tr>
<td>HBV Carrier (5% to 10%)</td>
<td>0.09-0.18</td>
<td>0.18-0.48</td>
</tr>
<tr>
<td>Chronic HB (25% Carriers)</td>
<td>0.02-0.04</td>
<td>0.04-0.11</td>
</tr>
<tr>
<td>Fulminant Death (1.25%)</td>
<td>0.002</td>
<td>0.004-0.006</td>
</tr>
<tr>
<td>Death—Cirrhosis (1.7%)</td>
<td>0.03</td>
<td>0.06-0.08</td>
</tr>
<tr>
<td>Death—HCC (0.4%)</td>
<td>0.007</td>
<td>0.014-0.018</td>
</tr>
<tr>
<td>All Deaths (2.225%)</td>
<td>0.04</td>
<td>0.08-0.10</td>
</tr>
</tbody>
</table>

* Risks expressed as the number of events per 1000 at risk.
* Exposed workers are workers with occupational exposure to blood and other potentially infectious materials.
* Risks for exposed workers are estimated assuming 15% and 30% of the workers had a previous infection and are thus immune.
* Primary hepatocellular carcinoma.

Table F shows that for every 1000 workers with frequent exposure to blood or other potentially infectious materials, between 75 and 119 will become infected with HBV over the course of their working lifetime because of occupational exposure to the virus. Of these, 20 to 31 will suffer clinical illness and 4 to 6 will need hospitalization. Between 4 and 13 of these workers will become chronic carriers, and 1 to 3 of them will suffer from chronic hepatitis. HBV infection from occupational exposure will lead to the death of 2 to 3 of these 1000 exposed workers.

OSHA's estimate of the risk of HBV infection attributable to occupational exposure for workers with frequent exposure to blood or other potentially infectious materials is probably much lower than OSHA's estimate of the background risk since

simply the difference between the annual risk faced by exposed workers and the annual risk faced by the adult population, both given in Table D.

Because section (6)(b)(5) of the OSH Act states that no employee shall suffer "material impairment of health or functional capacity even if such an employee has regular exposure to the hazard dealt with" for the period of his working life," OSHA has converted the attributable annual risk into an attributable lifetime risk on the assumption that the a worker is employed in his or her occupation for 45 years.

Table F.—HBV Risk Attributable to Occupational Exposure for Workers Exposed to Blood or Other Potentially Infectious Materials

<table>
<thead>
<tr>
<th>Category</th>
<th>Adult population</th>
<th>Life-time occupational risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV Infections</td>
<td>1.74-2.30</td>
<td>75.36-119.54</td>
</tr>
<tr>
<td>Clinical Illness (25%)</td>
<td>0.44-0.70</td>
<td>19.61-31.02</td>
</tr>
<tr>
<td>Hospitalized (5%)</td>
<td>0.09-0.14</td>
<td>4.04-6.28</td>
</tr>
<tr>
<td>HBV Carrier (5% to 10%)</td>
<td>0.06-0.26</td>
<td>4.04-12.52</td>
</tr>
<tr>
<td>Chronic HB (25% Carriers)</td>
<td>0.02-0.07</td>
<td>0.09-0.18</td>
</tr>
<tr>
<td>Fulminant Death (1.25%)</td>
<td>0.002-0.004</td>
<td>0.09-0.18</td>
</tr>
<tr>
<td>Death—Cirrhosis (1.7%)</td>
<td>0.03-0.05</td>
<td>1.35-2.25</td>
</tr>
<tr>
<td>Death—HCC (0.4%)</td>
<td>0.007-0.011</td>
<td>0.51-0.69</td>
</tr>
<tr>
<td>All Deaths (2.225%)</td>
<td>0.04-0.06</td>
<td>1.80-2.70</td>
</tr>
</tbody>
</table>

* Risks are expressed as the number of events per 1000 at risk.
* Risks for exposed workers are estimated assuming 15% and 30% of the workers had a previous infection and are thus immune.
* Assumes 45 years of occupational exposure and is calculated as 1-(1- p)^t, where p is the annual risk.
* Primary hepatocellular carcinoma.

Table F presents the risk attributable to occupational exposure for HBV infection and its outcomes per 1000 exposed workers. The annual risk attributable to occupational exposure is
the majority of adults do not engage in high risk behaviors associated with a large proportion of HBV infections. By overestimating the background risk, OSHA has overestimated the risk attributable to occupational exposure. Nonetheless, OSHA’s calculations show that exposed workers are at an increased risk of infection, clinical illnesses, hospitalization, chronic hepatitis, and death over the course of their working lifetime. In addition, these workers are at an increased risk of becoming HBV carriers and of transmitting the infection sexually and perinatally.

Since 1982, a plasma-derived HB vaccine has been available. In July of 1986, a new genetically engineered HB vaccine was licensed by the U.S. Food and Drug Administration. When given in the recommended three dose series, the new vaccine has been found to induce protective antibodies in over 95% of healthy adults 20-39 years of age, but like the plasma-derived vaccine, the new vaccine induced a somewhat lower antibody response in older adults (Ex. 6-170). Assuming that both vaccines are 90% effective in preventing HBV infection, OSHA believes that administration of either vaccine will lead to a significant reduction in the HBV infection risk faced by workers with frequent exposure to blood or other potentially infectious materials.

OSHA’s Office of Regulatory Analysis estimates that there are 5.3 million workers with frequent exposure to blood or other potentially infectious materials who would be covered by this standard (see Section VII of this preamble). Approximately 4.7 million of these exposed workers are employed in the health care field, (OSHA estimates that there are approximately 600,000 health care workers who would not be covered by this standard) (see Section VII of this preamble). Approximately 600,000 of these 5.3 million exposed workers are employed in fields other than healthcare. If it is assumed that 23% of the 4.7 million health care workers have been vaccinated (1,081,000) and that between 15% and 30% are immune to HBV because of prior infection and are thus immune, CDC reported the number of infected persons in the U.S. (Ex. 6-356). Between 1 million and 1.5 million HIV-infected persons in the U.S. (Ex. 6-356).

The CDC estimates that there are between 1 million and 1.5 million HIV-infected persons in the U.S. (Ex. 6-356). While the exact number of infections is unknown, CDC reported the number of adults with AIDS to be 78,312 as of November, 1988 (Ex. 6-379). Occupational information is available for 61,929 of the cases, and of these, 90% are employees in the health care field who have been vaccinated or are immune to HBV from prior infection. Because 95% of all people vaccinated have been in the health care field, it is reasonable to assume that this group of nonhealthcare workers has been vaccinated at a rate more like the entire adult population (.1%) than like the population of exposed health care workers. Because these workers have frequent exposure to blood or other potentially infectious materials, however, it is reasonable to assume that like the health care workers, between 15% and 30% are immune to HBV because of previous HBV infection. If it is assumed that 0.1% of the 600,000 other workers have been vaccinated (660) and that between 15% and 30% are immune to HBV because of previous HBV infection (90,000 to 180,000), then there are between 419,340 and 509,340 other workers who are both at risk for HBV and would be covered by this standard.

In total, OSHA estimates that between 2,629,340 and 3,423,340 workers with frequent exposure to blood or other potentially infectious materials are at risk for HBV. If all of these workers were vaccinated with a 90% effective HBV vaccine, then over a 45 year working lifetime, OSHA estimates that between 232,000 and 280,000 HBV infections would be prevented, between 60,000 and 73,000 cases of clinical illness would be prevented, and between 5500 and 6400 deaths would be prevented. The numbers of HBV infections and their outcomes which would be prevented by this provision are presented in Table G.

Table G—HBV Infections and Outcomes Prevented in Workers With Lifetime Occupational Exposure to Blood and Other Potentially Infectious Material After Administration of HB Vaccine With 90% Efficiency 1

| HBV Infections | 232,246-280,407 |
| Clinical illness | 60,419-73,376 |
| Hospitalized | 12,447-14,655 |
| HBV carrier | 12,447-29,616 |
| Chronic HB | 2.773-7,451 |
| Fulminant death | 277-426 |
| Death—cirrhosis | 4,159-5,322 |
| Death—PBC | 955-1,159 |
| All deaths | 5,546-6,387 |

1 Numbers calculated assuming that vaccine is given to all workers with frequent exposure to blood and other potentially infectious materials who are covered by this standard and who have not been vaccinated or had a prior HBV infection. The population at risk is estimated to be between 2,629,340 and 3,423,340. Numbers are calculated by applying 90% of the lifetime HBV risk attributable to occupational exposure given in Table F to the estimates of the population at risk. See text for details.

2 Risks for all exposed workers are estimated assuming 15% and 30% had a previous infection and are thus immune.

3 Smaller number assumes that 30% of the workers are immune due to prior infection and 5% of the workers infected will become HBV carriers. Larger number assumes that 15% of the workers are immune due to prior infection and 10% of the workers infected will become HBV carriers.

* Primary hepatocellular carcinoma.

Table H presents the lifetime risk of HBV infection and its outcomes attributable to occupational exposure after administration of a 90% efficacious HB vaccine. The numbers show that even with a vaccine which is 90% effective, there remains an increased risk of HBV infection to workers with occupational exposure to blood and other potentially infectious materials.

Table H—Estimate of HBV Infection and its Outcomes Among Workers With Exposure to Blood or Other Potentially Infectious Materials After Administration of HB Vaccine With 90% Efficiency 1

| HBV Infections | 7.54-11.85 |
| Clinical illness | 1.96-3.10 |
| Hospitalized | 0.40-0.63 |
| HBV carrier | 0.40-1.25 |
| Chronic HB | 0.09-0.52 |
| Fulminant death | 0.009-0.018 |
| Death—cirrhosis | 0.14-0.23 |
| Death—PBC | 0.03-0.05 |
| All deaths | 0.18-0.27 |

1 Risks are expressed as the number of events per 1000 at risk.

2 Risks for exposed workers are estimated assuming 15% and 30% of the workers had a previous infection and are thus immune.

* Assumes 45 years of occupational exposure.
* Primary hepatocellular carcinoma.

(D) Qualitative Assessment of HIV Risk

The CDC estimates that there are between 1 million and 1.5 million HIV-infected persons in the U.S. (Ex. 6-356).

Occupational information is available for 61,929 of the cases, and of these,
3,182 or 5.1% are health care workers (Ex. 6-378). This proportion is similar to the proportion of the labor force employed in the health care field. Most health care workers with AIDS also belong to some other group which places them at high risk for HIV infection (e.g. homosexual men, intravenous drug users, etc.). There is, however, a statistically significantly larger proportion of health care workers with no known risk factors (5.3%), than the proportion of other AIDS cases (i.e. individuals with AIDS not in the health care field) with no known risk factors (2.6%). These 168 health care workers with no known risk factors are being studied further. CDC reports that 44 could not be assigned to a risk group after follow-up, 23 had either died or refused to be interviewed, and 91 were still under investigation (Ex. 6-378).

Adequate data do not exist for quantifying the risk of infection to health care or other workers with frequent occupational exposure to blood or other potentially infectious material. Because the extent of HIV infection in the general population is unclear, it is not possible to estimate an "expected" infection rate, and because the prevalence of HIV infection among health care and other workers with frequent exposure to blood or other potentially infectious material is unknown, it is not possible to estimate an "observed" infection rate. Therefore, it is not possible to quantify the risk as was done for occupational exposure to HBV. Certain deductions, however, can be made. It is known that the virus is present only in blood or certain body fluids and that exposure to these fluids from an HIV-infected person puts one at risk for HIV-infection. Therefore, workers who have frequent contact with blood or certain body fluids are at risk.

No case of infection due to casual contact with these fluids has been documented. Rather, infection can occur only if infectious fluids enter the body, either through a percutaneous or mucosal route, although exposure by either of these routes does not mean that infection will occur. In several prospective studies of health care workers with HIV exposures, seroconversions have been observed. Although the rate of infection is low, it is not insignificant.

The most recent report from the CDC Cooperative Needlestick Surveillance Group (Marcus et al) shows that of 800 health care workers with an exposure to HIV-infected blood through needlestick or cut from sharps instruments, 3 workers became infected with the virus (Ex. 6-372). This leads to a seroconversion rate of 3.5 per 1000 exposures to infected blood through needlestick or cut, with a 95% upper confidence limit of 9 per 1000 exposures. Gerberding et al recently reported that of 180 workers with 215 exposures to HIV-infected blood through needlesticks, 1 worker became infected with the virus (Ex. 6-375). This leads to a seroconversion rate of 4.7 per 1000 exposures to infected blood through needlesticks, with a 95% upper confidence limit of 14 per 1000 exposures. The HIV infection rates reported by both of these studies are very close, and the upper confidence limit from each includes the estimated infection rate from the other. The upper confidence limit constructed from the Gerberding et al data is much larger than the upper confidence limit constructed from the CDC data because of the smaller sample size.

Both the CDC and the Gerberding et al studies provide estimates of the risk of infection given parenteral exposure to HIV-infected blood. Neither study, however, provides estimates of the risk of all occupational exposure. On approach to this problem has been suggested by Wormser et al who estimated the probability of HIV infection in terms of HIV-infected patient-days for hospital staff caring for HIV-infected patients (Ex. 6-388). For the 18 month period from January of 1986 to June of 1987, the authors observed a needlestick rate of 1.9 per 1000 HIV-infected patient-days, (Ex. 6-375). This leads to a seroconversion rate of 4.7 per 1000 HIV-infected patient-days among staff caring for HIV-infected patients. This rate was substantially lower than the needlestick rates of 4.3 and 4.6 per 1000 HIV-infected patient-days reported at the hospital for 1985 and 1984, respectively.

Using the observed rate of 1.9 needlesticks per 1000 HIV-infected patient-days, Wormser et al estimated the expected number of needlesticks for different numbers of HIV-infected patient-days. For example, for 45,000 HIV-infected patient-days (750 HIV-infected patients hospitalized for 60 days, 1500 HIV-infected patients hospitalized for 30 days, etc.), the expected number of needlesticks is 86 (1.9/1000 x 45,000). Wormser et al then estimated the probability of at least one exposed worker becoming infected with HIV as 1 — [(1—p)n], where n is the number of needlesticks and p is the probability of becoming infected with HIV given needlestick exposure to HIV-infected blood, which the authors assumed to be 0.0035. The estimated probabilities, which are expressed per expected number of needlesticks or per HIV-infected patient-days, are presented in Table I. In addition, OSHA has calculated these probabilities using Gerberding et al's estimate of 4.7 infections per 1000 needlestick exposures to HIV-infected blood and has included them in Table I.

In reviewing Table I, it is important to remember that the probabilities presented there do not represent an estimate of the number of exposed workers who will become infected with HIV. "Number of workers exposed" is not used in any of the calculations, and therefore an expected number of infections per some number of workers caring for HIV-infected patients can not be calculated. One worker may experience more than one needlestick. The probabilities in Table I depend only upon the number of needlesticks which, in turn, depends only upon the number of HIV-infected patient-days and the assumption that needlesticks occur at a rate of 1.9 per 1000 HIV-infected patient-days.

Table I shows that the probability of HIV infection for at least one health care worker caring for HIV-infected patients does not increase linearly as the number of HIV-infected patient-days increases. A ten-fold increase in HIV-infected patient-days from 20,000 to 200,000 leads only to a six-fold increase in the probability of at least one infection. If one were to assume that the needlestick rate were two times higher than the rate used in Table I (i.e. 3.8 needlesticks per 1000 HIV-infected patient-days instead of 1.9 needlesticks per 1000 HIV-infected patient-days), the probability of at least one infection doubles at 5000 HIV-infected patient-days but increases only 6% at 440,000 HIV-infected patient-days. If one were to assume that the needlestick rate were half as high as the rate used in Table I, (i.e. 0.85 needlesticks per 1000 HIV-infected patient-days instead of 1.9 needlesticks per 1000 HIV-infected patient-days), the probability of at least one infection is one-third smaller at 5000 HIV-infected patient-days but only one-fifth smaller at 440,000 HIV-infected patient-days.

<table>
<thead>
<tr>
<th>Estimated Number of Needlesticks</th>
<th>Probability of at least 1 infection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Wormser a</td>
</tr>
<tr>
<td>5,000</td>
<td>0.03</td>
</tr>
<tr>
<td>20,000</td>
<td>0.12</td>
</tr>
<tr>
<td>45,000</td>
<td>0.26</td>
</tr>
<tr>
<td>105,000</td>
<td>0.50</td>
</tr>
<tr>
<td>200,000</td>
<td>0.74</td>
</tr>
<tr>
<td>440,000</td>
<td>0.95</td>
</tr>
</tbody>
</table>

Table I.—Probability of at least one infection due to needlestick exposure to HIV-infected blood *
This approach to estimating the risk of HIV infection would apply only to staff caring for HIV-infected patients because Wormser et al used a needlestick rate per HIV-infected patient-days which was estimated from this population. Instead of expressing the risk for a limited population in terms of HIV-infected patient-days, it has been suggested that the risk of HIV infection be expressed for all workers performing a certain procedure in terms of the number of procedures performed. The cumulative probability of HIV-infection would be estimated by

\[ 1 - (1 - p)^N \]

where \( N \) is the number of procedures performed and \( p \) is the probability of HIV infection for a single procedure. This probability is estimated by the product of the probability that blood or other potentially infectious material is infected with HIV, the probability that the worker is exposed while performing the procedure, and the probability that the workers becomes infected if the blood or other potentially infectious material is HIV-infected and the worker is exposed. OSHA seeks comments on this approach for estimating the HIV infection risk to workers with frequent exposure to blood or other potentially infectious material.

Clearly, reducing the risk of needlestick will reduce the probability of HIV infection. CDC reported that of 1,201 exposures to HIV-infected blood through needlesticks, cuts with sharp objects, contamination of open wounds, or contamination of mucous membranes, 37% of the exposures could have been prevented if recommended infection control precautions had been followed. Recapping of needles accounted for 17% of the 1,201 exposures, improper disposal of needles or sharp objects accounted for 14%, and contamination of open wounds accounted for 6% (Ex. 6-37).

A study of needlestick injuries among hospital personnel by Jagger et al found that the risk of injury depended upon the type of device used and that devices requiring disassembly had the highest risks (Ex. 6-350). Jagger investigated 326 needlestick injuries over a 10 month period and found that 17% occurred before or during use of the devices and 13% occurred during or after disposal of the devices. The majority (70%), however, occurred after use but before disposal of the devices. The single largest cause of injury was due to recapping. Workers missed the cap and stabbed themselves when attempting to cover a used needle in 17.8% of the injuries. Other major causes of injury were needles piercing caps when recapped after use (12.3%), contacting needle caps exposed surfaces after use (10.7%), and needles protruding from trash (8.9%). The largest number of injuries was associated with disposable syringes, but when the injury rate for various devices was adjusted for the number of each type of device purchased, disposable syringes had the lowest accident rate at 6.9 per 100,000 purchased. All of the devices requiring disassembly had higher accident rates ranging from 8.3 per 100,000 purchased for prefilled cartridge injection syringes to 36.7 per 100,000 purchased for intravenous tubing and needle assemblies.

While most of the epidemiological investigations have concentrated on assessing the risk of HIV infection to health care workers exposed to HIV-infected blood through needlesticks or cuts with sharp objects, there is evidence that workers in research and production laboratories routinely exposed to high concentrations of the virus are also at risk of infection. Weiss et al prospectively studied 265 laboratory and affiliated workers and found one worker infected with the same strain of HIV as was used in the laboratory (Ex. 6-187). The infected worker reported occurrences of HIV contamination in the work area but could not recall any episode of direct skin exposure with the virus and denied any parenteral exposures. The worker reported that double gloves were worn whenever there were bandaged cuts on fingers or hands. An episode of nonspecific dermatitis on the arm was recalled, but the affected area was always covered by a cloth laboratory gown. There was no contact of potentially infectious material with these areas as has been reported for health care workers infected after clinical exposure to HIV-infected fluids (see Case Reports in the discussion of HIV health effects). For 99 workers who shared a work environment involving exposure to concentrated virus, the authors estimated the HIV infection rate to be 48 per 100 person-years with a 95% upper confidence limit of 2.39 infections per 100 person-years. Over a 45 year working lifetime, this would lead to a risk of 105 per 1000 exposed workers in research and production laboratories with a 95% upper confidence limit of 663 per 1000.

Weiss et al also reported a second incident of HIV infection in a research laboratory worker who was employed in the production of concentrated virus and who was cut on the hand with a potentially contaminated stainless steel needle used for cleaning an apparatus. The worker was not part of the Weiss et al cohort, and it is not yet known whether the virus which infected this worker is the same (i.e., genetically identical) as was found in the laboratory. Weiss et al noted that although the infected workers were careful, neither was fully conversant with or strictly adhered to biosafety guidelines in day to day procedures at all times. Weiss et al concluded that the infection of laboratory workers under prescribed Biosafety Level 3 containment "suggests the need to review carefully all operations involving highly concentrated infectious material and to ensure proficiency in the conduct of recommended safeguards" (Ex. 6-167).

Although it is not possible to quantify the risk of HIV infection in health care or other workers with frequent exposure to blood or other potentially infectious material or with direct exposure to the virus itself, the data show that a risk does exist. As the number of people with HIV-associated illnesses increases, the probability that workers exposed to blood or infectious material will also be exposed to HIV increases. Given needlestick exposure to HIV-infected blood, the risk of seroconversion is estimated to be between 3.5 and 4.7 per 1000 exposures, with 95% upper confidence limits of 9 and 14 per 1000 exposures respectively. For research and production laboratory workers with occupational exposure to high concentrations of the virus, the risk of seroconversion is estimated to be 4.8 per 1000 person-years, with a 95% upper confidence limit of 24 per 1000 person-years. Over a 45 year working lifetime, the risk would be 195 per 1000 exposed workers. By reducing the risk of exposure to blood and other potentially infectious material and by strictly adhering to biosafety procedures in handling the virus in laboratories, the risk of HIV infection can be reduced.

(2) Risk from Other Bloodborne Pathogens

As described in the health effects discussions, there are other bloodborne pathogens, such as syphilis and malaria which are present in blood during certain phases of infection. During these phases, the blood of infected individuals...
poses a risk to exposed workers. Although this risk has not been quantified, it is unambiguous and will be minimized or eliminated by preventing occupational exposure to blood.

VI. Significance of Risk

Section 6(b)(5) of the OSH Act vests authority in the Secretary of Labor to issue health standards. This section provides, in part, that:

The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

OSHA’s overall analytic approach for setting worker health standards is a four-step process consistent with recent court interpretations of the OSH Act and rational, objective policy formulation. In the first step, a quantitative risk assessment is performed where possible and considered with other relevant factors to determine whether the substance to be regulated poses a significant risk to workers. In the second step, OSHA considers which, if any, of the regulatory alternatives being considered will substantially reduce the risk. In the third step, OSHA looks at the best available data to set the most protective requirements that are both technologically and economically feasible. In the fourth and final step, OSHA considers the most cost-effective way to achieve the objective.

In the Benzene decision, the Supreme Court indicated when a reasonable person might well consider the risk significant and take steps to decrease it. The Court stated:

It is the Agency’s responsibility to determine in the first instance what it considers to be a “significant” risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. (L.U.D. v. A.P.I. 448 U.S. at 655).

The Supreme Court’s language indicates that the examples given were of excess risk over a lifetime. It speaks of “regular inhalation” which implies that it takes place over a substantial period of time and refers to the “odds” that a person will die,” obviously a once in a lifetime occurrence. The Court indicated, however, that the significant risk determination required by the OSH act is “not a mathematical straitjacket” and that “OSHA is not required to support its findings with anything approaching scientific certainty.” The Court ruled that “a reviewing court (is) to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge” (and that) * * * the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection” (448 U.S. at 655, 656).

As part of the overall significant risk determination, OSHA considers a number of factors. These include the type of risk presented, the quality of the underlying data, the reasonableness of the risk assessments, and the statistical significance of the findings. The risks presented by the transmission of bloodborne pathogens are serious, as detailed above in the section on health effects. Hepatitis B is a viral infection that can cause acute and chronic disease. Symptoms of the disease can range from a flu-like illness to a more severe clinical illness characterized by jaundice, dark urine, nausea, vomiting, loss of appetite, abdominal pain and diarrhea. Chronic infection may also occur resulting in frequent periods of illness, and continual, usually life-long, infectious status. When an individual is infectious, either because of acute infection or because the individual has become a carrier, his or her blood and certain body fluids can transmit the virus to others. The infected individual’s family at risk. There is a 30% chance that a sexual partner will become infected if the patient has an acute infection. If the patient is a carrier the probability is much higher. Perinatal transmission from an infected employee to her infant is an efficient mode of transmission with a particularly serious outcome. In the most extreme cases of infection death can result from fulminant hepatitis, viral cirrhosis of the liver or liver cancer. (See Section IV—Health Effects).

HIV, the other major bloodborne pathogen, attacks the immune system, causing disease and death. Within a month following infection, the individual may experience an acute retroviral syndrome characterized by a mononucleosis-like syndrome. Later signs and symptoms can include persistent, generalized lymphadenopathy, fever, and constitutional illness characterized by wasting syndrome which may lead to death. HIV infected individuals who have developed AIDS may develop neurologic problems or cancer as well as opportunistic infections. Common conditions include encephalopathy, dementia, Pneumocystis carinii pneumonia; Kaposi’s sarcoma; candidiasis of the esophagus, trachea bronchi or lungs; as well as bacterial infections. The blood and certain other body fluids from an infected individual are capable of transmitting the infection to others.

In this proposed standard, OSHA has presented quantitative estimates of the risk of death and clinical illness from occupational exposure to HBV infected blood and other potentially infectious materials. Qualitative evidence of occupational transmission of HIV is also included in OSHA’s risk assessment.

OSHA estimates the lifetime risk of infection from HBV to be from 75 to 119 cases per thousand, the risks of material impairment of health or functional capacity, that is, clinical hepatitis, to be from 20 to 31 per thousand. The risk of death from HBV is 2 to 3 per one thousand. These estimates are based on the assumption of exposure to HBV for the period of a working lifetime of 45 years. Moreover, OSHA’s risk assessment shows that even if every employee were to receive the HBV vaccine there would still be a remaining risk of material impairment of health of 2 to 3 per one thousand workers based on the 90% efficacy of the vaccine. OSHA believes these preliminary estimates may understate the risk; the actual risks attributable to occupational exposure to bloodborne diseases may be much higher as suggested in the previous section.

In the benzeine decision the Court wrote of deaths from carcinogens, but the Act requires the Agency to assure that no employee will suffer * * * material impairment of health or functional capacity * * *. Obviously, material impairment includes not only death, the risk of which is more than twice the risk the Supreme Court suggested might be significant, but also serious illnesses or the development of permanent infectious status (HBV carrier). For HBV infection, material impairment occurs when the patient presents acute symptoms, suffers chronic hepatitis, or becomes a carrier.

As detailed above in Section IV—Health Effects, HBV infection can result in very serious and debilitating illnesses. Any one of the symptoms characterizing an acute or chronic infection such as fatigue, fever,
vomiting, abdominal pain, diarrhea and jaundice, by itself, is enough to prevent an employee from doing his or her job effectively, efficiently or at all. An infection that requires hospitalization, such as occurs in 20% of the cases of clinical hepatitis, will prevent an employee from working. The shortest period that an employee would be unable to work would be the time he or she is hospitalized, but undoubtedly the out-of-work time would be longer as additional recovery time is invariably required following hospital discharge. Since symptoms typically last from several weeks to several months and, in the case of chronic hepatitis, several years, there can be considerable lost work time. Becoming a carrier is a material impairment of health even though the carrier may have no symptoms. This is because the carrier will remain infectious, probably for the rest of his or her life, and any person who is not immune to HBV who comes in contact with the carrier’s blood or certain other body fluids will be at risk of becoming infected.

OSHA’s preliminary risk estimates from HBV are comparable to other risks which OSHA has concluded are significant, and are substantially higher than the example presented by the Supreme Court.

Public response to the ANPR indicated general agreement that the risk to employers of contracting HBV are unacceptably high. Indeed, many employers have already instituted or upgraded their infection control programs and are vaccinating their employees. Industry response to the various pertinent CDC guidelines, the Joint Advisory Notice published by DOL and HHS, and the OSHA compliance initiative has been generally positive, indicating an acceptance by employers that employees who are not provided the protections that would be mandated by this proposed standard are at risk of contracting HBV.

After thoroughly considering the magnitude of the risk as shown by the quantitative and qualitative data, OSHA preliminarily concludes that the risk of death and material impairment of health resulting from acute and chronic HBV infection is significant, that HBV presents a significant risk to both unvaccinated employees and employees who have been vaccinated but have not developed immunity. Moreover, because HBV is not the only bloodborne pathogen capable of causing disease, all employees who are exposed to blood and other potentially infectious materials, whether they are HBV-vaccinated or not, are at risk of infection.

At this time, OSHA believes that there are not sufficient data on HIV to quantify the occupational risk of infection. Nevertheless, the epidemiological data on HIV provide additional qualitative evidence that another bloodborne pathogen can be transmitted in the workplace and serve to further illustrate risk remaining after the major protection measure of HBV vaccination is implemented. OSHA’s preliminary determination that employees who work in virus research and production facilities are at risk is supported by the report of one employee out of a population of less than 100 who were working with concentrated HIV who seroconverted. These employees are at risk because the virus is concentrated and is present in much higher titers than in blood, thus increasing the likelihood of the employee becoming infected following an exposure incident.

OSHA also preliminarily concludes that the new bloodborne pathogen standard will result in a substantial reduction of significant risk. The risk of HBV infection is most efficiently and dramatically reduced by vaccinating all workers exposed to blood and other potentially infectious materials. Based on OSHA’s estimate of risk, vaccination of all workers would result in 2 fewer deaths and 18 to 28 fewer cases of material impairment of health per 1000 workers exposed over a working lifetime. If 30% of the population at risk is immune to HBV because of prior infection, then vaccinating the remaining 70% at risk will prevent approximately 290,407 infections, over 73,378 of which will be clinical infections including, in addition to cases of acute and chronic symptomatic illness, 29,616 carriers and 6,387 deaths over 45 years. If only 15% of the population at risk is immune, the number of infections prevented by vaccinating the remaining 85% at risk is estimated to be approximately 232,246 including 90,419 cases of clinical disease, over 12,447 carriers and more than 5,546 deaths over 45 years.

Despite these dramatic decreases in infections, OSHA’s risk assessment estimates 8 to 12 HBV infections with 2 to 3 cases of clinical hepatitis per 1000 workers would occur even if all exposed employees were to receive the HBV vaccine. This is because the vaccine is effective for only 90% of the people to whom it is given. Even this remaining risk is probably an underestimate of the number of HBV infections that are likely to occur because it is unlikely that all workers will agree to be vaccinated. Moreover, the HBV vaccine will not protect employees from other bloodborne pathogens such as HIV. Based on these data, OSHA has preliminarily concluded that widespread administration of the vaccine will not completely eliminate significant risks.

Congress passed the Occupational Safety and Health Act of 1970 because of a determination that occupational safety and health risks were too high. Based on this, it is clear that Congress gave OSHA authority to reduce risks of average or above average magnitude when feasible. Typical occupational risk of death (from all causes including accidents and illness) in occupations of average risk are 2.7 per 1,000 for all manufacturing and 1.62 per 1,000 for all service employment derived from 1979 and 1980 Bureau of Labor Statistics data from employers with 11 or more employees adjusted to 45 years of employment for 46 weeks per year. As OSHA believes the proposed standard for bloodborne pathogens will reduce HBV associated risk of death and material impairment of health from 20 to 31 per thousand to 3 to 4 per 1000, the Agency is carrying out the Congressional intent and is not attempting to reduce insignificant risks.

Under both the Congressional intent and the Supreme Court rationale, OSHA must, if feasible, reduce all significant risks including those remaining after administration of the HBV vaccine. OSHA expects that the proposed rule as drafted will reduce the risks of exposure to levels well below those estimated. This is because the estimates of risk reduction only quantify the reduction achieved with universal vaccination, and do not fully take into account the other protective provisions of the proposed standard such as the infection control program, and methods of compliance including universal precautions, engineering controls, work practices and personal protective equipment, as well as medical surveillance and training. For the purpose of this discussion, the decrease in risk to be achieved by the additional provisions is not quantified beyond a determination that they will add to the protection provided by the requirement to vaccinate alone.

OSHA has considered various regulatory alternatives in addressing the risks of occupational exposure to bloodborne pathogens. These include informing employers and employees of the risk through the Joint Advisory Notice published in the Federal Register by the Department of Labor and the Department of Health and Human Services and the institution of an
enforcement program. Although these efforts have been fruitful, they have not eliminated the risks and therefore OSHA has preliminarily concluded that a standard specifically addressing the risks of bloodborne pathogens is necessary. OSHA’s current data indicate that the alternative selected is both technologically and economically feasible. OSHA’s preliminary analysis of technological and economic feasibility of the proposed standard is discussed in the following section of the preamble.

VII. Preliminary Regulatory Impact and Regulatory Flexibility Analysis

Executive Summary

The Occupational Safety and Health Administration (OSHA) has prepared a Preliminary Regulatory Impact and Regulatory Flexibility Analysis for the proposed Bloodborne Pathogens standard. The analysis is presented in six sections: Introduction; Industry Profile; Benefits; Technological Feasibility; Costs of Compliance; and Economic Impacts.

Industry Profile

Industries where workers are in contact with or handle blood and other potentially infectious materials will be affected by the proposed standard. Sixteen such industry sectors were identified for this analysis: hospitals (SIC 806); dental offices (SIC 802); offices of physicians (SIC 802.803); medical and dental laboratories (SIC 807); nursing homes (SIC 806); residential care facilities (SIC 836); outpatient care facilities (SIC 806); blood collections and processing (SIC 809); health clinics in industrial facilities (various SIC codes); research laboratories (SIC 7391); law enforcement (SIC 9221); (fire protection (SIC 9224); correctional institutions (SIC 9223); funeral homes (SIC 726); personnel services (SIC 7362); and medical and dental equipment repair (SIC 384.769).

Table E.S-1 provides a summary of the number of affected establishments and employees by SIC classification. Over 616,000 establishments are estimated to be affected by the proposed rule. Most of these establishments, about 595,000, are in the health care sector.

Any employee who is routinely exposed to human blood or other potentially infectious material as part of their assigned duties and who comes under OSHA’s purview is affected by the proposed standard. On this basis, it is estimated that approximately 5.3 million workers will be affected by the standard. Approximately 87 percent of these workers, over 4.6 million people, are employed in health care occupations.

### Table E.S.-1.—SUMMARY OF AFFECTED ESTABLISHMENTS AND POPULATION AT RISK

<table>
<thead>
<tr>
<th>SIC code</th>
<th>Type of establishment</th>
<th>Number of establishments</th>
<th>Population at risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>801, 803</td>
<td>Offices of physicians</td>
<td>179,405</td>
<td>596,122</td>
</tr>
<tr>
<td>802</td>
<td>Offices of dentists</td>
<td>34,464</td>
<td>322,876</td>
</tr>
<tr>
<td>805</td>
<td>Nursing homes</td>
<td>18,347</td>
<td>778,975</td>
</tr>
<tr>
<td>806</td>
<td>Hospitals</td>
<td>5,983</td>
<td>2,145,140</td>
</tr>
<tr>
<td>807</td>
<td>Medical and dental labs</td>
<td>4,195</td>
<td>40,822</td>
</tr>
<tr>
<td></td>
<td>Dental</td>
<td>7,279</td>
<td></td>
</tr>
<tr>
<td>808</td>
<td>Outpatient care</td>
<td>23,706</td>
<td>370,514</td>
</tr>
<tr>
<td>809</td>
<td>Blood/ plasma/ tissue centers</td>
<td>672</td>
<td>22,198</td>
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<tr>
<td>836</td>
<td>Residential care</td>
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<tr>
<td>7362</td>
<td>Personnel services</td>
<td>1,815</td>
<td>155,844</td>
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<td>726</td>
<td>Funeral services</td>
<td>15,051</td>
<td>26,407</td>
</tr>
<tr>
<td>(*)</td>
<td>Health units in industry</td>
<td>221,850</td>
<td>223,900</td>
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<td>7391</td>
<td>Research labs</td>
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<td>9221</td>
<td>Law enforcement **</td>
<td>6,265</td>
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<td>9224</td>
<td>Fire and rescue***</td>
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<td>9223</td>
<td>Correctional facilities</td>
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<tr>
<td>384</td>
<td>Medical equipment repair</td>
<td>2,967</td>
<td>1,862</td>
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<tr>
<td>Totals</td>
<td></td>
<td>616,880</td>
<td>5,311,554</td>
</tr>
</tbody>
</table>

* Includes various SIC codes.
** Includes state and local departments only.
*** Includes fire departments and private ambulance services.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Benefits

After adjusting for background risk, OSHA has estimated that occupational exposures are responsible for between 5,853 and 7,416 cases of hepatitis B virus (HBV) infections per year. In total, considering the full combination of proposed provisions, including vaccination, engineering controls, work practices, protective equipment, housekeeping, and training, OSHA believes that the great majority of these HBV cases can be avoided. Compliance with the standard is estimated to prevent between 5,859 and 6,324 cases of occupationally induced HBV infection per year, of which 1,272 to 1,581 would have resulted in acute symptoms, and 113 to 141 in death.

In addition, OSHA estimates that between 3,653 and 4,132 non-occupationally induced cases of hepatitis B infection will be prevented annually, of which 81 to 92 would be fatal. These cases will be prevented due to the substantial elimination of background risk (non-occupational risk) for vaccinated workers and due to the reduced transmission of infections to sex partners of employees. In total, OSHA expects the proposed standard to prevent between 9,221 and 9,977 infections and between 205 and 222 deaths annually.

In addition to hepatitis B, the provisions of the standard will greatly reduce workers’ risk of contracting acquired immune deficiency syndrome (AIDS) and other bloodborne diseases. Since at least 25 cases of human immunodeficiency virus (HIV) infection were reported to be associated with occupational exposure, OSHA believes that at least some cases of AIDS will be avoided.

Technological Feasibility

Limiting worker exposure to bloodborne diseases is achieved through the implementation of the following categories of controls:
• Training and education programs
• Use of personal protective equipment, especially gloves, gowns, masks, and eye protection
• Use of mouth pieces, resuscitation bags or other ventilation devices
• Work practices, such as careful hand-washing after each patient contact and procedures for handling sharps
• Engineering controls, such as the use of puncture resistant containers
• Immunization programs
• Disposal and handling of contaminated waste
• Use of disinfectants
• Post exposure follow-up
• Labeling and signs

The requirements of the standard follow closely the guidelines issued by the Centers for Disease Control (CDC) on universal precautions (UP). As a consequence, the efforts by many organizations to adopt UP have created a solid base of practices and technology for the implementation of the standard. Table E.S.-2 provides a tabular summary of estimated current rates of compliance with the various provisions of the proposed standard.

OSHA findings with respect to the technological feasibility of the proposed Bloodborne Pathogens Standard are that the provisions of the standard permit practical means to reduce the risk now faced by those employees working with blood and other infectious materials and that there do not appear to be any major obstacles to implementing the proposed rule.

Costs of Compliance

Net compliance costs were estimated for each provision of the proposed standard by each facility type affected. These costs represent the additional costs of fully complying with the requirements of the standard, after deducting from total cost the current baseline activities that already voluntarily occur at affected facilities.

Table E.S.-3 summarizes annual net compliance costs by facility type and by provision. While Table E.S.-4 provides cost by provision components. The total annual costs amount to about $852 million.

![Table E.S.-2.—SUMMARY OF CURRENT COMPLIANCE](image1)

![Table E.S.-3.—SUMMARY OF COMPLIANCE COSTS](image2)

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1 Includes $3.628 for signs.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.
TABLE E.S.-4.—SUMMARY OF COMPLIANCE COSTS BY PROVISION

<table>
<thead>
<tr>
<th>Provision</th>
<th>Costs (millions)</th>
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<tbody>
<tr>
<td>Infection Control Plan</td>
<td>16,502,710</td>
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<tr>
<td>Vaccination/Follow-up</td>
<td>76,374,079</td>
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<td>Vaccination</td>
<td>60,366,624</td>
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<tr>
<td>Program</td>
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<tr>
<td>Post-Exposure Follow-up</td>
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<tr>
<td>PPE</td>
<td>400,717,716</td>
</tr>
<tr>
<td>Gloves</td>
<td>161,144,593</td>
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<tr>
<td>Masks</td>
<td>159,330,782</td>
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<tr>
<td>Gowns</td>
<td>62,914,128</td>
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<tr>
<td>Goggles</td>
<td>6,695,468</td>
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<tr>
<td>Respirators</td>
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<tr>
<td>Devices</td>
<td>8,432,726</td>
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<tr>
<td>Training</td>
<td>162,151,255</td>
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<tr>
<td>Housekeeping</td>
<td>188,677,264</td>
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<tr>
<td>Sharps Disposal</td>
<td>28,484,263</td>
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<tr>
<td>Biohazard Bags</td>
<td>28,348,556</td>
</tr>
<tr>
<td>Infectious Waste Disposal</td>
<td>117,217,433</td>
</tr>
<tr>
<td>Covering</td>
<td></td>
</tr>
<tr>
<td>(Dental Offices)</td>
<td>14,863,312</td>
</tr>
<tr>
<td>Labeling/Signs</td>
<td>3,626</td>
</tr>
<tr>
<td>Recordkeeping</td>
<td>5,554,209</td>
</tr>
<tr>
<td>Total</td>
<td>852,180,862</td>
</tr>
</tbody>
</table>

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Personal protective equipment accounts for the largest amount of net compliance costs ($400 million per year). Housekeeping ($162 million), training ($162 million), and vaccination and post exposure follow-up ($78 million) were also found to be significant cost components.

Economic Feasibility and Regulatory Flexibility Analysis

Table E.S.-5 provides a summary of economic impacts for the facility types affected by the proposed standard. The cost of the standard is largest relative to profits for temporary help services, where costs may represent over 12% of profits. Profit impacts also exceed 10% for dental offices (11%), though the impact estimate uses a profit figure which is exclusive of dentists’ salaries. Dental offices have the highest costs relative to revenue. Two other high impact sectors are nursing homes (over 9 percent) and residential care facilities (over 5 percent).

It is probable that a large part of the compliance costs for establishments in SIC 80 (health care) will be passed on to consumers and third party payers. Also, the structure of health care financing in the United States dictates that a large proportion of the cost impact will be borne by federal, state and local government.

OSHA finds that a large number of small businesses, defined as firms with annual revenues of less than $3.5 million, will be affected by the proposed rule. With the exception of hospitals, over 50 percent of all health care facility types are small businesses. Thus, the impact on small business should not differ significantly from the impact on the affected universe as a whole. In the hospital sector, one consequence may be some increased industry consolidation, as smaller hospitals report lower operating margins than larger hospitals (Ex. 13, p. IV-16).

TABLE E.S.-5—SUMMARY OF ECONOMIC IMPACTS

<table>
<thead>
<tr>
<th>Industry</th>
<th>Revenue/budget ($ million)</th>
<th>Profits ($ million)</th>
<th>Annual costs ($ million)</th>
<th>Costs/revenue (percent)</th>
<th>Costs/profits (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>92,900</td>
<td>$6,000</td>
<td>149,599</td>
<td>0.161</td>
<td>2.168</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>25,700</td>
<td>$2,030</td>
<td>223,577</td>
<td>0.870</td>
<td>11.013</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>30,000</td>
<td>$19,000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitals</td>
<td>161,000</td>
<td>$5,181</td>
<td>194,911</td>
<td>0.114</td>
<td>2.231</td>
</tr>
<tr>
<td>Medical/Dental Labs</td>
<td>7,100</td>
<td>$5,181</td>
<td>194,911</td>
<td>0.114</td>
<td>2.231</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>33,750</td>
<td>$1,039</td>
<td>38,399</td>
<td>0.114</td>
<td>2.231</td>
</tr>
<tr>
<td>Blood/Plasma/Tissue centers</td>
<td>1,420</td>
<td>$961</td>
<td>122,886</td>
<td>0.402</td>
<td>9.309</td>
</tr>
<tr>
<td>Residential care</td>
<td>8,700</td>
<td>$254</td>
<td>21,641</td>
<td>0.249</td>
<td>5.754</td>
</tr>
<tr>
<td>Personal services</td>
<td>3,200</td>
<td>$1,118</td>
<td>11,507</td>
<td>0.359</td>
<td>11.979</td>
</tr>
<tr>
<td>Funeral services</td>
<td>5,500</td>
<td>$390</td>
<td>2,121</td>
<td>0.039</td>
<td>0.543</td>
</tr>
<tr>
<td>Research Labs</td>
<td>10,300</td>
<td>$433</td>
<td>13,661</td>
<td>0.133</td>
<td>2.017</td>
</tr>
<tr>
<td>Fire and rescue</td>
<td>4,000</td>
<td>$433</td>
<td>13,661</td>
<td>0.133</td>
<td>2.017</td>
</tr>
<tr>
<td>Corrections</td>
<td>9,900</td>
<td>$433</td>
<td>13,661</td>
<td>0.133</td>
<td>2.017</td>
</tr>
<tr>
<td>Police</td>
<td>16,900</td>
<td>$433</td>
<td>13,661</td>
<td>0.133</td>
<td>2.017</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>($7)</td>
<td>$433</td>
<td>13,661</td>
<td>0.133</td>
<td>2.017</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>18,700</td>
<td>$1,000</td>
<td>4,436</td>
<td>0.022</td>
<td>0.042</td>
</tr>
</tbody>
</table>

* Profit totals reflect proprietary firms only.
* Profits exclusive of salary.
* Profits including salaries.
* Based on profit margin of ambulatory facilities.
* Based on profit margin of nursing home sector.
* Medical equipment supply firms only.
* Ratio reflects private firms only.
* Health care budgets not estimated.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

a. Introduction. Executive Order 12291 (46 FR 13197, February 19, 1981) requires that a regulatory impact analysis be conducted for any rule having major economic consequences on the national economy, individual industries, geographical regions, or levels of government. Similarly, the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires the Occupational Safety and Health Administration (OSHA) to consider the impact of the regulation on small entities.

Consistent with these requirements, OSHA has prepared a preliminary Regulatory Impact and Regulatory Flexibility Analysis for the proposed Bloodborne Pathogens standard. This analysis describes the industries affected by the standard, the potential benefits that will be realized by health care workers and others who are currently at risk, the current infection control practices in the workplace, the costs of compliance, and OSHA’s assessment of the technological and economic feasibility of the standard.

b. Industry Profile. Of interest in this proposed rulemaking are those workplaces in which employees are exposed to blood or other potentially infectious materials (as defined earlier in this preamble) during the performance of their duties. OSHA has
included sixteen industry sectors in this analysis: hospitals (SIC 806); dental offices (SIC 802); offices of physicians (SIC 805); medical and dental laboratories (SIC 807); nursing homes (SIC 806); residential care facilities (SIC 836); outpatient care facilities (SIC 808); blood collections and processing (SIC 809); health clinics in industrial facilities (various SIC codes); research laboratories (SIC 7391); law enforcement (SIC 9221); fire protection (SIC 9224); correctional institutions (SIC 9223); funeral homes (SIC 726); personnel services (SIC 7362); and medical and dental equipment repair (SIC 384,7699).

Estimates of the number of affected establishments were based largely on government statistical publications as presented in a report to OSHA by Jack Faucett Associates [JFA] [Ex. 13]. Table VII-1 enumerates affected establishments by SIC code. As shown in the table, an estimated 616,880 establishments will be affected by the proposed rule.

JFA also provided estimates of the affected worker population. The major occupational groups exposed to blood and other infectious materials include nurses, physicians, dental professionals, laboratory workers, phlebotomists, and emergency responders. Table VII-2 provides a tabular summary of the population at risk. (Except where otherwise noted, population at risk data are based on the Bureau of Labor Statistics' [BLS] Industry Occupation Matrix for 1986). The 3.3 million workers identified do not include state and local government workers in states without state occupational safety and health plans, because these workers are not covered by OSHA. Thus, unless noted otherwise, estimates of the population at risk and the number of affected establishments used below reflect state and local governments only to the extent that state occupational safety and health plans are in place. Moreover, the estimate does not include the reported 190,000 self-employed physicians and dentists who would not fall under OSHA's purview.

The most common routes of exposure are by needlestick or entry through mucousal membranes or non-intact skin. These types of exposure occur across all of the affected industry sectors and throughout the various occupational categories. Exposure also takes place via cuts with sharp instruments or broken glass. Other routes of exposure are more or less confined to certain types of procedures. For example, laboratory employees may be exposed to contaminated equipment such as centrifuges or pipetting devices.

The remainder of this section briefly examines each industry, developing estimates of the number of affected establishments and employees, and describing the industry structure. Sources of exposure are also discussed.

<table>
<thead>
<tr>
<th>SIC code</th>
<th>Type of establishment</th>
<th>Number of establishments</th>
</tr>
</thead>
<tbody>
<tr>
<td>801-803</td>
<td>Offices of physicians</td>
<td>179,405</td>
</tr>
<tr>
<td>802</td>
<td>Offices of Dentists</td>
<td>94,994</td>
</tr>
<tr>
<td>803</td>
<td>Nursing homes</td>
<td>19,347</td>
</tr>
<tr>
<td>806</td>
<td>Hospitals</td>
<td>9,683</td>
</tr>
<tr>
<td>807</td>
<td>Medical and dental labs.</td>
<td>12,195</td>
</tr>
<tr>
<td>808</td>
<td>Medical</td>
<td>4,916</td>
</tr>
<tr>
<td>809</td>
<td>Dental</td>
<td>7,279</td>
</tr>
<tr>
<td>836</td>
<td>Residential care</td>
<td>2,057</td>
</tr>
<tr>
<td>7362</td>
<td>Personnel services</td>
<td>1,615</td>
</tr>
<tr>
<td>736</td>
<td>Health units in industry.</td>
<td>18,023</td>
</tr>
<tr>
<td>7391</td>
<td>Research labs</td>
<td>2,145</td>
</tr>
<tr>
<td>9221</td>
<td>Law enforcement</td>
<td>6,205</td>
</tr>
<tr>
<td>9224</td>
<td>Fire and rescue</td>
<td>3,174</td>
</tr>
<tr>
<td>9223</td>
<td>Correctional facilities.</td>
<td>2,333</td>
</tr>
<tr>
<td>384</td>
<td>Medical equipment repair.</td>
<td>2,967</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>616,833</td>
</tr>
</tbody>
</table>

1 Includes various SIC codes.
2 Includes state and local departments only.
3 Includes fire departments and private ambulance services.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.
### Table VII-2.—Summary of Population at Risk

<table>
<thead>
<tr>
<th></th>
<th>Hospitals</th>
<th>Dental offices</th>
<th>Physicians offices</th>
<th>Med./dent. labs</th>
<th>Re-search labs</th>
<th>Police depats.</th>
<th>Fire &amp; rescue</th>
<th>Nursing homes</th>
<th>Residential care</th>
<th>Outpatient care</th>
<th>Funer-al homes</th>
<th>Person-nel services</th>
<th>Correc-tional institu-tions</th>
<th>Blood/tissue collection</th>
<th>Industr-i-clinic</th>
<th>Equip-ment repair</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians</td>
<td>100,460</td>
<td>1,194</td>
<td>206,929</td>
<td>2,222</td>
<td>2,294</td>
<td>579</td>
<td>50,586</td>
<td>2,251</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>368,516</td>
</tr>
<tr>
<td>Dentists</td>
<td>4,938</td>
<td>74,976</td>
<td>451</td>
<td>233</td>
<td>295</td>
<td>2,371</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>79,967</td>
</tr>
<tr>
<td>Registered nurses</td>
<td>756,836</td>
<td>1,505</td>
<td>67,515</td>
<td>534</td>
<td>10,366</td>
<td>1,074</td>
<td>119,877</td>
<td>43,455</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>1,031,162</td>
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<tr>
<td>Lic. practice nurses</td>
<td>30,195</td>
<td>496</td>
<td>52,759</td>
<td>248</td>
<td>116,565</td>
<td>8,125</td>
<td>32,530</td>
<td>28,556</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>542,220</td>
</tr>
<tr>
<td>Occupational nurse</td>
<td>83,730</td>
<td>136</td>
<td>5,815</td>
<td>229</td>
<td>23,297</td>
<td>1,460</td>
<td>14,124</td>
<td>2,235</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8,492</td>
</tr>
<tr>
<td>Therapists</td>
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<td>1,191</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>21,949</td>
</tr>
<tr>
<td>Dentist hygienists</td>
<td>620</td>
<td>84,332</td>
<td>495</td>
<td>164</td>
<td>50</td>
<td>800</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>86,551</td>
</tr>
<tr>
<td>Laboratory tech.</td>
<td>132,619</td>
<td>566</td>
<td>30,075</td>
<td>28,065</td>
<td>7,820</td>
<td>233</td>
<td>14,281</td>
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<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Emerg. med. tech.</td>
<td>12,921</td>
<td>77</td>
<td>864</td>
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<td>25,290</td>
<td>2550</td>
<td>11,621</td>
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<tr>
<td>Surgical tech.</td>
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<td>31,497</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50,331</td>
</tr>
<tr>
<td>Other health prof.</td>
<td>54,327</td>
<td>886</td>
<td>6,026</td>
<td>2,399</td>
<td>302</td>
<td>2,800</td>
<td>4,387</td>
<td>27,359</td>
<td>357</td>
<td>38,486</td>
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<td>Dental asst.</td>
<td>1,390</td>
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<td>211</td>
<td>165</td>
<td>3,983</td>
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<td></td>
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<tr>
<td>Nursing aids/ orderlies</td>
<td>325,743</td>
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<td></td>
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<td>Ambulance drivers</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Janitors &amp; cleaners</td>
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<td>103,182</td>
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<td></td>
<td></td>
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<td>97,945</td>
</tr>
<tr>
<td>Police officers</td>
<td>200,873</td>
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<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>200,873</td>
</tr>
<tr>
<td>Fire fighters</td>
<td>170,515</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>170,515</td>
</tr>
<tr>
<td>Embarllers</td>
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<td></td>
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<td></td>
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<td>20,921</td>
</tr>
<tr>
<td>Corrections staff</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>97,945</td>
</tr>
<tr>
<td>Nurses/ phlebotomists</td>
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<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>9,300</td>
</tr>
<tr>
<td>Blood bank lab workers</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6,510</td>
</tr>
<tr>
<td>Plasma center workers</td>
<td>5,600</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>Emergency personnel</td>
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<td>234,536</td>
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<td>Unpackers/ cleaners</td>
<td>1,882</td>
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<tr>
<td>Total affected</td>
<td>2,145,140</td>
<td>322,678</td>
<td>536,122</td>
<td>40,822</td>
<td>98,715</td>
<td>208,689</td>
<td>201,749</td>
<td>778,375</td>
<td>80,569</td>
<td>370,514</td>
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<td>22,198</td>
<td>223,903</td>
<td>1.882</td>
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Source: Occupational Safety and Health Administration, Office of Regulatory Analysis; Bureau of Labor Statistics; and Jack Faucett Associates.
Fluids would be expected in a hospital's occupational category, with over 148,000 offices. As most hospitals perform a great deal of work, the difference between the total revenue and expenses is estimated at $174 billion (Ex. 13, p. I-38).

The potentially exposed workforce includes physicians (2,223), phlebotomists (84,332), and medical technologists (2,849) and nurses (782). As most hospitals perform a great deal of work, the difference between the total revenue and expenses is estimated at $174 billion (Ex. 13, p. I-38).

Physicians performing gynecological examinations or examining patients for sexually transmitted diseases are most commonly encountered. When disinfecting dental instruments, evidence suggests that a common route of exposure in the dental office is allowing chapped or abraded skin to come into contact with saliva and/or tissue fluids also increases risk. Dental workers are at risk in hospitals. Nurses and laboratory technicians, and janitors collectively make up an additional 20 percent (Ex. 13, p. 1-10).

As most hospitals perform a great variety of services, there are many different exposure scenarios. The most frequently reported route of exposure for hospital personnel is by needlestick, with the greatest potential for exposure occurring during needle recap (Ex. 13, p. 1-12). Other hospital procedures that are associated with frequent exposure include phlebotomy, IV line placement, bronchoscopy, intubation, airway suction, endoscopy, colonoscopy, and proctosigmoidoscopy (Ex. 13, p. II-19). The highest risk areas in hospitals include the emergency room, surgical suite, hemodialysis center, and intensive care unit. Laundry workers and janitors may be exposed when handling contaminated linen or refuse.

Total revenue in 1986 for all hospitals is estimated at $774 billion (Ex. 13, p. I-10), about 84% of which was received by community hospitals. The total margin for hospitals, that is, the difference between revenue from all sources and total expenses expressed as a percentage of total revenue, is estimated to be about 4.5 to 5% (Ex. 13, p. I-10). U.S. Commerce Department estimates indicate that the 1988 total revenue for hospitals affected by the standard will be $199.1 billion with profits for proprietary hospitals totalling $1.6 billion.

Offices of Physicians. As shown in Table VII-1, an estimated 179,405 physicians' offices will be covered by the proposed rule. (This estimate is based on 1982 Census of Service Industries for offices with salaried employees).

While exposure to blood and body fluids would be expected in a physician's office, the increase in the number of physician office laboratories (POLs) now provides an even greater potential for exposure. These office-based laboratory facilities have recently grown in number by about 15 percent annually, though the total number of such facilities is unknown (Ex. 13, p. I-38).

The number of potentially exposed workers in physicians' offices is estimated to be 336,122 (Ex. 13, p. I-37). Physicians are the predominant occupational group, making up just under 40 percent of the total. As noted above, 119,000 self-employed physicians are excluded. Nurses comprise approximately 28 percent of the total and medical assistants about 17 percent.

Frequency and type of exposure in a physician's office depends on the type of practice and the distribution of tasks. It is likely that phlebotomy is performed in a large number of offices, especially those with laboratory facilities. This task is typically performed by nurses. Nurses also change wound dressings, physicians performing gynecological examinations or examining patients for sexually transmitted diseases are most certainly at risk. Invasive procedures and examination of mucous membranes can also put the examining physician at risk. Other types of procedures commonly encountered which place physicians and physicians' assistants at risk are. dirt treatment of lacerations, abrasions, and compound fractures.

Revenue for SIC codes 801 and 803 (offices of medical doctors and of doctors of osteopathy, respectively) totalled $76.7 billion in 1986 and are expected to climb to about $92 billion in 1988. Pre-tax profits are expected to reach $6.9 billion, non-inclusive of physicians' salaries. Profits including physicians' salaries are expected to total $57.5 billion (Ex. 13, p. I-33, -36).

Offices of Dentists. Based on 1982 Census data, OSHA estimates that 9.494 dental facilities will be affected by the proposed rule. (As noted above for Offices of Physicians, this includes offices with salaried employees). Dentist office laboratories numbered 9,737 in 1982, which is consistent with the American Dental Association (ADA) report that 41% of dentists practice in an office with a laboratory. However, only 8.4% of these offices employ a lab technician (Ex. 13, p. I-26).

The potentially exposed workforce numbers 322,676 (Ex. 13, p. I-23). Dental Assistants are the predominant occupational category, with over 148,000 listed by BLS. The number of dental hygienists is estimated to be 84,332 and the number of dentists is approximately 74,679. (The 71,000 dentists who are reported as self-employed were not included in this figure). Data from the ADA indicate that 51% of all dental practices employ hygienists, with a mean workweek of 23 hours for this occupation. About 86% of dental practices employ a dental assistant (Ex. 13, p. I-27, -28).

Evidence suggests that a common route of exposure in the dental office is allowing chapped or abraded skin to come into contact with saliva and for blood. Also, dental staff receive on average in excess of one needlestick injury per month, a result consistent with the high percentage of dental staff who engage in recap (Ex. 13, p. 11-52). Instances where the face or eyes are splashed or splattered with saliva, blood, or tissue fluids also increases risk. Dental workers are also exposed if improper procedures or improper techniques are used when disinfecting dental instruments.

Revenues for dental offices for 1986 were reported by the U.S. Commerce Department to be $21.4 billion. Operating profits were 7.7% of revenues, according to data from Robert Morris Associates. Commerce Department estimates indicate that 1988 total revenues for dentists will be $25.7 billion. Applying the 1987 profit margin of 7.9% yields total profits for 1988 of $2 billion (Ex. 13, p. I-27).

Total income, including dentists' salaries, was also estimated. ADA data from 1983 indicate that general practitioners had average annual gross income of $154,830 and average net income of $55,570. For specialists, average gross income was $213,700, and net income was $84,250 (Ex. 13, p. I-28). Assuming an average net income of $50,000, an average number of dentists per practice of 3.4, and a number of affected practices of 49,994, yields a total income estimate of approximately $19 billion.

Medical and Dental Laboratories. Census data from 1982 indicate that approximately 12,000 medical and dental labs will be affected by the proposed rule. An estimated 7,279 dental laboratories and 4,916 medical laboratories were identified (Ex. 13, p. I-39).

The population at risk in medical and dental labs totals 40,822 workers (Ex. 13, p. I-41). Laboratory technicians comprise 68 percent of this total. Other occupational categories represented include physicians (2,223), phlebotomists and medical technologists (4,754), and nurses (782). According to census data, medical labs averaged 13 employees each and dental labs averaged 5 employees each in 1984.
Procedures that most often result in exposure in the laboratory are specimen collection and specimen processing. Workers are exposed through needles (phlebotomists), spills, or the improper use of laboratory equipment, such as the centrifuge. Phlebotomists appear to have the highest rate of exposure incidents (Ex. 13, p. II-69).

Revenues for medical labs were $4.4 billion in 1986, and dental lab receipts totaled $1.0 billion for that year. Based on Robert Morris data, medical labs realized pre-tax profits of 7.5% of total receipts in 1986, and thus earned net profits of $300 million. Assuming the same margin is applicable for dental labs yields a net profit figure of $120 million for 1986. Revenue for medical and dental labs is estimated to be $7.1 billion in 1988, with profits totaling $475 million (Ex. 13, p. I-39).

Nursing Homes. This sector includes three types of facilities: nursing homes, of which there are estimated to be about 17,000; homes for emotionally disturbed children, of which there are 322; and homes for the mentally ill, of which there are 1,341. (Preliminary data on number of establishments were obtained from the 1986 National Center for Health Statistics survey of nursing and related care homes and from the Public Health Service.) It was reported that in 1986 roughly 72% of nursing homes were proprietary (Ex. 13, pp. I-55, I-56).

The potentially exposed workforce for this sector is estimated at 778,375. Nursing aids and orderlies are by far the most numerous workers, comprising over 65% of the total. Over 125,000 nurses are potentially exposed, as well as over 100,000 janitors and cleaners (Ex. 13, p. I-59).

It is the nursing staff who most often come into contact with body fluids of patients. Although the types of care rendered do not put staff into direct contact with blood very often, some contact with blood occurs. Needlesticks and sharps do not appear to present a great hazard, as the number of invasive procedures performed by staff is generally low (Ex. 13, p. II-97). Nonetheless, the number of these exposures is increasing as cost-containment measures by hospitals encourage early patient release. As OSHA learns of new cases of exposure in these job tasks, the Agency requests additional public comment on the nature of employee exposures to blood and other infectious materials in nursing homes.

The 1986 revenue for nursing homes was $26.4 billion, representing 9.4% of the national health care budget. Based on Commerce Department information, gross revenues for those homes affected by the proposed rule will be $30.6 billion in 1988 (Ex. 13, pp. I-60). Using the 1987 Robert Morris pre-tax profit estimate of 4.3% of receipts, 1988 profits for proprietary homes are estimated to be $960 million.

Residential Care. Residential care establishments affected by the proposed rule number about 20,537, based on information obtained from the National Center for Health Statistics for 1986. These include homes for the elderly and homes for the developmentally disabled. About 83% of homes for the elderly and 43% of homes for the developmentally disabled are proprietary. Homes for the elderly are generally quite small, with about 60% consisting of only 3 to 9 beds (Ex. 13, p. I-64, I-65).

BLS employment data suggest that 80,569 workers are at risk in residential care facilities. As in nursing homes, nursing aids and orderlies make up the largest percentage of workers. About 50% of all potentially exposed workers fall into this category. Janitors and cleaners make up another 25% and over 9,000 nurses are at risk (Ex. 13, p. I-69).

As in nursing homes, blood exposures in residential care facilities do not occur often, but contact with blood does occur. The risk of exposure is greatest where unprotected chapped or non-intact skin comes into contact with blood or other potentially infectious materials. As noted above for nursing homes, OSHA requests additional public comment on the nature of potential exposures in this sector.

Estimated 1986 revenues for residential facilities affected by the standard were $7.4 billion. Estimated revenues for 1986 are $9.7 billion (Ex. 13, p. I-66) and estimated profits for proprietary facilities are estimated to be approximately $254 million.

Outpatient Care Facilities. Most outpatient care facilities fall into one of the following six categories: Health Maintenance Organizations (HMOs), freestanding ambulatory, hospices, home health care, drug treatment, or hemodialysis.

An estimate of the number of HMOs is based on the 1987 Census of Health Maintenance Organizations conducted by Interstudy and includes 654 establishments (Ex. 13, p. I-72). Most HMOs are independent, but some are administered by insurance companies (31 plans), hospital chains (10 plans), and corporations or consulting firms (15 plans) (Ex. 13, p. I-72).

The number of ambulatory care facilities is estimated to be 4,500, based on information for 1967 from the National Association of Ambulatory Care (NAAC). A reported 41.4% of these facilities are owned by corporations (Ex. 13, p. I-74).

Information published in 1987 puts the number of hospice care facilities at about 812, excluding hospices based in hospitals or home health establishments. The vast majority of hospices are non-profit, with 42% being independent, community based organizations (Ex. 13, p. I-74).

The number of home health care facilities that would be affected is estimated to be 7,000, based on 1986 data on Medicare-certified establishments and on 1987 data from the National Association of Home Health Care (Ex. 13, p. I-72).

The most recent data regarding drug treatment centers, a 1982 survey by the National Institute on Alcohol Abuse and Alcoholism, placed the number of such facilities at 4,816. Excluding those facilities based in hospitals and correctional facilities leaves an estimated 3,887 centers that classify as outpatient facilities (Ex. 13, p. I-75).

Medicare-certified hemodialysis centers numbered 1,578 in 1986, but only 861 were freestanding. About 80% of these facilities are for-profit (Ex. 13, p. I-75).

Also, 10,483 government outpatient care facilities are estimated to be in operation (Ex. 13, p. I-75A). It is likely that this total includes a number of facilities which provide care for the mentally retarded.

Thus, the total number of outpatient facilities believed to be covered by the proposed rule is 29,706.

The affected worker population totals 370,514 (Ex. 13, p. I-79). Over 150,000 nurses are at risk in this sector, as well as approximately 61,000 nursing aids and orderlies. An estimated 50,580 physicians and surgeons are also at risk.

With so many different kinds of services offered within this SIC, all major routes of exposure are expected. Ambulatory centers and HMOs perform many of the same procedures that are performed in a physician's office, and thus exposure routes are similar to those outlined for that sector. Home health and hospice services perform many of the same procedures performed in a nursing home or residential care facility, and thus the exposure potential is similar. Over 14,000 laboratory technicians were identified in this sector by BLS, so exposure via laboratory procedures and equipment is probable.

Revenues for home health care establishments is estimated at $8 billion, as this was the level of expenditure on such services in 1986. Total revenue for ambulatory centers is estimated at $2 billion, based on 1983 data compiled by
NAAC. Profit levels for ambulatory care centers were reportedly 5.1% of profits (Ex. 13, pp. 1-75, -77). In 1988, outpatient facilities are projected to receive about $1.97 billion in revenues and proprietary facilities are projected to receive about $1.0 billion in profits.

Blood Collections and Processing. According to information received from the American Association of Blood Banks (AABB), there are 290 independent blood centers in operation. About 400 plasma centers and 12 tissue banks will also be affected by the proposed rule, based on information supplied by the American Blood Resources Association (ABRA) and the American Association of Tissue Banks (Ex. 13, pp. 1-95).

The population at risk for this sector is estimated to be 22,156 workers (Ex. 13, pp. 1-96). Phlebotomists, nurses, and laboratory workers are the predominant occupational categories for blood banks, and it is reasonable to assume that this is also true for plasma centers and tissue banks. Over 40% of all blood center employees are part-time.

Workers in this sector are exposed most often during blood collection and blood processing. As in medical and dental labs (discussed above), workers in this SIC are exposed through needlesticks (phlebotomists), mucous membrane contacts, spills, or the improper use of laboratory equipment, such as the centrifuge (Ex. 13, pp. 125-127).

Revenue for blood centers was estimated at $1.3 billion in 1987, based on data obtained from 106 members of AABB. Using this figure as an indicator for the sector as a whole yields a total revenue estimate of $1.42 billion for SIC 809.

Health Clinics in Industrial Facilities. Of the 16 sectors included in this analysis, this sector includes the most facilities, as 221,650 industrial health clinics have been identified (Ex. 13, p. 1-10). These services are in operation throughout industry and are not peculiar to any SIC code or industry sector.

The potentially exposed workforce is estimated to be 98,715 (Ex. 13, p. 1-46). These workers are scientists, research assistants, and laboratory technicians.

Exposure incidents in this sector, as in all others, tend to be linked to procedures. Workers in these types of establishments, however, have little or no patient contact. Spills, which may cause infectious material to come into contact with non-intact skin, mucous membrane contamination, and cuts with sharp instruments are the most frequent routes of exposure in these facilities. Reduction of risk will be almost totally dependent upon the use of engineering controls and proper laboratory work practices when handling potentially infectious materials. Paragraph (e) of the standard contains special requirements for research laboratories and production facilities handling the concentrated virus. Additional training requirements for employees in these facilities are found in paragraph (9)(2)(v).

Based on a study by the National Science Foundation, approximately 28% of funds expended for private research went for medical research. This translates to an annual budget of $2.5 billion for 1986. Additionally, $3.8 billion was spent in the U.S. on pharmaceutical research in 1986. Profit margins for commercial and development labs were 43.7 percent of receipts for that year.

Information obtained by BAH indicates that federally sponsored labs have average budgets of $2.2 million. Assuming this figure is applicable to medical research labs, the 100 federally sponsored medical labs would have a total budget of about $220 million (Ex. JFA, pp. 1-43-44).

Total revenues for this sector are estimated to be $10.3 billion (Ex. 13, p. 1-44). Profits for proprietary labs are estimated at $433 million.

Law Enforcement. The total number of law enforcement establishments affected is approximately 6,205 (Ex. 13, p. 1-47). This number includes state and local police departments in states with state occupational safety and health plans. These departments employ approximately 170,000 workers who are at risk. Based on Bureau of Justice Statistics (BJS) and Census Bureau data, federal law enforcement personnel at risk number approximately 31,000.

These personnel, at risk because their jobs provide potential for contact with blood and blood contaminated weapons and drug paraphernalia, are estimated to represent 70 percent of all law enforcement officers (Ex. 13, p. 1-46). Additionally, approximately 8,000 laboratory technicians are estimated to be at risk in police labs (Ex. 13, p. 1-49).

Law enforcement personnel are at risk because they may come into contact with blood or other potentially infectious materials during the course of duty. In the event that violent crime or life-saving situations are encountered, appropriate precautions need to be taken in the form of proper work practices and personal protective equipment. The frequency of these exposures varies with the locality and the rate of violent crime, but OSHA estimates that about 10% of these employees are exposed on a fairly frequent basis.

According to BJS, expenditures for law enforcement totalled $22 billion for fiscal year 1984-85. State and local governments spent $19.2 billion and federal expenditures were $2.8 billion (Ex. JFA, p. 1-47). It is estimated that 1988 expenditures will be $30.8 billion, with 47.5%, or $16.7 billion, occurring in state-plan states.

Fire Protection. About 3,174 fire departments will be covered by the proposed rule. All-volunteer fire departments do not come under OSHA's purview and thus are not included in this estimate. (The actual number of stations, however, appears to be roughly 5,232, as many departments operate out of more than one station.) Private emergency medical establishments number about 500 (Ex. 13, p. 1-51).

The potentially exposed workforce is estimated to be 201,749 workers. These are mostly career fire fighters plus volunteers who are paid part-time wages. Private rescue services employ 25,550 of these potentially exposed workers (Ex. 13, p. 1-53).

Emergency responders, who are estimated to comprise about 30% of these employees, are very often in situations where there is a potential for occupational exposure. Emergency
medical technicians perform invasive procedures and administer resuscitation. These workers are frequently exposed to blood.

Expenditures on fire protection in state plan states is estimated to be approximately $40.0 billion [Ex. 13, p. 1-82].

Correctional Institutions. An estimated 2,333 correctional institutions are affected by the proposed rule. Of these, 47 facilities are federally administered. A reported 65 of the 2,333 facilities identified medical treatment or hospitalization as a primary function. (These figures are based on BLS census information for the years 1983 and 1984). [Ex. 13, p. 1-92]

The number of state and local custody and security employees estimated to be at risk is 74,000. Additionally, 12,000 treatment, and education employees are estimated to be at risk in state and local facilities. Adding the 12,000 federal workers at risk yields a total population at risk of $89,000 [Ex. 13, p. 1-92].

Situations putting correctional employees at risk of blood exposure include violence and emergency medical treatment. While exposure to other potentially infectious materials takes place in correctional facilities, such situations do not occur on a daily basis. Expenditures for corrections in state plan states is estimated to have reached $5.9 billion in fiscal year 1984-85. Federal government expenditures were $770 million in 1985. Total expenditures are expected to be $9.9 billion in 1988 [Ex. 13, p. 1-92].

Funeral Homes. The number of funeral homes believed to be affected by the proposed rule is 15,051. This is based on the 1982 Census of Service Industries [Ex. 13, p. 1-84]. The total number of workers estimated to be at risk in funeral homes is 26,407 [Ex. 13, p. 1-87]. The majority of these workers are embalmers (about 83%) with janitors making up most of those remaining.

Procedures placing funeral home workers at risk of exposure are embalming, cleaning, disinfecting, and transporting cadavers. Embalmers are at risk due to the presence of uncontained blood, and the need to handle various body parts and tissues and to suture incisions.

According to census data, revenues for all funeral services and crematories were $5.5 billion in 1988. Average profit margins were estimated to have been 7.1% in 1987, making profit levels for the industry about $390 million [Ex. 13, p. 1-84].

Personnel Services. JFA estimates that between 1,301 and 1,615 personnel firms worked with registered nurses in 1983 [Ex. 13, p. 1-88]. For the purposes of this analysis, OSHA assumes that there are 1,615 affected establishments in this sector.

OSHA estimates that only about one-tenth of all temporary workers work in the health field. This potentially exposed workforce is estimated to be at risk. These workers are primarily temporary nurses and nursing aides.

The risk of exposure for temporary nurses and nursing aides is the same as for permanent nurses.

Revenues for personnel supply companies were $10.4 billion in 1986, according to the Service Annual Survey. On the assumption that revenues are divided by establishment share, $2.7 billion is estimated to have been earned by those personnel service companies affected by the proposed rule. Similarly, pre-tax profits were estimated at $70 million, based on data reported by Robert Morris Associates. Revenues in 1988 are projected to be $3.2 billion while profits are projected to be $96 million [Ex. 13, p. 1-92]

Medical Equipment Repair. OSHA estimates that 2,967 facilities that repair medical or dental equipment will be affected by the proposed rule. The 1982 Census of Manufactures includes 2,711 of these establishments in the medical instrument industry. Industry sectors included: Surgical and Medical Instruments (SIC 3841); Surgical Appliances and Supplies (SIC 3842); and Dental Equipment and Supplies (SIC 3843). In addition, 256 firms were identified which exclusively repair and service medical equipment [Ex. 13, p. 1-104].

The affected workforce, which is estimated to be 1,392 workers [Ex. 13, p. 1-107], includes only those workers who unpack, clean and disinfect the equipment prior to servicing. The total value of shipments for this sector is estimated to be $18.7 billion, based on Commerce Department data. Assuming profit margins are approximately equal to those of 1987, profits for this industry will be $1 billion [Ex. 13, p. 1-105].

b. Benefits—Introduction. OSHA’s standard to reduce occupational exposure to bloodborne pathogens, including hepatitis B virus (HBV), non-A, non-B hepatitis virus, and human immunodeficiency virus (HIV), includes provisions applicable to the wide range of occupational settings where potential exposure to such bloodborne pathogens exist. This section describes how the standard will reduce the risk and estimates the expected reduction in HBV cases among the employees affected by the standard. These estimates are based on data and information provided to OSHA by Jack Faucett Associates, the Centers for Disease Control (CDC), and commenters to the rulemaking record.

Hazard Abatement. OSHA’s standard for reducing worker exposure to bloodborne pathogens includes eight primary categories of control. The standard is based on the adoption of universal precautions as a method of infection control. Fundamentally different from traditional procedures that isolate known infectious individuals and materials in the health care setting, this approach assumes that all human blood and certain body fluids and tissues are potentially infectious for HIV, HBV, and other bloodborne pathogens. The rationale for this approach is that carriers of these diseases are not always identifiable in the health care giving setting, and that contaminated materials are not always properly labelled. Thus, the exposed worker can be at great risk without warning.

All exposed employees must participate in employer provided training, which is to be accomplished within 90 days of the effective date of the standard or at the time of employment, and at least annually thereafter. The training must include clinical and epidemiologic information about infectious diseases, modes of transmission, and means to reduce risks of exposure. It must designate specific procedures to be used in the work setting and specific policies to deal with exposures.

In a series of case studies conducted by Jack Faucett Associates, hospitals reported that one of the most important aspects of employee compliance with infection control programs was an understanding of the risk. The employee training that conveys this risk becomes
an indispensable link in hazard abatement.

Another requirement of the standard is that employers offer prescreening and HBV vaccine to those employees who are exposed to blood or other potentially infectious materials on average once or more times per month. HBV vaccination is a means of achieving substantial reduction in the risk of infection for non-immune employees, achieving up to a 98 percent rate of efficacy (Exs. 4-20; 6-45).

The standard also requires post exposure evaluation and treatment. This includes testing to determine whether there has been transmission of infection, and follow-up treatment and counseling. In the case of exposure to HBV, follow-up treatment can prevent illness. Thus, procedures for reporting exposures are an important part of the infection control program. Additional controls that employers will use include engineering controls, work practices, personal protective equipment and housekeeping measures.

There is a clear understanding that effective hazard abatement in health care settings will require a full range of protective measures, with personal protective clothing being integral to the program. Engineering controls such as splash guards and biosafety cabinets will complement work practices involving safe use of centrifuges and housekeeping provisions for disposal of needles and sharps. In one study, approximately 41% of the laboratory accidents preceding infection were related to needles and sharps and an additional 27% were related to spillage and splashes, especially from centrifuge use (Ex. 13, p. II-79). Collins also reports that 37% of the infected laboratory staff were not trained.

Work practices can also have a substantial impact on hazard abatement by altering the manner in which a task is performed. Needlesticks, which occur frequently when recapping contaminated needles, have been identified as a major route of exposure. Indeed, the most commonly reported route of exposure to blood and other potentially infectious materials is the needlestick or cut with other types of sharps. Health care facilities report an average of 4 to 16 needlesticks per 100 employees per year (Ex. 6-62; Ex. 4-13), and these figures may underestimate the actual exposure rate by 40 to 50 percent (Ex. 13, p. II-19; Ex. 6-100). Maynard and Hollinger have estimated that at least 1 percent of hospitalized patients are HBV carriers, and Gerberding has estimated a seroconversion rate of 19 to 27 percent for HBV after accidental percutaneous injection of blood serum from patients who are positive for HBs antigen (highly contagious) (Ex. 6-114).

In conjunction with a firmly enforced policy of not recapping needles by hand, adequate and accessible puncture resistant disposal containers must be provided in order to substantially reduce these exposures (Ex. 13, p. II-29). Studies suggest that adopting a point-of-use, puncture resistant container system may reduce injuries for housekeeping, medical and nursing staff (Ex. 13, p. II-30).

Under this standard the employer shall make appropriate personal protective equipment readily accessible if there is a potential for exposure to blood or other potentially infectious materials. The equipment shall include gloves, masks, face shields, gowns, and aprons of appropriate material. In addition, emergency ventilation devices shall be used to minimize the need for mouth-to-mouth resuscitation.

The use of personal protective equipment is a direct line of defense for health care workers whose exposures occur through contact with infected patients. Gowns and gloves, used for many years in surgery and nurseries, are now routinely used by many emergency room and hemodialysis personnel to reduce the risk of infection and disease transmission. The effectiveness of these controls in reducing the incidence of HBV infections is exemplified by the experience of a large mid-western hospital, which in the 1970’s had a growing number of infections among its staff. After instituting a full range of infection control practices the hospital reported no known HBV infection in 1980 and 1987 (Ex. 13, p. 88). In order to evaluate such programs, OSHA requests additional public comment on infection control experiences of other affected institutions.

Since linens or waste products contaminated with blood or other potentially infectious products may present a risk of disease transmission, the proposed standard establishes procedures for the handling of contaminated linens and waste by housekeeping or laundry staff. The standard provides measures that will reduce contact with contaminated linens and waste by requiring clearly labelled, leakproof containers or bags.

Under the standard, laboratories producing HIV and HBV for research or laboratories concentrating these viruses shall conduct procedures according to paragraph (e) of the proposed standard. These procedures were derived from the NIH/CDC guidelines for Biosafety Level (BSL) 2 and BSL 3. As documented earlier in this preamble, concentrated HBV and HIV present a high risk for infection in the laboratory environment, thus emphasizing the importance of implementing stringent infection control practices in this facility type.

Population-at-Risk. Table VII-3 identifies by SIC code and facility type OSHA’s estimates of the total number of workers at risk of exposure to HBV and HIV. The population-at-risk of HBV infection is a subset of the total population at risk of HIV infection because prior exposure or vaccination may result in immunity to HBV infection.

Quantification of Benefits. Bloodborne pathogens are associated with a variety of diseases among employees exposed to infectious materials, and OSHA has not been able to quantify all of the potential benefits expected from the proposed standard. Most importantly, the relatively short history of the HIV epidemic has made it difficult to develop a precise projection of the number of job-related AIDS cases that will be averted. It is known that the probability of HIV transmission in most workplace settings is low; only 25 cases of HIV infection associated with occupational exposure have been documented (see Health Effects). Nonetheless, the prevalence of AIDS continues to climb rapidly among the general population, and in the absence of strict infection control, the rate of occupational risk will grow accordingly. A recent study conducted by CDC found that 37% of the reported exposures to the HIV virus could have been prevented if routine precautions had been followed (Ex. 6-372).

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<tr>
<td>8020</td>
<td>Dental Offices</td>
<td>322,676</td>
</tr>
</tbody>
</table>

TABLE VII-3—POPULATION AT RISK: HEALTH CARE AND OTHER EMPLOYEES AT RISK BY SIC AND FACILITY
In contrast to the limited knowledge concerning the risk of AIDS, the risk of contracting hepatitis B at the workplace has been studied extensively for many years. OSHA therefore has developed quantitative estimates of the effect of the proposed standard on the future number of hepatitis B infection cases among the employees at risk. First, OSHA addressed the vaccine provision by estimating the annual number of cases of each type of hepatitis B that would be avoided by offering all eligible employees the opportunity for vaccination. The basic assumptions for this benefits analysis are that 15% to 30% of the workers have acquired lifetime immunity from past exposure to HBV, and that 23% of the health care workers and 0.1% of the non-health care workers at risk have already received the vaccine (see Preliminary Quantitative Risk Assessment). Of the remaining exposed workers, OSHA assumes that all of the identified employees, except for 70% of the firemen and 90% of the police, are potentially exposed more than once a month and therefore will be eligible for the vaccination program. OSHA assumes that 50% of these employees will choose to participate and, if found not to be immune, to receive the HBV vaccine. The efficacy rate for the vaccine is assumed to be 90% (Ex. 4–20; 6–45; Ex. 13, p. II–32).

Next, OSHA multiplied estimates of the number of employees at risk by the extent of the excess risk. As developed earlier in this preamble, the annual occupational risk of contracting HBV infection for these employees is estimated at from 1.74 to 2.80 per thousand employees. For the employees exposed less often than once a month, OSHA assumed that the excess risk would be one-half as large. The first four columns of Table VII–4 present estimates of the baseline annual incidence of work-related cases of HBV infection and the number of these cases that would be avoided annually following the implementation of the new vaccination programs. As shown, OSHA estimates that the current number of occupationally-related cases is between 5,953 and 7,416 per year, of which over 40% would be prevented by offering vaccination. (More cases are predicted for the higher natural immunity rate (30%) because, given the reported number of cases and the fixed background incidence, it implies a proportionately greater risk of occupationally-related disease among employees who are not immune.)

The 1.7 to 2.1 million workers at risk who will not be protected by vaccination must rely on the other provisions of the standard, including engineering controls, work practices, personal protective equipment, post-exposure medical evaluation, housekeeping and training. In the midwestern hospital mentioned earlier, less than 20% of the eligible employees chose to receive the vaccine, yet this facility was able to reduce its incidence of reported HBV infection from 160 cases during a 2-year period in the early 1970s to one case in 1985 and none in 1986 and 1987. This was accomplished through the establishment of a comprehensive program of infection control practices, including aggressive post-exposure protocol, and supports OSHA’s belief that although HBV vaccination is a key protective measure, a very high degree of disease avoidance can be maintained through ancillary infection control practices. Thus, OSHA has assumed that 75% of the remaining risk would be prevented by implementing the non-vaccine related provisions of the standard.

### Table VII–3—Population at Risk: Health Care and Other Employees at Risk by SIC and Facility—Continued

<table>
<thead>
<tr>
<th>SIC</th>
<th>Facility name</th>
<th>Total employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>6010, 1830</td>
<td>Physician’s Offices</td>
<td>536,122</td>
</tr>
<tr>
<td>6070</td>
<td>Medical and Dental Labs ...</td>
<td>40,822</td>
</tr>
<tr>
<td>6050</td>
<td>Nursing Homes</td>
<td>778,375</td>
</tr>
<tr>
<td>6060</td>
<td>Residential Facilities ...</td>
<td>80,569</td>
</tr>
<tr>
<td>6090</td>
<td>Outpatient Care Facilities ...</td>
<td>370,514</td>
</tr>
<tr>
<td>8090</td>
<td>Blood Banks and Others ...</td>
<td>22,198</td>
</tr>
<tr>
<td>7360</td>
<td>Industrial Clinics</td>
<td>223,909</td>
</tr>
<tr>
<td>7260</td>
<td>Temporary Workers</td>
<td>155,844</td>
</tr>
<tr>
<td>9221</td>
<td>Funeral Homes</td>
<td>28,407</td>
</tr>
<tr>
<td>9224</td>
<td>Police</td>
<td>201,749</td>
</tr>
<tr>
<td>9223</td>
<td>Fire Department</td>
<td>97,945</td>
</tr>
<tr>
<td>7381</td>
<td>Correction Workers</td>
<td>98,715</td>
</tr>
<tr>
<td></td>
<td>Research Laboratories ...</td>
<td>1,882</td>
</tr>
<tr>
<td></td>
<td>Medical Equipment</td>
<td>635,391</td>
</tr>
<tr>
<td></td>
<td></td>
<td>444,202–539,510</td>
</tr>
<tr>
<td></td>
<td>Total at Risk of HIV</td>
<td>5,311,554</td>
</tr>
<tr>
<td></td>
<td>Total at Risk of HBV, Assuming 23% Of</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Employees Are Now Vaccinated And A 15%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>To 30% Natural Immunity Rate.</td>
<td>2,764,638–3,561,370</td>
</tr>
<tr>
<td>Other employees at risk:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7260</td>
<td>Funeral Homes</td>
<td>28,407</td>
</tr>
<tr>
<td>9224</td>
<td>Police</td>
<td>201,749</td>
</tr>
<tr>
<td>9223</td>
<td>Fire Department</td>
<td>97,945</td>
</tr>
<tr>
<td>7381</td>
<td>Correction Workers</td>
<td>98,715</td>
</tr>
<tr>
<td></td>
<td>Research Laboratories ...</td>
<td>1,882</td>
</tr>
<tr>
<td></td>
<td>Medical Equipment</td>
<td>635,391</td>
</tr>
<tr>
<td></td>
<td></td>
<td>444,202–539,510</td>
</tr>
<tr>
<td></td>
<td>Total at Risk of HIV</td>
<td>5,311,554</td>
</tr>
<tr>
<td></td>
<td>Total at Risk of HBV, Assuming 0.1% Of</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Employees Are Now Vaccinated, And A 15%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>To 30% Natural Immunity Rate.</td>
<td>2,764,638–3,561,370</td>
</tr>
<tr>
<td></td>
<td>Total Population At Risk Of HIV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total Population At Risk Of HBV, Given</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vaccinations and Immunity</td>
<td></td>
</tr>
</tbody>
</table>

### TABLE VIII-4.—ANNUAL BASELINE CASES AND CASES AVOIDED OF OCCUPationally INDUCED HEPATITIS B

<table>
<thead>
<tr>
<th></th>
<th>Baseline cases</th>
<th>Cases avoided due to vaccine</th>
<th>Total cases avoided</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15 immune</td>
<td>30 immune</td>
<td>15 immune</td>
</tr>
<tr>
<td>HBV Infections</td>
<td>2,498</td>
<td>3,049</td>
<td>5,089</td>
</tr>
<tr>
<td>Acute Symptoms</td>
<td>1,458</td>
<td>1,854</td>
<td>1,272</td>
</tr>
<tr>
<td>Chronic HB</td>
<td>296</td>
<td>374</td>
<td>245</td>
</tr>
<tr>
<td>Fulminant Death</td>
<td>7</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>HBV Carrier</td>
<td>104</td>
<td>136</td>
<td>254</td>
</tr>
<tr>
<td>Death PHC</td>
<td>24</td>
<td>30</td>
<td>10</td>
</tr>
<tr>
<td>All Deaths</td>
<td>132</td>
<td>165</td>
<td>56</td>
</tr>
</tbody>
</table>


In total, considering the full combination of provisions, including vaccination, engineering controls, work practices, protective clothing, housekeeping, and training, OSHA believes that the great majority of HBV cases caused by workplace exposure can be avoided. The final columns of Table VII-4 display OSHA’s estimate that compliance with the standard will prevent from between 5,089 and 6,324 cases of occupationally-contracted HBV infection per year, of which from 1,272 to 1,581 would have resulted in acute symptoms, and from 113 to 141 in death.

In addition, a considerable number of non-occupationally induced illnesses will be prevented. OSHA estimates the background risk of HBV to be 1.74 cases per 1000 employees. On this basis, immunizing the 1,210,407 to 1,595,097 employees who are estimated to be vaccinated as a result of this standard will prevent about 1,921 to 2,532 background cases per year.

Furthermore, sex partners of those with HBV infections will become infected about 30% of the time (Ex. 6-425; 6-430). As over 60% of the U.S. workforce is married, OSHA assumes that about 70% of the HBV victims could potentially infect their sex partners. Therefore, OSHA estimates that the great majority of HBV cases caused by workplace exposure will boost the full benefits of the standard by about 21% (30% x 70%) per year. These results, which are displayed in Table VII-5, indicate that this standard will prevent from 3,653 to 4,132 cases of non-occupationally induced cases of hepatitis B, of which from 81 to 92 would be fatal. Table VII-6 combines the estimates presented in the two previous tables and shows that OSHA expects the standard, in total, to prevent from 9,221 to 9,977 infections and from 205 to 222 deaths per year from both occupational and non-occupationally induced cases of hepatitis B.

### TABLE VII-5.—ANNUAL CASES AVOIDED OF NONOCCUPationally INDUCED HEPATITIS B

<table>
<thead>
<tr>
<th>Cases avoided due to vaccine</th>
<th>Cases avoided due to sex partners</th>
<th>Total cases avoided</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15 percent immune</td>
<td>30 percent immune</td>
</tr>
<tr>
<td>HBV infections</td>
<td>2,532</td>
<td>1,921</td>
</tr>
<tr>
<td>Acute Symptoms</td>
<td>633</td>
<td>480</td>
</tr>
<tr>
<td>Hospitalized</td>
<td>127</td>
<td>96</td>
</tr>
<tr>
<td>Fulminant Death</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>HBV Carrier</td>
<td>253</td>
<td>192</td>
</tr>
<tr>
<td>Chronic HB</td>
<td>63</td>
<td>48</td>
</tr>
<tr>
<td>Death Cirrhosis</td>
<td>43</td>
<td>33</td>
</tr>
<tr>
<td>Death PHC</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>All Deaths</td>
<td>56</td>
<td>43</td>
</tr>
</tbody>
</table>


### TABLE VII-6.—ANNUAL NUMBER OF OCCUPATIONAL AND NONOCCUPATIONAL HEPATITIS B CASES AVOIDED

<table>
<thead>
<tr>
<th></th>
<th>Occupational cases avoided</th>
<th>Nonoccupational cases avoided</th>
<th>Total cases avoided</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15 percent immune</td>
<td>30 percent immune</td>
<td>15 percent immune</td>
</tr>
<tr>
<td>HBV infections</td>
<td>5,089</td>
<td>6,324</td>
<td>4,192</td>
</tr>
<tr>
<td>Acute Symptoms</td>
<td>1,272</td>
<td>1,581</td>
<td>1,033</td>
</tr>
<tr>
<td>Hospitalized</td>
<td>254</td>
<td>316</td>
<td>207</td>
</tr>
<tr>
<td>Fulminant Death</td>
<td>6</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>HBV Carrier</td>
<td>254</td>
<td>632</td>
<td>413</td>
</tr>
<tr>
<td>Chronic HB</td>
<td>64</td>
<td>158</td>
<td>109</td>
</tr>
<tr>
<td>Death Cirrhosis</td>
<td>67</td>
<td>108</td>
<td>70</td>
</tr>
<tr>
<td>Death PHC</td>
<td>20</td>
<td>25</td>
<td>17</td>
</tr>
<tr>
<td>All Deaths</td>
<td>113</td>
<td>141</td>
<td>92</td>
</tr>
</tbody>
</table>

D. Technological Feasibility. In this section, the provisions of the proposed standard are examined with respect to their role in reducing the occupational risk faced by workers within the 16 industry sectors identified. Baseline conditions, or the level of current compliance with the provisions of the proposed rule, will also be discussed and compliance rates, expressed as a percentage of full compliance, are presented. Finally, issues of feasibility regarding the implementation of the provisions of the proposed standard are addressed.

Compliance rates were based on information in the public record. OSHA inspection files, and site visits conducted by Jack Faucett Associates [JFA]. These sources generally provided one of two different measures of current compliance. The first measure is the extent of partial compliance with a particular provision, assuming that all affected facilities have instituted a program of infection control. For example, a partial compliance rate of 50% estimated for a sector with respect to the post exposure follow-up provision indicates that facilities have follow-up programs in place, but that only 50% of the workers at risk are in fact offered treatment and counseling. The alternative measure provides an estimate of the proportion of facilities in a sector that are in full compliance with a particular provision of the proposed rule. For example, a compliance rate of 50% for the post exposure follow-up provision using this measure of compliance indicates that within a particular sector one-half of the facilities have instituted a program but that all affected workers within those facilities are offered treatment and counseling. The interpretation given to these respective measures of baseline data is dependent upon the way in which the data are presented. The most appropriate interpretation is used in each case.

The provisions of the proposed rule are expected to make a substantial reduction in the occupational risk of those workers potentially exposed to blood or other infectious materials. The provisions having the greatest impact on occupational risk are those requiring, at no cost to the employee, the vaccine and post-exposure prophylaxis against the hepatitis B virus (HBV), the use of personal protective equipment, the training and information programs, the implementation of engineering controls, and the practicing of safe work procedures. Additional provisions address the use of proper procedures for the handling and disposing of contaminated waste, labeling, and recordkeeping.

HBV Vaccination and Post Exposure Follow-up. The most effective method of infection control against HBV is the hepatitis B vaccine. While there are two types of vaccine, serum derived and genetically engineered, immunogenicity is reported to be similar for both [Ex. 13, p. II-32]. Evidence indicates that HBV vaccine will induce antibody in 85 to 98 percent of healthy young adults [Exs. 4-20; 6-45]. There do not appear to be any technical obstacles to this provision.

The proposed standard requires that all employees who incur occupational exposures to blood on average one or more times per month be offered the vaccine. The current rate of employee acceptance in many sectors is only about 15%. However, refusal seems to be in large part linked to concerns regarding the safety of the vaccine [Ex. 4-31]. Thus, following the provision of new educational programs [Ex. 11-86, p. 15], OSHA expects that at least 50% of the unvaccinated employees at risk will participate in the vaccination program.

The proposed standard also includes a provision for post-exposure prophylaxis against HBV. This prophylaxis consists of the hepatitis B immune globulin (HBIG) injection. Post-exposure treatment appears to be highly effective in preventing HBV infection when administered shortly after the exposure incident [Ex. 6-45]. JFA estimated the levels of baseline compliance with this provision [Ex. 13, Table III-18]. (Table VII-7 provides a summary of compliance rates for all provisions, by SIC code.) A serious obstacle to the implementation of this requirement, however, is that not all exposures are reported [Ex. 6-100].

Thus, HBV vaccination and post exposure follow-up can provide effective protection for those exposed employees who are at risk of contracting HBV. The limitations of this provision are that not all workers will participate in the vaccine program, not all exposures will be reported, and, finally, workers will still be at risk for other bloodborne diseases, such as AIDS and non-A, non-B hepatitis.

**TABLE VIII-7.—SUMMARY OF CURRENT COMPLIANCE**

<table>
<thead>
<tr>
<th>Industry</th>
<th>PPE</th>
<th>Other</th>
<th>Containers</th>
<th>Waste disposal</th>
<th>Post exposure follow-up</th>
<th>Records</th>
<th>Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gloves:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Offices of doctors</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hospitals</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Blood/plasma/issue centers</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Residential care</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Personal services</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Funeral services</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Research labs</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Fire &amp; rescue</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Corrections</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Police</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>75</td>
<td>40</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis. (Adapted from Ex. 13, Table II-31).
Personal Protective Equipment. The proposed standard also requires employers to provide personal protective equipment (PPE) to all potentially exposed workers and to ensure its proper use. This type of equipment will reduce risk from all bloodborne pathogens. Gloves will provide an effective barrier against entry of pathogens through non-intact skin and can be worn by virtually all workers in all sectors. For example, health care workers performing phlebotomy will be protected in the event that this task results in blood contamination of the hands. Laundry workers and janitors who are at risk of exposure from contaminated laundry or waste can substantially reduce their risk by wearing utility gloves.

Other types of PPE include coats or gowns, masks and eye protection (such as safety glasses or goggles), and face shields. Like gloves, these items serve as a barrier between the infectious material and the worker. Not all workers would be expected to require these items, however. Dentists will need eye and face protection when performing oral surgery or any other procedure which may result in the splattering or spraying of blood or saliva contaminated with blood, but this level of protection would seldom be necessary for a physician in an outpatient facility. Likewise, protective foot coverings may be required to reduce risk in a surgical or autopsy suite but would rarely be necessary for a nurse in a residential care facility.

Respiratory equipment such as ambubags or pocket respirators are another type of PPE. These devices are most useful for emergency responders in reducing risk where the emergency situation requires resuscitation. Estimates of current compliance rates for PPE appear in table VII-7. No sector is believed to be currently complying at a rate of less than 25%.

Limitations in implementing a PPE program include availability, interference with the performance of certain tasks, and physical variability of the workforce. For example, commenters have reported that certain types of gloves are in short supply [Exs. 11-73, 11-124]. OSHA is aware of this problem, but finds that many new sources of supply are being developed and that current producers of the types of gloves that are required by this proposed rule should have ample time to adjust their production schedules to meet the required demand. As a great many establishments are already providing gloves for their employees who are at risk, incremental glove usage is not expected to be a serious obstacle to implementation by the time that a final rule is promulgated.

Commenters have also asserted that during certain procedures requiring manual dexterity, such as phlebotomy, glove use will not allow the proper performance of the task [Ex. 11-124]. OSHA recognizes that many workers who are at risk are performing their duties in the manner that is most comfortable for them, and may have been doing so for some time. However, the proposed rule also provides for training in and monitoring of proper work practices (this provision will be discussed more fully below) and employers shall be expected to instruct workers in a manner that will increase their proficiency in performing all tasks while using the appropriate precautions.

Finally, some workers may be susceptible to dermatitis from frequent handwashing (handwashing is required by the proposed standard whenever gloves are changed). Others may be allergic to certain types of gloves or the powder they contain. OSHA does not believe that the impact of the proposed rule will be such that an excessive amount of additional handwashing will be required. Additionally, it is OSHA's understanding that hypoallergenic gloves are available [Ex. 13, p. II-27]. Administrative controls, such as rotating employees, would also be useful, when possible, to avoid these instances.

Training and Information Programs. This provision of the proposed rule is applicable to all workers at risk throughout all industry sectors. A comprehensive training program is paramount in the implementation of a standard such as this, since protective measures such as PPE and proper work practices will be ineffective unless employees are instructed in their correct use. Training is also an important factor in risk reduction because not all employees are aware of the risks that they routinely face in the workplace. As noted above, information programs can increase employee acceptance of HBV vaccine [Ex. II-68, p. 15]. The provision also requires employers to ensure that employees understand the employer's infection control program. In one hospital, PPE usage increased from 50-75% to 95-98% when proper work practices were explained and enforced [Ex. II-21]. Also, evidence indicates that adherence to established work practice procedures could reduce needlestick exposures by as much as 40% [Ex. 6-160].

While employers will be required to train all employees at risk, the content of the training program will not be the same for all occupational categories. For example, registered nurses employed at a hospital will require a more detailed program than will housekeepers employed at such an establishment.

Estimates of the current level of compliance with this provision indicate that a substantial number of establishments are currently providing some level of training to their at-risk employees. Most facilities, then, will only need to adjust their programs incrementally rather than to construct a training program from the ground up.

Limitations of the training requirement are minor. As little information is available regarding the relative effectiveness of different training methods [Ex. 13, p. II-24], employers may need to "experiment" a bit until they find the method that is best suited for their particular establishment or worker population. This should not delay, however, the implementation of an initial program of education and information necessary to protect at-risk employees, as such a program may subsequently be modified as appropriate.

OSHA finds, therefore, that a program of training offered to all at-risk employees is central to the implementation of the proposed standard and will significantly contribute to the overall reduction of risk to workers potentially exposed to infectious materials. No major problems are foreseen for compliance with this provision.

Engineering Controls. The most ubiquitous engineering control required by the proposed rule is the puncture-resistant sharps containers. The purpose of the container is to eliminate the need for employees to transport needles and other sharps while looking for a place to dispose of them, and to support the prohibition against recapping, bending, breaking, or otherwise manipulating sharps by hand. Injuries also occur to housekeeping personnel when contaminated sharps are left on a bed, concealed in linens. It is expected that a number of unnecessary disposal-related exposures will be prevented by this control [Ex. 13, p. II-30].

Other engineering controls that will be required are mechanical pipetting devices, biosafety cabinets, and safety equipment for centrifuges. (Pipetting is a procedure by which fluid is drawn into a narrow tube by suction. The fluid may then be dispensed as needed.) Risk will be reduced as these controls, like the sharps containers, tend to confine or isolate the infectious material from the worker. While these controls will be necessary only in a laboratory environment, many types of establishments operate laboratories. For
example, such controls might be necessary in a police lab or in a physician’s office, as well as in a hospital.

Baseline information, where available, indicates that most facilities are already in compliance with the container requirement. (Baseline information on sharps containers appears under “Housekeeping” in Table VII-2.) Further, it is assumed that research laboratories involved in biosafety level 2 or biosafety level 3 work are equipped with the necessary cabinets and centrifuge safety equipment. Since mouth pipetting has been discouraged for some time, it is probable that mechanical pipettes are standard equipment in most medical and research labs.

Affected establishments should not experience difficulty introducing sharps containers. One concern noted by industry is the potential for unauthorized tampering with the sharps containers [Ex. 13, p. II-30]. There are, however, safety features such as locking mechanisms to prevent removal of the containers until they are ready to be replaced. Also, containers are now made with a “mail box” drop system so that discarded sharps cannot be retrieved.

It is clear that engineering controls can reduce risk by confining or isolating infectious material. The equipment is readily available and should present few difficulties in its implementation. Moreover, a number of new technologies are being developed, which would effectively eliminate many types of needlestick incidents. OSHA solicits public comment on the progress of these new technologies.

Work Practice Controls. Work practice controls are extremely important in preventing the spread of infection. This provision will reduce risk by requiring employers to ensure that at-risk employees are performing their tasks in the safest manner possible, consistent with universal precautions. The forbidding of needle recapping by hand when disposable needles are used is one work practice which should provide significant reductions in needlestick exposures, as this procedure has been shown to be associated with needlestick injury [Ex. 6-350]. In certain circumstances, however, such as where injections are administered in series, some effort may be required to find the best technology or to develop new procedures. Simply ensuring that disposable needles are used wherever possible will also reduce risk.

In any environment where engineering controls are available, workers must use such equipment properly. For example, safety cups for use during centrifuging will not be effective if not used correctly. Thus, all training programs should provide at-risk workers with comprehensive instructions regarding the safest procedures for performing each employee’s respective tasks.

In conclusion, the provisions of the proposed rule are expected to reduce substantially the risk now faced by workers who must come into contact with blood and other potentially infectious material. The provisions of the standard operate in concert, maximizing the rule’s effectiveness. The provision of PPE will not be effective without comprehensive training and monitoring of proper work practices.

Offering the HBV vaccine will likewise not be effective unless workers are provided with information on the risks of contracting hepatitis B and the safety and efficacy of the vaccine. Many establishments are currently complying with much of OSHA’s proposed rule, but additional effort must be made to ensure that all workers are protected. Finally, there do not appear to be any major obstacles to implementing the proposed rule, though certain situations may require sophisticated approaches.

E. Costs of Compliance. This section presents OSHA’s estimates of total net compliance costs, which are total costs less the amount associated with current compliance, for each provision of the proposed standard. The costs are based on data collected by Jack Faucett Associates [Ex. 13] and other information in the public record, and are developed in the following sequence: development of the infection control plan, HBV vaccination and post exposure follow-up, personal protective equipment (PPE), engineering controls, training, housekeeping (including costs incurred for the disposal of infectious waste), labeling and signs, and recordkeeping.

Development of the Infection Control Plan. Costs incurred for this task are due to the time expended to prepare the written determination of risk, the schedule of implementation for each applicable provision of the proposed rule, and the training program. OSHA believes that much of the required information is currently compiled and will only need to be restructured to reflect compliance with the proposed standard. In calculating the incremental costs for performing this task, OSHA estimates that the time required will be 16 hours for large establishments, such as hospitals and nursing homes, 8 hours for health maintenance organizations, and 4 hours for all other facilities.

Assuming a wage rate of $23.26 per hour for the infection control official (this is equivalent to the compensation rate for head nurses) the costs for this provision are computed as:

\[
\text{ \$23.26 \times \text{ (time required) }}
\]

It is not likely that this type of documentation has been developed by many facilities; consequently, incremental costs are estimated to be 100% of total compliance costs except for hospitals, where a 10% baseline was used for current compliance.

Costs were annualized using a five year payback period and a 10% interest rate. (This five year period reflects the need to periodically revise the plan.) Table VII-8 summarizes costs for this provision.

Total annual costs for the infection control plan are estimated to be $16.5 million. Cost per facility will average about $26.60.

<table>
<thead>
<tr>
<th>Industry</th>
<th>Total annual costs</th>
<th>Total annual costs per facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>4,403,308</td>
<td>24.54</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>2,331,528</td>
<td>24.54</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>895,707</td>
<td>47.83</td>
</tr>
<tr>
<td>Hospitals</td>
<td>629,647</td>
<td>89.69</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>293,313</td>
<td>24.54</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>745,154</td>
<td>25.08</td>
</tr>
<tr>
<td>Blood/plasma/tissue centers</td>
<td>16,494</td>
<td>25.69</td>
</tr>
<tr>
<td>Residential care</td>
<td>1,008,118</td>
<td>49.09</td>
</tr>
<tr>
<td>Personnel services</td>
<td>39,338</td>
<td>24.54</td>
</tr>
<tr>
<td>Funeral services</td>
<td>969,411</td>
<td>24.54</td>
</tr>
<tr>
<td>Research labs</td>
<td>52,671</td>
<td>24.54</td>
</tr>
<tr>
<td>Fire and rescue</td>
<td>90,174</td>
<td>23.98</td>
</tr>
<tr>
<td>Corrections</td>
<td>67,261</td>
<td>24.54</td>
</tr>
<tr>
<td>Police</td>
<td>152,205</td>
<td>24.54</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>5,440,167</td>
<td>24.54</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>72,822</td>
<td>24.54</td>
</tr>
<tr>
<td>Total</td>
<td>$16,502,710</td>
<td>$26.59</td>
</tr>
</tbody>
</table>

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Hepatitis B Vaccination and Post Exposure Follow-Up. Since a portion of the cost of both the HBV vaccination and post exposure follow-up provisions will be incurred as compensation for the time spent by employees in receiving medical care, data on wage rates were necessary to calculate total annual costs. Turnover rates were also estimated, since new employees not previously vaccinated will be offered the HBV vaccine.

Wage data were obtained from BLS national (March, 1987) and hospital (1983) survey data, and wages were
updated to 1988 dollars using the BLS Employment Cost Index.

Turnover rates were calculated by JFA using unpublished job tenure data from the January, 1987 Current Population Survey of BLS [Ex. 13, p. 17—21]. Annual job turnover was estimated as the percentage of workers with one year or less tenure with their current employer minus the rate of industry wide employment growth. Alternatively, annual occupational turnover is used as an indicator of how often workers will be entering health care and other occupations of interest for the first time.

In assigning turnover and wage rates to occupational categories, workers were judged to fall into one of seven employment classifications. Table VII-9 provides a summary of occupational classifications and worker populations within each of the affected industry sectors. Wage and turnover rates for the seven classifications are as follows:

**Table VII-9—Employment Classification Scheme**

<table>
<thead>
<tr>
<th>Office of Physicians</th>
<th>Office of Dentists</th>
<th>Nursing Homes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diagnosing</strong></td>
<td>Physicians and Surgeons; Dentists.—Affected Population: 102,386.</td>
<td>Physicians and Surgeons; Dentists.—Affected Population: 5,058.</td>
</tr>
<tr>
<td>Treatment</td>
<td>Registered Nurses; Therapists; Dental Hygienists; Lab Technicians; Emergency Medical Technicians; Surgical Technicians; Other Health Professionals.—Affected Population: 1,978,651.</td>
<td>Registered Nurses; Therapists; Dental Hygienists; Lab Technicians; Other Health Professionals.—Affected Population: 53,050.</td>
</tr>
<tr>
<td>Service</td>
<td>Licensed Practical Nurse; Therapy Assistants; Dental Assistants; Other Health Service; Physician Assistants, Medical Assistants; Nursing Aides.—Affected Population: 772,666.</td>
<td>Licensed Practical Nurse; Dental Assistants; Other Health Service; Medical Assistants.—Affected Population: 2,814.</td>
</tr>
<tr>
<td><strong>Hospitals</strong></td>
<td>Physicians and Surgeons; Dentists.—Affected Population: 102,386.</td>
<td>Physicians and Surgeons; Dentists.—Affected Population: 5,058.</td>
</tr>
<tr>
<td>Treatment</td>
<td>Registered Nurses; Therapists; Dental Hygienists; Lab Technicians; Emergency Medical Technicians; Surgical Technicians; Other Health Professionals.—Affected Population: 1,978,651.</td>
<td>Registered Nurses; Therapists; Dental Hygienists; Lab Technicians; Other Health Professionals.—Affected Population: 53,050.</td>
</tr>
<tr>
<td>Service</td>
<td>Licensed Practical Nurse; Therapy Assistants; Dental Assistants; Other Health Service; Physician Assistants, Medical Assistants; Ambulance Drivers.—Affected Population: 2,589.</td>
<td>Licensed Practical Nurse; Dental Assistants; Other Health Service; Medical Assistants.—Affected Population: 2,814.</td>
</tr>
<tr>
<td>Treatment</td>
<td>Registered Nurses; Therapists; Other Health Professionals.—Affected Population: 6,226.</td>
<td>Registered Nurses; Therapists; Other Health Professionals.—Affected Population: 6,226.</td>
</tr>
<tr>
<td>Service</td>
<td>Licensed Practical Nurse; Nursing Aides and Orderlies; Psychiatric Aides; Other Health Service.—Affected Population: 52,142.</td>
<td>Licensed Practical Nurse; Nursing Aides and Orderlies; Psychiatric Aides; Other Health Service.—Affected Population: 52,142.</td>
</tr>
<tr>
<td>Treatment</td>
<td>Emergency Medical Technicians; Other Health Professionals; Ambulance Drivers and Attendants.—Affected Population: 31,234.</td>
<td>Emergency Medical Technicians; Other Health Professionals; Ambulance Drivers and Attendants.—Affected Population: 31,234.</td>
</tr>
<tr>
<td>Service</td>
<td>Treatment and Education Staff.—Affected Population: 13,712.</td>
<td>Treatment and Education Staff.—Affected Population: 13,712.</td>
</tr>
</tbody>
</table>

Cost formulas for the HBV vaccination and post exposure follow-up provisions were developed separately, as shown below.
I assumed that each candidate will who are offered the vaccine will enter health care workers, the natural immunity. For participating non-participate in the program will have a of those health care workers agreeing to that on average 29% \[22%/(100%-23%)\] immune employees, OSHA estimates vaccinated (23%) are distinct from the immunity rates). Since it is assumed that section for source of vaccination and workers and 0.1% of the non-health care estimates that 23% of the health care worker, preparing treatment rooms, transporting patients, assisting therapists, and mixing pharmaceutical preparations. To the extent that this employment category may include service personnel not at risk of exposure to infectious materials, the affected population may be somewhat overstated.

As a result, it is assumed that 71% (100%-29%) of those health care workers agreeing to participate in the program will have a natural immunity. For participating non-health care workers, the natural immunity rate is still estimated at 22%. As a result, it is assumed that 71% (100%-29%) of those health care workers and 78% of those non-health care workers who are tested under the new program will receive the vaccination. The compliance costs are estimated assuming employer pre-screening of all vaccine candidates. That is, it is assumed that each candidate will receive a hepatitis B test to determine antibody status prior to being vaccinated and even though in some circumstances it may be more cost-effective to administer vaccine without testing.

Estimates were computed for each of the seven occupational categories, to reflect the effect of varying employee wage and turnover rates. In most sectors, the time required to take the antibody test is estimated to be about 5 minutes. However, as noted above, physicians are not typically located at research labs, funeral homes, personnel service offices, fire stations, medical equipment repair facilities, or dental offices. In these sectors, the test is assumed to take 20 minutes of employee time. Where the vaccine is indicated, it is assumed that the additional time required will be one quarter hour for the entire three-dose-series in most facilities. For those sectors mentioned above where a physician would not normally be on the premises, the added employee time is assumed to be one hour. Costs were computed as follows:

**Initial**

\[
\text{([# of workers] \times (1-prior vaccination rate) \times (participation rate) \times ([antibody test cost + (employee time \times wage)] + (non-immunity rate \times (vaccine cost + [employee time \times wage])))}
\]

**Recurring**

\[
\text{(initial costs) \times (occupational turnover rate)}
\]

**Total Annual Costs**

\[
\text{([initial costs] \times (capital recovery factor)) + (recurring costs)}
\]

Initial costs were annualized using a 20-year payback period and 10% interest rate.¹

The cost for the antibody test is reported to be $24.50 [Ex. 13, p. III-27] and the cost for the vaccine series is estimated to be $108 [Ex. 13, p. III-27]. [It should be noted that Smith, Kline, & French Laboratories (SKF) have applied for Food and Drug Administration approval of a recombinant hepatitis B vaccine [Ex. 5-477]. In countries where the SKF vaccine has already been approved, competition has reportedly reduced the vaccine cost by approximately 40%.] For example, the initial costs per facility for the treatment employees in physicians' offices would be:

\[
(41,029 \times 0.07 \times 0.5) \times ([24.50 + (0.25 \times 0.08) + (12 \times 0.1175)] + 84.233 + 74.12 + 7.87)
\]

The recurring costs would be:

\[
84.233 \times 0.125 = 4.12
\]

and the total annual costs would be:

\[
(51.92 \times 0.125) = 4.12 \times 4.12 = 7.87
\]

For all sectors, the total annual costs of the HBV vaccination program will be about $80.4 million.

One commenter, Baylor University Medical Center, provided estimates of

¹ Though the initial vaccination could be considered a one time cost for which annualization should be carried into perpetuity, a more conservative approach is used in this analysis.

<table>
<thead>
<tr>
<th>TABLE VII.9 — EMPLOYMENT CLASSIFICATION SCHEME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Laboratories</td>
</tr>
<tr>
<td>-----------------------</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Law Enforcement</td>
</tr>
<tr>
<td>Janitor/ Housekeeper</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Law Enforcement</td>
</tr>
<tr>
<td>Diagnosing Treatment</td>
</tr>
<tr>
<td>Service</td>
</tr>
<tr>
<td>Janitor/ Housekeeper</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

¹ This employment category may include professionals not at risk of exposure to infectious materials, such as radiologic or orthopedic technicians. The affected population may, therefore, be somewhat overstated.

¹ Includes persons who assist and work under the direction of physicians, dentists, nurses, therapists, pharmacists, and other health-related professional, paraprofessional, and technical workers. Workers in these occupations provide auxiliary services, such as assisting in the care of patients, relaying nurses of heavier work, preparing treatment rooms, transporting patients, assisting therapists, and mixing pharmaceutical preparations. To the extent that this employment category may include service personnel not at risk of exposure to infectious materials, the affected population may be somewhat overstated.

¹ Includes 14,580 workers in independent labs, 54,050 workers in captive Labs, and 7,000 workers in federal labs.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis and Bureau of Labor Statistics.
the costs of compliance with the HBV vaccination provision [Ex. 11-210]. It is not clear from the information submitted, however, whether these costs reflect worker participation rates (estimated by OSHA to be about 50%); neither is it clearly stated that their estimates are of incremental costs only.

Post Exposure Follow-up. Cost formulas for the post exposure follow-up provision vary due to different follow-up recommendations for possible exposure to the AIDS virus (HIV) and to HBV. Both costs will depend on the number of exposure incidents that will occur per year. Exposure estimates as developed by Jack Faucett Associates are presented in Table VII-10, tabulated by industry and by occupational classification within each industry. These estimates were based on studies primarily of hospital workers and on limited site visit data and take into account the following potential reductions due to implementation of the proposed standard: needlestick reduction, 50%; mucous membrane exposure reduction, 90%; open wound exposure reduction, 90%; and other sharps injuries reduction, 50%. Costs will also depend on the turnover and wage rates presented above.

Additional input for these costing formulas included an estimate that on average, while an employee will recall the source of the reported exposure, the source patient will agree to be tested only 50% of the time. Seropositivity for HIV is expected 0.5% of the time, and for HBV 0.42% of the time in all sectors but hospitals, where the HBV rate is estimated to be 1.25%. The reported unit costs are $17.50 for the HIV antibody test [Ex. 13, p. III-30], $24.50 for the HBV antibody test, and $211 for administering immune globulin [Ex. 13, p. III-38].

One final input is the wage rate of a counselor, whose services would be required in those instances where a possible exposure to HIV has occurred. This wage rate is taken to be $16.44, that of a registered nurse.

The following cost formulas for post-exposure monitoring and treatment were developed to project costs for providing antibody testing and counseling for potential HIV infection, antibody testing for potential HBV infection, and immune globulin for potential HBV infection.

**Antibody Testing and Counseling for HIV Infection**

\[(1) \times \text{# of exposures} \times 0.5 \times (0.5 + (0.5 \times 0.005)) \times \frac{\text{cost of HIV antibody test}}{\text{employee time}} + (\text{counselor time})\]

The equation above reflects OSHA’s estimate that each exposed employee will wish to learn their HIV antibody status only about 50% of the time. In those instances, a sequence of four HIV antibody tests will be offered in the 50% of the cases where the source of exposure does not agree to be tested and for the 0.25% of the cases where the source is tested and found to be positive (0.5 \times 0.005). (The time required for the HIV antibody testing by employees is assumed to be the same as that required for the HBV antibody testing used above in the vaccine calculations.) Also, additional costs will be incurred to test all source subjects who agree to be tested:

\[(2) \times \text{# of exposures} \times 0.5 \times (\text{cost of HIV antibody test})\]

This equation will tend to overestimate costs to the extent that the HIV status of patients is already known. Costs will also be incurred for counseling for the possibility of exposure to HIV exists.

\[(3) \times \text{# of exposures} \times 0.5 \times (0.5 + (0.5 \times 0.005)) \times 2 \times \frac{\text{employee time}}{\text{wage}} + (\text{counselor time}) \times \text{wage}\]

This equation reflects costs for two counseling sessions for each employee who accepts the offer of HIV testing. It is estimated that approximately 15 minutes will be required for each session and that the sessions will take place during the first and last antibody test periods.

---

**TABLE VII-10—ESTIMATES OF FREQUENCY OF EXPOSURE**

[Exposures Per Year]

<table>
<thead>
<tr>
<th></th>
<th>Needles Stick</th>
<th>Mucous membrane</th>
<th>Open wound</th>
<th>Other sharps</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians’ Offices:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosing Personnel</td>
<td>25,368</td>
<td>2,357</td>
<td>1,660</td>
<td>6,784</td>
<td>36,170</td>
</tr>
<tr>
<td>Treating Personnel</td>
<td>17,087</td>
<td>1,588</td>
<td>1,118</td>
<td>4,569</td>
<td>24,362</td>
</tr>
<tr>
<td>Service Personnel</td>
<td>19,011</td>
<td>1,767</td>
<td>1,244</td>
<td>5,064</td>
<td>27,180</td>
</tr>
<tr>
<td>Housekeeping Personnel</td>
<td>3,490</td>
<td>324</td>
<td>229</td>
<td>933</td>
<td>4,975</td>
</tr>
<tr>
<td>Total</td>
<td>64,957</td>
<td>6,036</td>
<td>4,251</td>
<td>17,370</td>
<td>92,614</td>
</tr>
<tr>
<td>Dentists’ Offices:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosing Personnel</td>
<td>9,193</td>
<td>854</td>
<td>602</td>
<td>2,458</td>
<td>13,107</td>
</tr>
<tr>
<td>Treating Personnel</td>
<td>10,602</td>
<td>965</td>
<td>694</td>
<td>2,636</td>
<td>15,116</td>
</tr>
<tr>
<td>Service Personnel</td>
<td>18,248</td>
<td>1,696</td>
<td>1,194</td>
<td>4,880</td>
<td>25,016</td>
</tr>
<tr>
<td>Housekeeping Personnel</td>
<td>1,053</td>
<td>69</td>
<td>282</td>
<td>1,051</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>39,096</td>
<td>3,633</td>
<td>2,559</td>
<td>10,455</td>
<td>55,745</td>
</tr>
<tr>
<td>Nursing Homes:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosing Personnel</td>
<td>314</td>
<td>29</td>
<td>21</td>
<td>84</td>
<td>447</td>
</tr>
<tr>
<td>Treating Personnel</td>
<td>4,453</td>
<td>414</td>
<td>291</td>
<td>1,191</td>
<td>6,349</td>
</tr>
<tr>
<td>Service Personnel</td>
<td>77,039</td>
<td>7,158</td>
<td>5,042</td>
<td>20,601</td>
<td>109,841</td>
</tr>
<tr>
<td>Housekeeping Personnel</td>
<td>12,522</td>
<td>1,184</td>
<td>820</td>
<td>3,349</td>
<td>17,854</td>
</tr>
<tr>
<td>Total</td>
<td>94,328</td>
<td>8,765</td>
<td>6,174</td>
<td>25,225</td>
<td>134,492</td>
</tr>
<tr>
<td>Hospitals:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosing Personnel</td>
<td>12,407</td>
<td>1,153</td>
<td>812</td>
<td>3,318</td>
<td>17,689</td>
</tr>
<tr>
<td>Treating Personnel</td>
<td>130,692</td>
<td>12,144</td>
<td>6,554</td>
<td>34,949</td>
<td>186,338</td>
</tr>
<tr>
<td>Service Personnel</td>
<td>93,616</td>
<td>8,699</td>
<td>6,127</td>
<td>25,034</td>
<td>132,477</td>
</tr>
<tr>
<td>Housekeeping Personnel</td>
<td>25,497</td>
<td>2,369</td>
<td>1,669</td>
<td>6,818</td>
<td>36,353</td>
</tr>
<tr>
<td>Total</td>
<td>262,211</td>
<td>24,364</td>
<td>17,162</td>
<td>70,119</td>
<td>373,857</td>
</tr>
<tr>
<td>Medical and Dental Labs:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosing Personnel</td>
<td>643</td>
<td>60</td>
<td>42</td>
<td>172</td>
<td>916</td>
</tr>
<tr>
<td>Treating Personnel</td>
<td>3,803</td>
<td>320</td>
<td>249</td>
<td>1,017</td>
<td>5,423</td>
</tr>
<tr>
<td>Service Personnel</td>
<td>341</td>
<td>32</td>
<td>22</td>
<td>91</td>
<td>488</td>
</tr>
</tbody>
</table>
Antibody tests for potential HBV infection. Table VII-11 displays OSHA’s estimates of the conditional probabilities of the various post-exposure HBV medical evaluation programs. It is assumed that HBV antibody tests will be administered to both source patients and employees at the rates shown on the chart. For those exposed workers who have previously been vaccinated, it is estimated that an employee test will be performed 10% of the time. Source testing, which will reflect both the non-response rate of the vaccine (10%) and the rate of acceptance...
of the sources to be tested (50%), will be performed 0.5% (0.1 \times 0.1 \times 0.5) of the time. (It is assumed that sources will not be asked to submit to a test unless the exposed, vaccinated employee is found to be a non-responder.)

For those cases where workers have not been vaccinated and source patients will not be tested, it is estimated that exposed employees would agree to be tested only for the 5% of the exposures that are attributable to a member of a high risk group. Thus, employee tests will be performed 2.5% of the time (0.5 \times 0.05) when a source does not agree to testing. When a source agrees to be tested, employee tests were estimated to be performed at a rate of (0.5 \times rate of source infection), as employees would be tested only if the source is found to be HBV positive. The formulas for calculating total costs for antibody testing are given below. Equation (4) represents employee testing for vaccinated workers and equation (5) represents employee testing for non-vaccinated workers. Equation (6) represents source testing.

\begin{align*}
(4) \quad & \text{(# of exposures)} \times (\% \text{ vaccinated}) \times [\text{antibody test cost} - (\text{employee time} \times \text{wage})] \times 0.1 \\
(5) \quad & \text{(# of exposures)} \times (1 - \% \text{ vaccinated}) \times [\text{antibody test cost} + (\text{employee time} \times \text{wage})] \times [(0.5 \times \text{rate of source infection}) + ((1 - 0.5) \times 0.05)] \\
(6) \quad & \text{(# of exposures)} \times (\% \text{ vaccinated}) \times (0.1 \times 0.1 \times 0.5) + (1 - \% \text{ vaccinated}) \times (0.5) \times (\text{cost of antibody test}) \\
\end{align*}

where: (\% \text{ vaccinated}) = \text{prior vaccination rate} + 0.5 \times (1 - \text{prior vaccination rate}) \times \text{non-immunity rate.}

\text{BILLING CODE 4510-26-M}
### Table VII-11

#### ESTIMATED PROBABILITY OF POST-EXPOSURE HBV MEDICAL ACTIVITIES

<table>
<thead>
<tr>
<th>Vaccinated</th>
<th>.5*</th>
<th>Exposure</th>
<th>.5*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>.1</td>
<td>Not Vaccinated</td>
<td>.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>.5 x .05</td>
</tr>
</tbody>
</table>

#### Test Source

- .1 x .5
- .0042

#### Test Employee

- .1 x .5 x .05

---

**HBIG**

---

**Source:** Occupational Safety and Health Administration, Office of Regulatory Analysis.

* The rates shown are for health workers. The non-health care worker rates are .39 for vaccinated and .61 for not-vaccinated workers.

** For the hospital sector this rate is .0125.

*** The rate shown is for health workers. The non-health care worker rate is .78.

*BILLING CODE 4510-26-C*
Immune globulin for potential HBV infection. Immune globulin (IG) will be provided at rates estimated as shown in Table VII-11. For all workers, OSHA estimates that IG will be considered whenever a source is tested and found to be positive or whenever a high risk source refuses to be tested. It is assumed that IG will be offered only to those vaccinated workers who are found to be non-responders and to those non-vaccinated employees who are found not to have natural immunity. Equation (7) represents costs for IG administration to vaccinated workers (IG is administered in a two dose sequence) and equation (8) represents costs for non-vaccinated workers. This cost is calculated as:

\[ \text{(7) } 24,362 \times 0.5 \times 0.1 \times (\text{IG cost} + 2 \times \text{employee time \times wage}) \times (0.5 \times 0.1 \times \text{rate of source infection}) \times (0.1 \times 0.5 \times 0.05) \]

\[ \text{(8) } 24,362 \times 0.5 \times (\text{source time \times wage}) \times (0.5 \times 0.1 \times \text{rate of source infection}) \times (1 - 0.5 \times 0.05) \times 0.0042 \]

\[ = 706; \]

\[ = 24,362 \times 0.5 \times 0.1 \times 0.0042 \times 0.1 \times 0.5 \times 0.05 = 706; \]

\[ = 24,362 \times 0.5 \times (0.217 + 2 \times \{0.1 \times 0.1 \times 0.1 \times 0.5 \}) \times 0.71 \times 0.0042 \]

Summing the totals computed above and dividing by the number of facilities yields an annual cost per facility for post exposure treatment for this employee category of $5.67.

For all sectors, total annual costs of post exposure follow-up were estimated to be $18 million.

Total costs for vaccination and post exposure follow-up, at the facility level and industry wide, can now be computed for the treatment workers in physicians' offices using the appropriate baseline factors:

\[ (7.87) + (5.67 \times 1.00) = 13.54 \times \text{per facility;} \]

\[ 13.54 \times 179,405 \times 0.24 \times \text{million.} \]

Applying this methodology to all categories of affected workers and factoring in the baseline rates provided above (see Technological Feasibility), incremental annual costs for vaccination and post exposure follow-up are expected to be $78.4 million. Cost per facility will average $5.27. Costs are summarized in tables VII-12-A through VII-12-C.

Personal Protective Equipment. Costs for personal protective equipment (PPE) include all expenditures for gloves, masks, gowns, goggles, and resuscitation devices. A typical example of each item was chosen for cost estimation purposes based on technical adequacy, widespread use in current health care practice, and reasonableness of cost [Ex. 13, p. III-6]. Costs were calculated using a unit cost for each respective PPE item in conjunction with a rate of use for that item. Rates of utilization varied by industry sector and by occupation and appear in Table VII-13.

For six industry sectors, rates of use were based on occupational titles. (Titles are as reported in BLS' Industry-Occupation Matrix). For each title, judgment was used to classify workers as frequent contact personnel (FCP) or occasional contact personnel (OCP). Frequent contact personnel perform tasks which bring them into contact regularly with potentially infectious materials. Occasional contact personnel also come into contact with potentially infectious materials regularly, though not as often as FCP. Janitors and housekeepers are expected to wear utility gloves when working in areas where refuse or surfaces may be contaminated with infectious material. Table VII-14 provides a tabular summary of occupational titles, classified as either frequent contact or occasional contact for the six industries where this methodology was used. All workers were estimated to work 261 days per year.

Costs for gloves for those occupations where dexterity is desirable were based on the cost of the mil thickness disposable latex non-sterile gloves, as these gloves are representative of those in current use. The cost of such a pair of gloves is about $0.18 per pair. For occupations where dexterity may not be critical, such as dental assistant or police officer, costs were based on vinyl gloves at $0.11 per pair [Ex. 13, p. III-14]. For housekeeping and janitorial personnel, costs were based on utility gloves. The cost of a pair of utility gloves is about $1.59. The unit cost of a disposable surgical mouth/nose mask was estimated to be about $0.33 and that of a disposable apron (gown) about $2.30 [Ex. 13, pp. III-18, III-16]. The unit cost for goggles was estimated to be $3.25 while resuscitation devices were estimated to cost either $16.95 (ambulbag) or $6.00 (pocket resuscitator) [Ex. 13, pp. III-18-19].

| TABLE VII-12-A.—SUMMARY OF COMPLIANCE COSTS—VACCINATION PROGRAM |
|---------------------------|---------------------------|---------------------------|---------------------------|
| Industry                  | Annualized initial costs  | Recurring costs           | Total annual costs        | Total annual costs per |
| Office of physicians      | $2,514,966                | $3,092,260                | $5,707,226                | $1,318,806              |
| Office of dentists        | $1,765,420                | $2,403,739                | $4,193,159                | $941,194                |
| Nursing homes             | $3,551,033                | $8,747,877                | $12,301,874               | $2,777,136              |
| Hospitals                 | $10,254,921               | $14,821,678               | $29,076,606               | $6,270,634              |
| Medical/dental labs       | $1,165,542                | $2,016,178                | $3,181,720                | $681,896                |
| Outpatient care           | $1,771,400                | $2,024,825                | $3,796,225                | $820,934                |
| Blood/plasma/tissue centers | $105,999                 | $118,099                 | $223,497                 | $474.17                 |
| Residential care          | $377,928                  | $673,112                  | $1,040,040                | $213.54                 |
| Personal care             | $159,774                  | $265,114                  | $424,888                  | $874.64                 |
| Funeral services          | $153,969                  | $231,658                  | $385,627                  | $781.83                 |
| Research labs             | $731,455                  | $818,925                  | $1,550,380                | $312.38                 |
| Fire and rescue           | $606,250                  | $503,655                  | $1,109,905                | $221.97                 |
| Corrections               | $641,850                  | $465,114                  | $1,106,964                | $221.97                 |
| Police                    | $184,152                  | $218,173                  | $402,325                  | $804.63                 |
| Health units in industry  | $1,062,851                | $1,789,030                | $2,851,881                | $570,376                |
Table VII-12-A.—Summary of Compliance Costs—Vaccination Program—Continued

<table>
<thead>
<tr>
<th>Industry</th>
<th>Annualized Initial</th>
<th>Recurring costs</th>
<th>Total annual costs</th>
<th>Total annual costs per facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical equipment repair</td>
<td>13,322</td>
<td>25,619</td>
<td>38,940</td>
<td>13.12</td>
</tr>
<tr>
<td>Total</td>
<td>$25,012,992</td>
<td>$35,373,432</td>
<td>$60,386,424</td>
<td>$99.94</td>
</tr>
</tbody>
</table>

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Table VII-12-B.—Summary of Compliance Costs—Post-Exposure Follow-up

<table>
<thead>
<tr>
<th>Industry</th>
<th>Total annual costs</th>
<th>Total annual costs per facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>$4,079,213</td>
<td>22.74</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>677,551</td>
<td>7.13</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>4,366,620</td>
<td>233.16</td>
</tr>
<tr>
<td>Hospitals</td>
<td>3,911,667</td>
<td>662.99</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>267,346</td>
<td>21.92</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>363,039</td>
<td>12.22</td>
</tr>
<tr>
<td>Blood/plasma/tissue centers</td>
<td>28,806</td>
<td>44.87</td>
</tr>
</tbody>
</table>

Table VII-12-B.—Summary of Compliance Costs—Post-Exposure Follow-up—Continued

<table>
<thead>
<tr>
<th>Industry</th>
<th>Total annual costs</th>
<th>Total annual costs per facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residential care</td>
<td>413,289</td>
<td>20.12</td>
</tr>
<tr>
<td>Personnel services</td>
<td>385,633</td>
<td>236.78</td>
</tr>
<tr>
<td>Funeral services</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Research labs</td>
<td>734,547</td>
<td>342.43</td>
</tr>
<tr>
<td>Fire &amp; rescue</td>
<td>740,637</td>
<td>196.98</td>
</tr>
<tr>
<td>Corrections</td>
<td>301,021</td>
<td>129.03</td>
</tr>
<tr>
<td>Police</td>
<td>223,548</td>
<td>36.03</td>
</tr>
</tbody>
</table>

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Table VII-12-C.—Summary of Compliance Costs—Grand Total—Vaccination/Post-Exposure Follow-up

<table>
<thead>
<tr>
<th>Industry</th>
<th>Annualized Initial</th>
<th>Recurring costs</th>
<th>Total annual costs</th>
<th>Total annual costs per facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>$2,814,966</td>
<td>$7,171,473</td>
<td>$9,768,439</td>
<td>$54.55</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>1,795,620</td>
<td>3,081,209</td>
<td>4,676,909</td>
<td>51.34</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>9,651,033</td>
<td>11,144,498</td>
<td>14,795,531</td>
<td>788.42</td>
</tr>
<tr>
<td>Hospitals</td>
<td>10,254,561</td>
<td>18,533,346</td>
<td>28,787,707</td>
<td>4,879.27</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>159,682</td>
<td>485,519</td>
<td>645,200</td>
<td>55.66</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>1,771,400</td>
<td>2,687,864</td>
<td>4,459,264</td>
<td>150.11</td>
</tr>
<tr>
<td>Blood/plasma/tissue centers</td>
<td>105,399</td>
<td>146,905</td>
<td>252,304</td>
<td>303.00</td>
</tr>
<tr>
<td>Residential care</td>
<td>377,629</td>
<td>1,088,399</td>
<td>1,466,028</td>
<td>71.30</td>
</tr>
<tr>
<td>Personnel services</td>
<td>812,774</td>
<td>1,560,511</td>
<td>2,393,285</td>
<td>1,491.91</td>
</tr>
<tr>
<td>Funeral services</td>
<td>193,969</td>
<td>231,856</td>
<td>425,825</td>
<td>28.28</td>
</tr>
<tr>
<td>Research labs</td>
<td>731,455</td>
<td>1,553,772</td>
<td>2,285,227</td>
<td>1,064.86</td>
</tr>
<tr>
<td>Fire &amp; rescue</td>
<td>666,250</td>
<td>1,244,292</td>
<td>1,900,542</td>
<td>432.17</td>
</tr>
<tr>
<td>Corrections</td>
<td>191,542</td>
<td>231,856</td>
<td>425,825</td>
<td>28.28</td>
</tr>
<tr>
<td>Police</td>
<td>144,152</td>
<td>368,341</td>
<td>512,494</td>
<td>89.04</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>1,062,651</td>
<td>3,268,695</td>
<td>4,331,546</td>
<td>19.54</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>13,322</td>
<td>40,392</td>
<td>53,714</td>
<td>16.10</td>
</tr>
</tbody>
</table>

Total                        | 25,012,992         | 53,361,067      | 78,374,079         | 126.77                          |

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Table VII-13.—Rates of Usage of Personal Protective Equipment

<table>
<thead>
<tr>
<th>Industry</th>
<th>Rates of Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>FCP: One pr. disposable gloves per visit per employee. OCP: 2 pr. disposable gloves per day per employee. Janitors/Housekeepers: 1 pr. utility gloves per month per employee.</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>FCP: It is estimated that 40% of all office visits will require 1 mask to be used. OCP: 2 pr. disposable gloves per day per employee. Janitors/Housekeepers: 1 pr. utility gloves per month per employee.</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>FCP: One pr. disposable gloves per visit per employee. OCP: 2 pr. disposable gloves per day per employee. Janitors/Housekeepers: 1 pr. utility gloves per month per employee.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gloves</th>
<th>FCP: It is estimated that 40% of all office visits will require 1 mask to be used. OCP: 2 pr. disposable gloves per day per employee.</th>
</tr>
</thead>
<tbody>
<tr>
<td>FCP</td>
<td>30,171 pr. disposable gloves per facility per year. OCP: 2 pr. disposable gloves per day per employee.</td>
</tr>
<tr>
<td>OCP</td>
<td>81 masks per facility per year. OCP: 2 pr. disposable gloves per day per employee.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Masks</th>
<th>FCP: It is estimated that 20% of all office visits will require 1 mask to be used. OCP: 2 pr. disposable gloves per day per employee.</th>
</tr>
</thead>
<tbody>
<tr>
<td>FCP</td>
<td>4343 gowns per facility per year. OCP: 2 pr. disposable gloves per day per employee.</td>
</tr>
<tr>
<td>OCP</td>
<td>36 pr. disposable gloves per facility per year.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gowns</th>
<th>FCP: It is estimated that 3.3% of all office visits will require 1 gown to be used. OCP: 2 pr. disposable gloves per day per employee.</th>
</tr>
</thead>
<tbody>
<tr>
<td>FCP</td>
<td>One device per ofc, plus one additional device for every ten employees. OCP: 2 pr. disposable gloves per day per employee.</td>
</tr>
<tr>
<td>OCP</td>
<td>One device per ofc, plus one additional device for every ten employees.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Goggles</th>
<th>FCP: One pr. disposable gloves per visit per employee. OCP: 2 pr. disposable gloves per day per employee.</th>
</tr>
</thead>
<tbody>
<tr>
<td>FCP</td>
<td>One device per ofc, plus one additional device for every ten employees. OCP: 2 pr. disposable gloves per day per employee.</td>
</tr>
<tr>
<td>OCP</td>
<td>One device per ofc, plus one additional device for every ten employees.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Resuscitation devices</th>
<th>FCP: One pr. disposable gloves per visit per employee. OCP: 2 pr. disposable gloves per day per employee.</th>
</tr>
</thead>
<tbody>
<tr>
<td>FCP</td>
<td>One device per ofc, plus one additional device for every ten employees. OCP: 2 pr. disposable gloves per day per employee.</td>
</tr>
<tr>
<td>OCP</td>
<td>One device per ofc, plus one additional device for every ten employees.</td>
</tr>
<tr>
<td>Hospitals</td>
<td>Medical and dental labs</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Gloves</td>
<td>FCP: 4 pr. disposable gloves per employee per day</td>
</tr>
<tr>
<td></td>
<td>OCP: 2 pr. disposable gloves per employee per day</td>
</tr>
<tr>
<td>Masks</td>
<td>FCP: 2 masks per employee per day</td>
</tr>
<tr>
<td>Gowns</td>
<td>FCP: 2 gowns per employee per day</td>
</tr>
<tr>
<td>Goggles</td>
<td>FCP: 1 pr. goggles per employee per year</td>
</tr>
<tr>
<td>Resuscitation devices</td>
<td>One device per facility plus one additional device for every ten employees</td>
</tr>
</tbody>
</table>

**Blood banks**

| Gloves    | FCP: 4 pr. disposable gloves per employee per day | FCP: 2 pr. disposable gloves per employee per day |
|           | OCP: 2 pr. disposable gloves per employee per day | OCP: 2 pr. disposable gloves per employee per day |
| Masks     | FCP: 2 masks per employee per day | OCP: 1 mask per employee per day |
| Gowns     | FCP: 2 gowns per employee per day | OCP: 2 gloves per employee per day |
| Goggles   | FCP: 1 pr. goggles per employee per year | OCP: 1 pr. goggles per employee per year |
| Resuscitation devices | One device per facility plus one additional device for every ten employees | One device per facility plus one additional device for every ten employees |

**Research Labs**

| Gloves    | 4 pr. disposable gloves per employee per day | 3123 pr. disposable gloves per facility per year |
|           | 2 masks per employee per day | 80 masks per facility per year |
| Masks     | 2 gloves per employee per day | 655 gloves per facility per year |
| Gowns     | 1 pr. goggles per employee per year | 4 pr. goggles per facility per year |
| Goggles   | One device per facility plus one additional device for every ten employees | One device per facility plus one additional device for every ten employees |

**Industrial clinics**

| Gloves    | 1 pr. disposable gloves per emergency run | 4 pr. gloves per unpackaging employee per day |
|           | 1 pr. disposable gloves per emergency run | 2 masks per employee per day |
| Masks     | 1 pr. mask per employee per facility | 1 pr. gloves per employee per day |
| Gowns     | 1 pr. mask per employee per day | Goggles not required |
| Goggles   | 1 pr. mask per employee per day | One device per facility plus one additional device for every ten employees |
| Resuscitation devices | One device per facility | One device per facility |

**Law enforcement**

| Gloves    | 1 pr. disposable gloves per employee per day | 40% of the visits to health clinics in industrial settings will require the use of 1 pr. of disposable gloves |
|           | 2 masks per employee per day | 2 masks per employee per day |
| Masks     | 1 pr. mask per employee per day | Goggles not required |
| Gowns     | 1 pr. mask per employee per day | Goggles not required |
| Goggles   | One device per facility | One device per facility |
| Resuscitation devices | One device per facility | One device per facility |

**Resuscitation devices not required.**

*See Table VII-14 for occupational categories included in these classifications.

**Excludes Nurses and Phlebotomists.**

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis and Jack Faucett Associates.

### Table VII-14.—OCCUPATIONAL CLASSIFICATION BY FREQUENCY OF CONTACT WITH POTENTIALLY INFECTIOUS MATERIALS

<table>
<thead>
<tr>
<th>FCP (frequent contact personnel)</th>
<th>OCP (occasional contact personnel)</th>
<th>Janitors and cleaners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians and Surgeons; Registered Nurses; Licensed Practical Nurses; Laboratory Technicians; Emergency Medical Technician; Surgical Technician; Physician Assistant; Medical Assistant.</td>
<td>Therapists; Therapy Assistants; Other Health Professionals; Other Health Service; Nursing Aides.</td>
<td>Affected Population: 38,801.</td>
</tr>
<tr>
<td>Dentists; Physicians and Surgeons; Dental Hygienists; Dental Assistants; Laboratory Technicians; Registered Nurses; Medical Assistants; Surgical Technicians.</td>
<td>Licensed Practical Nurses; Other Health Professionals; Other Health Service; Therapists.</td>
<td>Affected Population: 1,973</td>
</tr>
<tr>
<td>Medical and dental laboratories.</td>
<td>Physicians and Surgeons; Dentists; Registered Nurses; Licensed Practical Nurses; Dental Hygienists; Dental Assistants; Laboratory Technicians; Life Scientists; Medical Assistants; Other Health Professionals; Other Health Service (Phlebotomists, Medical Technologists).</td>
<td>Therapists.</td>
</tr>
<tr>
<td>Occupational Category</td>
<td>FCP (Frequent Contact Personnel)</td>
<td>OCP (Occasional Contact Personnel)</td>
</tr>
<tr>
<td>-----------------------</td>
<td>---------------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Outpatient Care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physicians and Surgeons; Dentists; Registered Nurses; Licensed Practical Nurses; Dental Hygienists; Dental Assistants; Laboratory Technicians; Emergency Medical Technicians; Nursing Aides; Orderlies; Psychiatric Aides; Surgical Technicians; Physician Assistants; Medical Assistants; Ambulance Drivers</td>
<td>Affected Population: 312,526</td>
<td>Janitors/ Housekeepers (gloves only): (# of workers) x (usage rate) x (PPE unit cost)</td>
</tr>
<tr>
<td>Blood/Plasma centers.</td>
<td>Nurses; Phlebotomists; Laboratory Workers</td>
<td>Affected Population: 21,506</td>
</tr>
<tr>
<td>Funeral Homes</td>
<td>Embalmers</td>
<td>Affected Population: 20,921</td>
</tr>
</tbody>
</table>

### Cost Formulas

Cost formulas varied by industry sector, as dictated by available data. These formulas are presented below, and represent annual costs.

#### Offices of Physicians

There were a reported 520,789,311 patient visits to physicians' offices in 1985 [Ex. 13, p. III-41]. Using the FCP, OCP, and Janitor/ Housekeeper populations given in Table VII-14, PPE costs were estimated as follows:

- **Gloves, Masks, and Gowns**
  - FCP: (# of visits) x (usage rate) x (PPE unit cost)
  - OCP: (# of OCP) x (usage rate) x (days worked per year) x (PPE unit cost)
  - Janitors/Housekeepers (gloves only): (# of workers) x (usage rate) x (PPE unit cost)
  - Goggles: FCP: (# of FCP) x (PPE unit cost) x (usage rate)
  - Gowns: All FCP: (# of FCP) x (usage rate) x (PPE unit cost)

#### Offices of Dentists

PPE use for all FCP except hygienists were determined based on the average number of visits made to dentists' offices in 1985, reported to be 2,993. Hygienists were reported to see 2,049 patients that year. Populations of affected employees are given in Table VII-14. Personnel populations for all categories except dentists were converted to full time equivalent (FTE) personnel using a factor of 0.6 [Ex. 13, p. III-41]. PPE costs were estimated as follows:

- **Gloves, Masks**
  - FCP: (# of visits) x (usage rate) x (PPE unit cost)
  - OCP: (# of OCP) x (usage rate) x (days worked per year) x (PPE unit cost)

### Medical and Dental Laboratories

Costs were calculated for this industry sector on the basis of PPE use per inpatient-year. Using data obtained from site visits conducted at two hospitals believed to be at nearly full compliance, costs were computed at the facility level using the following formulas:

- **Gloves, Masks, Gowns**
  - FCP: (# of FCP) x (usage rate) x (days worked per year) x (PPE unit cost)
  - OCP: (# of OCP) x (usage rate) x (days worked per year) x (PPE unit cost)
  - Janitors/Housekeepers (gloves only): (# of workers) x (usage rate) x (PPE unit cost)
  - Goggles: FCP: (# of FCP) x (PPE unit cost) x (usage rate)
  - Gowns: All FCP: (# of FCP) x (usage rate) x (PPE unit cost)

### Outpatient Care Facilities

Costs were calculated as follows:

- **Gloves, Masks, Gowns**
  - FCP: (# of FCP) x (usage rate) x (days worked per year) x (PPE unit cost)
  - OCP: (# of OCP) x (usage rate) x (days worked per year) x (PPE unit cost)
  - Janitors/Housekeepers (gloves only): (# of workers) x (usage rate) x (PPE unit cost)
  - Goggles: FCP: (# of FCP) x (PPE unit cost) x (usage rate)
  - Gowns: All FCP: (# of FCP) x (usage rate) x (PPE unit cost)

### Blood/Plasma/Tissue Centers

Costs were calculated as follows:

- **Gloves, Masks, Gowns**
  - FCP: (# of FCP) x (usage rate) x (days worked per year) x (PPE unit cost)
  - OCP: (# of OCP) x (usage rate) x (days worked per year) x (PPE unit cost)
  - Janitors/Housekeepers (gloves only): (# of workers) x (usage rate) x (PPE unit cost)
  - Goggles: FCP: (# of FCP) x (PPE unit cost) x (usage rate)
  - Gowns: All FCP: (# of FCP) x (usage rate) x (PPE unit cost)

### Affected Populations

- **Physicians and Surgeons, Dentists, Registered Nurses, Licensed Practical Nurses, Dental Hygienists, Dental Assistants, Laboratory Technicians, Emergency Medical Technicians, Nursing Aides, Orderlies, Psychiatric Aides, Surgical Technicians, Physician Assistants, Medical Assistants, Ambulance Drivers**: Affected Population: 4,998.
- **Nurses, Phlebotomists, Laboratory Workers**: Affected Population: 692.
- **Ambulance Drivers & Attendants**: Affected Population: 4,375.

### Source

Occupational Safety and Health Administration, Office of Regulatory Analysis, Bureau of Labor Statistics, and Jack Faucett Associates.

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1. This employment category may include professionals not at risk of exposure to infectious materials, such as orthopedic technicians. The affected population may, therefore, be somewhat overstated.

2. Includes persons who assist and work under the direction of physicians, dentists, nurses, therapists, pharmacists, other health-related professionals, paraprofessional, and technical workers. Workers in these occupations provide auxiliary services, such as assisting in the care of patients, relieving nurses of heavier work, preparing treatment rooms, transporting patients, assisting therapists, and mixing pharmaceutical preparations. To the extent that this employment category may include professionals not at risk of exposure to infectious materials, the affected population may be somewhat overstated.
Gloves, Masks, Gowns
FCP: (# of FCP) \times \text{(usage rate)} \times \text{(days worked per year)} \times \text{(PPE unit cost)}

Janitors/Housekeepers (gloves only): (# of workers) \times \text{(usage rate)} \times \text{(PPE unit cost)}

Goggles
FCP: (# of FCP) \times \text{(usage rate)} \times \text{(PPE unit cost)}

Resuscitation Devices
(ambubag cost) \times \text{(usage rate)} \times \text{( # of facilities)}

Residential Care: Costs for these establishments were developed from those of nursing homes by using the ratio of the number of affected employees in residential care facilities to the number of affected employees in nursing homes. 0.1035 [Ex. 13, p. III-46].

Funeral Services: Costs for funeral homes were based on the number of necropsies performed yearly by such an establishment, 137.34 [Ex. 13, p. III-46]. The number of FCP per necropsy is 1.05 and the number of OCP per necropsy is 0.074.

Residential Care: Costs for this sector are based on an affected worker population of 97,945.

Resuscitation Devices
(# of workers) \times \text{(PPE unit cost)} \times \text{(usage rate)}

Low Enforcement: Costs for this sector are based on an affected worker population of 208,693.

Medical Equipment Repair:
Gloves, Masks
FPC: (# of FCP) \times \text{(usage rate)} \times \text{(days worked)} \times \text{(PPE unit cost)}

Goggles
FPC: (# of FPC) \times \text{(usage rate)} \times \text{(PPE unit cost)}

Medical Equipment Repair:
Gloves, Masks
FPC: (# of FCP) \times \text{(usage rate)} \times \text{(days worked)} \times \text{(PPE unit cost)}

Personnel Services: It is expected that PPE will be issued to temporary workers upon arrival at the worksite. Consequently, no costs under this provision are expected to be incurred by these establishments.

Costs for FPE are summarized in Table VII-15-A. Total annual costs per facility range from $260.65 to $78.67.
### TABLE VII-15-C—SUMMARY OF COMPLIANCE COSTS—PERSONAL PROTECTIVE EQUIPMENT (Gowns)

<table>
<thead>
<tr>
<th>Industry</th>
<th>Total annual costs</th>
<th>Total annual costs per facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>$2,756,014</td>
<td>$15.43</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>17,658,524</td>
<td>194.62</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>16,913,721</td>
<td>903.12</td>
</tr>
<tr>
<td>Hospitals</td>
<td>12,581,531</td>
<td>2,132.46</td>
</tr>
<tr>
<td>Medical/Dental labs</td>
<td>632,708</td>
<td>51.19</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>6,370,688</td>
<td>214.46</td>
</tr>
<tr>
<td>Blood/Plasma/Tissue centers</td>
<td>2,636,327</td>
<td>4,106.43</td>
</tr>
<tr>
<td>Residential care</td>
<td>1,759,570</td>
<td>65.24</td>
</tr>
<tr>
<td>Personnel services</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Funerals</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Research labs</td>
<td>1,587,925</td>
<td>729.95</td>
</tr>
<tr>
<td>Fire and rescue</td>
<td>115,676</td>
<td>30.82</td>
</tr>
<tr>
<td>Corrections</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Police</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>8,914,126</strong></td>
<td><strong>101.83</strong></td>
</tr>
</tbody>
</table>

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

### TABLE VII-15-E—SUMMARY OF COMPLIANCE COSTS—PERSONAL PROTECTIVE EQUIPMENT (Resuscitation Devices)

<table>
<thead>
<tr>
<th>Industry</th>
<th>Total annual costs</th>
<th>Total annual costs per facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>$1,216,366</td>
<td>$6.78</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>960,080</td>
<td>10.17</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>1,159,825</td>
<td>61.93</td>
</tr>
<tr>
<td>Hospitals</td>
<td>1,652,490</td>
<td>275.02</td>
</tr>
<tr>
<td>Medical/Dental labs</td>
<td>10,935</td>
<td>0.85</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>100,703</td>
<td>3.90</td>
</tr>
<tr>
<td>Blood/Plasma/Tissue centers</td>
<td>32,646</td>
<td>50.85</td>
</tr>
<tr>
<td>Residential care</td>
<td>261,077</td>
<td>12.71</td>
</tr>
<tr>
<td>Personal services</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Funeral services</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Research labs</td>
<td>21,825</td>
<td>10.17</td>
</tr>
<tr>
<td>Fire and rescue</td>
<td>260,434</td>
<td>69.28</td>
</tr>
<tr>
<td>Corrections</td>
<td>98,881</td>
<td>42.38</td>
</tr>
<tr>
<td>Police</td>
<td>920,492</td>
<td>129.49</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>1,878,484</td>
<td>6.48</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>6,432,726</strong></td>
<td><strong>13.65</strong></td>
</tr>
</tbody>
</table>

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

### TABLE VII-15-F—SUMMARY OF COMPLIANCE COSTS PERSONAL PROTECTIVE EQUIPMENT (Grand Totals)

<table>
<thead>
<tr>
<th>Industry</th>
<th>Total annual costs</th>
<th>Total annual costs per facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>$36,934,022</td>
<td>$203.98</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>161,759,927</td>
<td>1,702.91</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>69,527,733</td>
<td>7,177.84</td>
</tr>
<tr>
<td>Hospitals</td>
<td>90,338,514</td>
<td>15,311.61</td>
</tr>
<tr>
<td>Medical/Dental labs</td>
<td>1,250,881</td>
<td>102.58</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>17,911,806</td>
<td>284.63</td>
</tr>
<tr>
<td>Blood/Plasma/Tissue centers</td>
<td>6,344,858</td>
<td>945.67</td>
</tr>
<tr>
<td>Residential care</td>
<td>7,347,607</td>
<td>357.77</td>
</tr>
<tr>
<td>Personal services</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Funeral services</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Research labs</td>
<td>4,869,091</td>
<td>2,172.92</td>
</tr>
<tr>
<td>Fire and rescue</td>
<td>1,388,457</td>
<td>369.27</td>
</tr>
<tr>
<td>Corrections</td>
<td>98,881</td>
<td>42.38</td>
</tr>
<tr>
<td>Police</td>
<td>814,121</td>
<td>131.20</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>2,350,640</td>
<td>11.51</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>271,255</td>
<td>91.42</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>50,177,716</strong></td>
<td><strong>$648.15</strong></td>
</tr>
</tbody>
</table>

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

### Engineering Controls

Available information indicates that those facilities for which engineering controls would be appropriate are currently using such controls [Ex. 13, pp. III-35, 36]. These facilities include research labs, medical and dental labs, and labs located in hospital or outpatient medical establishments. Controls required and believed to be in use include biosafety cabinets (for biosafety level one and two facilities), centrifuge safety equipment, and mechanical pipetting devices. (Puncture resistant sharps containers are included under the housekeeping provision).

Thus, OSHA finds that costs attributable to the proposed provisions for engineering controls will be negligible.

Training. Costs for the training provision were calculated based on the same scheme of occupational classification as was used for medical surveillance, that is, workers were placed into seven different occupational categories with respect to appropriate wage and job turnover rates. (Table VII-9 provides the occupational breakdown into the seven categories along with the affected worker populations.) Additional input data includes the length and frequency of training.

Length of training is expected to vary with occupational classification and is expected to depend on whether training is initial or recurrent. Initial training sessions for diagnosing, treating, and service personnel (except equipment repair) are assumed to be 1 hour in duration while recurrent annual sessions are assumed to be one hour.

Initial training for housekeeping personnel, security personnel, police officers, firefighters, and equipment repair personnel are expected to last about 1 hour, with annual sessions at one-half hour.

Initial training costs consist of costs incurred for the time taken by the trainee and compensation for the trainer. (For firefighters, no costs were estimated for time lost to workers, since training can take place during idle hours). Compensation for the trainees and trainer will be paid as follows:

1. \((# \text{ of trainees}) \times (\text{trainee wage rate}) \times (\text{initial session time})\)
2. \((\text{trainer wage}) \times (\text{initial session time}) \times (# \text{ of sessions})\)

In general, OSHA assumes that one 2-
hour session and one 1-hour session will be offered initially. (For hospitals, it is estimated that 2 of each session will be offered). Compensation for trainers is assumed to be at a rate of $23.26 (head nurse) for sessions with diagnosing and treating employees and $16.44 (floor nurse) for sessions with service and housekeeping personnel. Equations (1) and (2) summed represent total initial costs.

New employees will need to be trained as they are hired. The costs for additional initial training given during the first year can be estimated thus: (3) Initial trainee compensation x (job turnover rate) (4) (trainer wage) x (initial session time) x (# of trainees/group) x (job turnover rate).

Equation (3) reflects the cost of time needed to train each new hire. Equation (4) represents compensation for the trainer. (For hospitals, nursing homes, temporary services, corrections, law enforcement, and fire fighters, it is assumed that new hires will be trained in groups of five. For all other sectors, new hires are assumed to be trained individually). Thus, total first year costs are represented by the summing of equations (1) through (4), which are performed for each of the seven occupational categories across all industries.

Costs for additional training given over all following years will consist of training new hires and tenured employees (in-service). The calculation to estimate the cost of training new hires in these subsequent years is identical to that described by equations (3) and (4) to represent training for new hires during the first year. Equations (5) and (6), given below, represent costs incurred for training tenured (in-service) employees during subsequent years:

\[ (5) \text{(# of trainees)} \times (1 - \text{job turnover rate}) \times \text{(initial session time)} \times \text{(in-service session time)} \times \text{(of sessions)} \]

Equation (5) reflects the cost of the time taken to train tenured employees. The second term of this equation accounts for the employees who will quit before being retrained. (Job turnover has been divided by two to reflect that, on average, only about one-half of the workers leaving over the course of the year will leave before that year's retraining). Equation (6) represents the compensation to the trainer. These calculations have been performed for each occupational category within each sector.

Total cost in each subsequent year (recurring cost) is then the sum of equations (5), (4), (5), and (6). Total annual costs for this provision are the sum of recurring costs plus the annualization of the difference between first year costs and recurring costs. (Annualization was performed using a twenty year payback period). Net costs are summarized in table VII-16. Total annual costs are estimated to be $162.2 million with average costs per facility at $282. The greatest share of incremental costs are expected to be borne by offices of physicians (33%) while the greatest cost per facility will be realized by personnel service establishments, $3,564.

### Table VII-16 — Summary of Compliance Costs— Training

<table>
<thead>
<tr>
<th>Industry</th>
<th>Annualized first year costs</th>
<th>Recurring costs</th>
<th>Total annual costs</th>
<th>Total annual costs per facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>$300,331</td>
<td>$53,461,639</td>
<td>$537,791,970</td>
<td>$299.67</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>$67,231</td>
<td>10,999,131</td>
<td>11,066,362</td>
<td>116.50</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>129,488</td>
<td>18,182,356</td>
<td>8,311,852</td>
<td>497.22</td>
</tr>
<tr>
<td>Hospitals</td>
<td>408,298</td>
<td>30,937,388</td>
<td>31,345,685</td>
<td>5,312.83</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>7,529</td>
<td>1,339,543</td>
<td>1,347,072</td>
<td>110.46</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>44,842</td>
<td>5,577,474</td>
<td>5,622,316</td>
<td>189.27</td>
</tr>
<tr>
<td>Blood/plasma/tissue centers</td>
<td>7,307</td>
<td>842,874</td>
<td>850,181</td>
<td>1,224.27</td>
</tr>
<tr>
<td>Residential care</td>
<td>12,597</td>
<td>1,870,840</td>
<td>1,883,237</td>
<td>91.70</td>
</tr>
<tr>
<td>Personnel services</td>
<td>284,958</td>
<td>3,577,866</td>
<td>3,862,844</td>
<td>5,364.05</td>
</tr>
<tr>
<td>Funeral services</td>
<td>9,988</td>
<td>1,138,926</td>
<td>1,148,914</td>
<td>5,457.68</td>
</tr>
<tr>
<td>Research labs</td>
<td>16,250</td>
<td>1,856,487</td>
<td>1,972,736</td>
<td>127.66</td>
</tr>
<tr>
<td>Fire and rescue</td>
<td>0</td>
<td>716,333</td>
<td>716,333</td>
<td>95.25</td>
</tr>
<tr>
<td>Corrections</td>
<td>7,156</td>
<td>1,139,612</td>
<td>1,209,767</td>
<td>518.65</td>
</tr>
<tr>
<td>Police</td>
<td>177,031</td>
<td>2,024,854</td>
<td>2,201,885</td>
<td>557.76</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>108,928</td>
<td>31,330,520</td>
<td>31,439,450</td>
<td>141.84</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>1,930</td>
<td>20,169</td>
<td>22,099</td>
<td>7.45</td>
</tr>
<tr>
<td>Total</td>
<td>1,640,973</td>
<td>160,510,282</td>
<td>162,151,255</td>
<td>262.42</td>
</tr>
</tbody>
</table>

1 Annualized first year costs (AFYC) were computed as follows: AFYC = (total first year cost - recurring cost) x capital recovery factor.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Housekeeping. Costs incurred for housekeeping will arise from five sources: puncture resistant sharps disposal containers; biowaste bags, or "red bags," for the containment of infectious waste; costs of disposal of infectious waste; costs for disinfecting surfaces and equipment; and use of fool coverings (offices of dentists only).

Costs for sharps disposal containers are based on data obtained from hospitals [Ex. 13, p. III-20]. First, the total cost per bed was multiplied by the number of hospital beds nationwide to arrive at a total cost figure for this sector. Costs were then divided by the overall number of diagnosing and treating workers employed by all hospitals to arrive at a cost per diagnosing/treating (D/T) employee. This estimate was in turn used to estimate sharps container costs across all other sectors by multiplying the unit cost per diagnosing/treating employee by the number of such employees in each respective sector. (The affected population of D/T employees for each sector is shown in Table VII-6). Input data for sharps containers included the following:

<table>
<thead>
<tr>
<th></th>
<th>Cost per D/T employee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital costs</td>
<td>$56.61</td>
</tr>
<tr>
<td>Annual labor and materials</td>
<td>$24.12</td>
</tr>
</tbody>
</table>

Thus, for each sector, annualized capital costs required for sharps containers were calculated using the following formula:

\[(1) \text{(# of D/T workers) x (unit capital cost per worker) x (capital recovery factor)}\]

where annualization occurs over 5 years and the capital recovery factor equals 0.2339.

Recurring annual costs for containers were calculated as

\[(2) \text{(# of D/T workers) x (annual cost per worker)}\]

Total annual costs for sharps containers were calculated by summing equations (1) and (2) and amount to $28.4 million. The costs by sector are summarized in Table VII-17-A.
For the purchase of biowaste bags, a similar methodology was used to estimate the added costs for hospitals (though no initial costs will be incurred). Input data included:

Cost per D/T bag

Annual cost

$35.13

Thus, total annual costs for biowaste bags in the hospital sector were calculated to be:

(3) (# of D/T workers) x (annual cost per worker)

Total annual costs for additional biowaste bags in other sectors were calculated by estimating approximate bag usage with respect to infectious waste disposal. Assuming each bag contains an average of two pounds of waste at disposal, the unit cost is $0.20 per bag, and the infectious waste generation rates are those shown in Table VII-17-C, costs were calculated thus:

(4) ([pounds of infectious waste generation per year]/2) x $0.20

Costs for biowaste bags are shown in Table VII-17-B and total $28.3 million per year.

Costs will also be incurred for the disposal of infectious waste, which is more costly to dispose of than general refuse, to the extent that establishments are not currently practicing proper identification of such waste prior to disposal.

Costs were determined by developing estimates of waste generation for each industry and then multiplying total annual volume by the unit cost of disposal. Rates of infectious waste generation, along with estimates of current compliance and unit costs, which were based largely on a survey of health care establishments in King County of Washington State, are presented in Table VII-17-C. The following formula was used to estimate costs for biowaste disposal:

(5) (total annual volume of waste) x (unit cost)

This total annual cost was then multiplied by the appropriate compliance factor to determine the incremental cost of $177.2 million. Costs for this component of housekeeping are summarized in Table VII-17-D.

The provision requiring the disinfecting of surfaces and equipment is not expected to generate significant cost. First, it is probable that surfaces and equipment are already being disinfected prior to use in almost all instances if visibly contaminated. The OSHA rule may simply alter the schedule of this activity so that disinfection takes place sooner. Second, accepted industry practice is to disinfect any equipment or instrument which comes into contact with patients as a means of preventing the spread of infection from patient to patient. Third, disjointed solutions are inexpensive and easy to prepare; therefore, any incremental increase in disinfection practices will be of insignificant burden.

The final cost included for this provision of the standard applies only to offices of dentists and is for the use of foil coverings to prevent the contamination of surfaces, switches, etc. Costs are based on the use of fresh foil for every patient at a cost of about $.05 per patient, as shown by the following equation:

(6) ([# of dentists] x (# of visits) + (# of hygienists) x (# of visits to hygienists)) x 0.05

Based on an estimated current compliance level of 25%, total annual costs for coverings amount to $14.9 million.

Costs for leakproof containers to protect workers handling blood in transport have not been estimated, since OSHA assumes that no significant costs would be realized. If public comment indicates otherwise, costs for these containers will be estimated.

Total costs will be the summation of equations (1) through (6) and are presented in Table VII-17-E. Total incremental annual costs for this provision are estimated at $186.9 million. Average cost per facility will be $506.

Labelling/Signs. Costs for signs were estimated based on the requirement that one sign will be posted at each entrance to a research laboratory or virus production facility that handles concentrated virus. Sign costs are estimated to be $13.75 each (the cost of a 10" x 14" aluminum sign, including $1.00 for mounting materials). Total costs for signs were estimated for the research lab sector by assuming that each of the 2,146 facilities identified in the Industry Profile will require two signs, and that one-quarter hour is required for mounting each sign. Signs are expected to be replaced every five years; thus, annualization was calculated based on this time period. The costs of signs were computed as follows:

([# of signs] x (unit cost) + (0.25 hrs. x $9.09)] x (annualization factor),

where $9.09 is the wage rate of maintenance personnel and costs are at the facility level.

Total annual costs for signs in research labs are thus estimated at $3,628. Annual costs per facility will be $1,690.

Labels are also required by the proposed rule. However, since containers and storage apparatus used for transporting and storing blood and other infectious materials would normally have a label affixed to them for the purposes of identification, it is not anticipated that measurable incremental costs will be involved in complying with this requirement. Label style, however, may need to be modified when new labels are ordered.
### TABLE VII-17-A—SUMMARY OF COMPLIANCE COSTS—HOUSEKEEPING—Continued

<table>
<thead>
<tr>
<th>Industry</th>
<th>Annualized initial</th>
<th>Recurring costs</th>
<th>Total annual costs</th>
<th>Total annual costs per facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>$3,139,746</td>
<td>$41,418,796</td>
<td>$44,558,542</td>
<td>$246,37</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>$1,219,898</td>
<td>41,998,950</td>
<td>43,218,848</td>
<td>454,96</td>
</tr>
<tr>
<td>Hospitals</td>
<td>$293,776</td>
<td>27,145,148</td>
<td>27,438,924</td>
<td>1,465,13</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>$3,527,001</td>
<td>38,337,002</td>
<td>41,864,003</td>
<td>708,68</td>
</tr>
<tr>
<td>Total</td>
<td>$4,510,222</td>
<td>$80,351,948</td>
<td>$84,862,170</td>
<td>$1,700,95</td>
</tr>
</tbody>
</table>

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

### TABLE VII-17-B—SUMMARY OF COMPLIANCE COSTS—HOUSEKEEPING

#### (Biohazard Bags)

<table>
<thead>
<tr>
<th>Industry</th>
<th>Total annual costs</th>
<th>Total annual costs per facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>$4,214,223</td>
<td>23.49</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>$2,479,343</td>
<td>26.10</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>$9,815,338</td>
<td>524.10</td>
</tr>
<tr>
<td>Hospitals</td>
<td>$8,298,050</td>
<td>1,406.45</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>$1,314,019</td>
<td>107.75</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>$58,391</td>
<td>49.30</td>
</tr>
<tr>
<td>Blood/plasma/tissue centers</td>
<td>$564,130</td>
<td>87.81</td>
</tr>
<tr>
<td>Residential care</td>
<td>$1,315,251</td>
<td>64.04</td>
</tr>
<tr>
<td>Personnel services</td>
<td>$0</td>
<td>0.00</td>
</tr>
<tr>
<td>Fire and rescue</td>
<td>$578,931</td>
<td>269.77</td>
</tr>
<tr>
<td>Corrections</td>
<td>$160,038</td>
<td>42.90</td>
</tr>
<tr>
<td>Police</td>
<td>$102,051</td>
<td>41.45</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>$110,621</td>
<td>0.50</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>$0</td>
<td>0.00</td>
</tr>
<tr>
<td>Total</td>
<td>$28,348,256</td>
<td>45.88</td>
</tr>
</tbody>
</table>

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

### TABLE VII-17-C—INFECTIOUS WASTE—WASTE GENERATION AND CURRENT COMPLIANCE RATES—Continued

#### (Disposal of Infectious Waste)

<table>
<thead>
<tr>
<th>Industry</th>
<th>Volume of infectious waste generated</th>
<th>Unit disposal costs (dollar)</th>
<th>Baseline rate (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals</td>
<td>1 LB/bag/day</td>
<td>0.44</td>
<td>81</td>
</tr>
<tr>
<td>Medical/ dental care</td>
<td>1.75 LB/day</td>
<td>0.56</td>
<td>86</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>1.5 LB/day</td>
<td>0.56</td>
<td>39</td>
</tr>
<tr>
<td>Blood/ medical/ tissue care</td>
<td>1.75 LB/day</td>
<td>0.56</td>
<td>86</td>
</tr>
<tr>
<td>Residential care</td>
<td>0.5 LB/bag/day</td>
<td>0.75</td>
<td>81</td>
</tr>
<tr>
<td>Personnel services</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Funeral services</td>
<td>0.5 LB/day</td>
<td>0.75</td>
<td>39</td>
</tr>
<tr>
<td>Research labs</td>
<td>1.75 LB/day</td>
<td>0.56</td>
<td>86</td>
</tr>
<tr>
<td>Fire and rescue</td>
<td>0.5 LB/day</td>
<td>0.75</td>
<td>39</td>
</tr>
<tr>
<td>Corrections</td>
<td>1 LB/treating personnel/day</td>
<td>0.75</td>
<td>39</td>
</tr>
<tr>
<td>Police</td>
<td>1 LB/treating personnel/day</td>
<td>0.75</td>
<td>39</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>0</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

### TABLE VII-17-E—SUMMARY OF COMPLIANCE COSTS—HOUSEKEEPING GRAND TOTALS

<table>
<thead>
<tr>
<th>Industry</th>
<th>Annualized initial</th>
<th>Recurring costs</th>
<th>Total annual costs</th>
<th>Total annual costs per facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>$3,139,746</td>
<td>$41,418,796</td>
<td>$44,558,542</td>
<td>$246,37</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>$1,219,898</td>
<td>41,998,950</td>
<td>43,218,848</td>
<td>454,96</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>$293,776</td>
<td>27,145,148</td>
<td>27,438,924</td>
<td>1,465,13</td>
</tr>
<tr>
<td>Hospitals</td>
<td>$3,527,001</td>
<td>38,337,002</td>
<td>41,864,003</td>
<td>708,68</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>$49,839</td>
<td>1,516,569</td>
<td>1,566,408</td>
<td>27.62</td>
</tr>
<tr>
<td>Total</td>
<td>$117,217,439</td>
<td>$186,72</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.
## TABLE VII-17—SUMMARY OF COMPLIANCE COSTS—HOUSEKEEPING GRAND TOTALS—Continued

<table>
<thead>
<tr>
<th>Industry</th>
<th>Annualized Initial</th>
<th>Recurring Costs</th>
<th>Total Annual Costs</th>
<th>Total Annual Costs per Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient care</td>
<td>1,802,694</td>
<td>7,465,666</td>
<td>9,268,560</td>
<td>312.01</td>
</tr>
<tr>
<td>Blood/plasma/tissue centers</td>
<td>208,757</td>
<td>1,671,414</td>
<td>1,880,171</td>
<td>2,926.62</td>
</tr>
<tr>
<td>Residential care</td>
<td>56,000</td>
<td>8,731,648</td>
<td>9,297,648</td>
<td>476.59</td>
</tr>
<tr>
<td>Personnel services</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Funeral services</td>
<td>0</td>
<td>472,850</td>
<td>472,850</td>
<td>31.42</td>
</tr>
<tr>
<td>Research labs</td>
<td>214,270</td>
<td>4,350,300</td>
<td>4,564,571</td>
<td>2,127.01</td>
</tr>
<tr>
<td>Fire and rescue</td>
<td>233,220</td>
<td>537,620</td>
<td>770,840</td>
<td>205.01</td>
</tr>
<tr>
<td>Corrections</td>
<td>0</td>
<td>1,637,316</td>
<td>1,637,316</td>
<td>701.81</td>
</tr>
<tr>
<td>Police</td>
<td>58,391</td>
<td>196,360</td>
<td>254,751</td>
<td>41.06</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>60,216</td>
<td>1,523,767</td>
<td>1,684,064</td>
<td>7.23</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Total</td>
<td>10,878,307</td>
<td>177,998,957</td>
<td>188,877,264</td>
<td>305.71</td>
</tr>
</tbody>
</table>

1 Recurring costs for dental offices include $14,863,312 for coverings.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Recordkeeping. Costs for recordkeeping will be incurred due to the need to keep medical and training records.

Initial costs for medical records will be for the establishment of a file for each employee. It is expected that ten minutes will be required for this task. The wage rate for the employee preparing this file is taken to be that of a service employee at $11.12. Annualized initial costs, computed based on a 20 year payback period, are then:

\[(\#\ of\ affected\ workers) \times \frac{1}{2}\ \text{hr.} \times 11.12\times (\text{capital\ recovery\ factor})\]

Recurring costs for medical records will be:

\[(\text{initial\ costs}) \times (\text{job\ turnover\ rate}) + (\#\ of\ exposure\ incidents) \times \frac{1}{2}\ \times 11.12\]

As each new employee will require a file and the records of those workers reporting exposure incidents will require updating, which is assumed to require about 3 minutes per file.

Total annual costs for medical records are the sum of annualized initial costs and recurring annual costs.

Although initial costs for establishing a training file will not be substantial, there will be annual recurring costs because the file must be updated subsequent to training sessions.

Recurring recordkeeping tasks will include recording will be due to the need to include the dates, trainers, and attending trainees for each training session. It was estimated that the time required to update the file will average about 1 minute per trainee. Thus, costs were estimated by the following formula:

\[(\#\ of\ trainees) \times [1 + (\text{job\ turnover}/2)] \times \frac{1}{2}\ \text{hr.} \times 11.12\]

(As explained above, job turnover has been divided by two to reflect that, on average, only about one-half of the workers leaving over the course of the year will leave before that year's in-service training. Thus, one-half of the workers eventually leaving will attend one of the sessions provided.)

Since the total first year costs will exceed the costs in succeeding years, this difference is annualized to calculate annual costs. Total annual costs for training records are thus the sum of recurring costs plus the annualization of the difference between first year costs and recurring costs.

Net costs for recordkeeping are summarized in Table VII-18. Annual incremental costs attributable to this provision are $5.6 million. Average cost per facility is expected to be $39.00, ranging from $346 for hospitals to $370 for medical equipment repair facilities.

## TABLE VIII-18—SUMMARY OF COMPLIANCE COSTS—RECORD KEEPING

<table>
<thead>
<tr>
<th>Industry</th>
<th>Annualized Initial</th>
<th>Recurring Costs</th>
<th>Total Annual Costs</th>
<th>Total Annual Costs per Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>116,750</td>
<td>364,646</td>
<td>481,395</td>
<td>2.68</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>70,388</td>
<td>243,786</td>
<td>314,161</td>
<td>3.31</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>166,515</td>
<td>672,938</td>
<td>839,453</td>
<td>44.98</td>
</tr>
<tr>
<td>Hospitals</td>
<td>472,060</td>
<td>1,568,104</td>
<td>2,040,164</td>
<td>345.98</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>8,890</td>
<td>40,203</td>
<td>49,093</td>
<td>4.03</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>80,885</td>
<td>257,575</td>
<td>338,460</td>
<td>11.39</td>
</tr>
<tr>
<td>Blood/plasma/tissue centers</td>
<td>4,034</td>
<td>14,255</td>
<td>18,289</td>
<td>29.73</td>
</tr>
<tr>
<td>Residential care</td>
<td>37,458</td>
<td>130,037</td>
<td>167,495</td>
<td>7.19</td>
</tr>
<tr>
<td>Personnel services</td>
<td>33,938</td>
<td>370,368</td>
<td>404,305</td>
<td>250.34</td>
</tr>
<tr>
<td>Funeral services</td>
<td>5,751</td>
<td>26,750</td>
<td>32,500</td>
<td>2.16</td>
</tr>
<tr>
<td>Research labs</td>
<td>33,184</td>
<td>164,004</td>
<td>197,188</td>
<td>101.21</td>
</tr>
<tr>
<td>Fire and Rescue</td>
<td>43,934</td>
<td>89,214</td>
<td>133,148</td>
<td>35.41</td>
</tr>
<tr>
<td>Corrections</td>
<td>21,329</td>
<td>91,153</td>
<td>112,482</td>
<td>48.21</td>
</tr>
<tr>
<td>Police</td>
<td>45,446</td>
<td>82,710</td>
<td>128,157</td>
<td>20.65</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>59,416</td>
<td>231,748</td>
<td>291,164</td>
<td>101.21</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>410</td>
<td>1,678</td>
<td>2,088</td>
<td>7.07</td>
</tr>
<tr>
<td>Totals</td>
<td>$1,183,956</td>
<td>$4,370,253</td>
<td>$5,554,209</td>
<td>$8.99</td>
</tr>
</tbody>
</table>

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.
### TABLE VII-19-A.—SUMMARY OF COMPLIANCE COSTS—GRAND TOTALS

<table>
<thead>
<tr>
<th>Industry</th>
<th>Annual cost by type of ownership</th>
<th>Total annual costs</th>
<th>Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Private</td>
<td>Federal</td>
<td>State/loc.</td>
</tr>
<tr>
<td>Offices of physicians</td>
<td>$149,586,276</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>223,573,678</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>119,405,026</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hospitals</td>
<td>180,802,717</td>
<td>$10,135,122</td>
<td>24,168,370</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>5,184,026</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>12,708,624</td>
<td>14,206,015</td>
<td>11,473,996</td>
</tr>
<tr>
<td>Blood/plasma/tissue centers</td>
<td>9,063,097</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Residential care</td>
<td>18,457,833</td>
<td>3,180,858</td>
<td>0</td>
</tr>
<tr>
<td>Personnel services</td>
<td>11,500,173</td>
<td>0</td>
<td>11,500,173</td>
</tr>
<tr>
<td>Research labs</td>
<td>8,741,832</td>
<td>682,959</td>
<td>4,254,325</td>
</tr>
<tr>
<td>Police</td>
<td>2,121,600</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Fire &amp; rescue</td>
<td>43,793</td>
<td>4,044,895</td>
<td>0</td>
</tr>
<tr>
<td>Corrections</td>
<td>0</td>
<td>0</td>
<td>49,150</td>
</tr>
<tr>
<td>Police</td>
<td>45,655,456</td>
<td>0</td>
<td>4,121,702</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>421,977</td>
<td>0</td>
<td>421,977</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>766,026,458</td>
<td>26,105,873</td>
<td>60,048,531</td>
</tr>
</tbody>
</table>

### TABLE VII-19-B.—SUMMARY OF COMPLIANCE COSTS—GRAND TOTALS

<table>
<thead>
<tr>
<th>Industry</th>
<th>Total annual costs</th>
<th>Totals</th>
<th>Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Offices of physicians</td>
<td>$4,403,308</td>
<td>2,331,528</td>
<td>$16,502,710</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>4,876,309</td>
<td>14,765,531</td>
<td>18,457,833</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>885,707</td>
<td>69,627,753</td>
<td>9,147,852</td>
</tr>
<tr>
<td>Hospitals</td>
<td>326,647</td>
<td>90,338,514</td>
<td>3,180,858</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>9,291,013</td>
<td>17,911,600</td>
<td>1,586,210</td>
</tr>
<tr>
<td>Residential care</td>
<td>59,638</td>
<td>3,863,097</td>
<td>12,430,783</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>15,494</td>
<td>6,044,856</td>
<td>10,441,161</td>
</tr>
<tr>
<td>Residential care</td>
<td>1,006,116</td>
<td>1,840,897</td>
<td>1,235,706</td>
</tr>
<tr>
<td>Personel services</td>
<td>1,144,328</td>
<td>7,245,507</td>
<td>1,089,327</td>
</tr>
<tr>
<td>Service units in industry</td>
<td>5,440,167</td>
<td>4,331,546</td>
<td>3,000,000</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>72,822</td>
<td>53,714</td>
<td>27,190</td>
</tr>
<tr>
<td>Totals</td>
<td>16,502,710</td>
<td>78,374,079</td>
<td>400,777,716</td>
</tr>
</tbody>
</table>

### TABLE VII-19-C.—SUMMARY OF COMPLIANCE COSTS—INITIAL COSTS

<table>
<thead>
<tr>
<th>Industry</th>
<th>Annual cost by type of ownership</th>
<th>Total annual costs</th>
<th>Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Private</td>
<td>Federal</td>
<td>State/loc.</td>
</tr>
<tr>
<td>Offices of physicians</td>
<td>$16,691,041</td>
<td>29,250,137</td>
<td>0</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>8,838,242</td>
<td>15,547,175</td>
<td>0</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>3,955,402</td>
<td>31,205,142</td>
<td>0</td>
</tr>
<tr>
<td>Hospitals</td>
<td>2,002,070</td>
<td>87,644,114</td>
<td>0</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>1,134,629</td>
<td>1,672,492</td>
<td>0</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>2,824,054</td>
<td>15,140,174</td>
<td>383,262</td>
</tr>
<tr>
<td>Blood/plasma/tissue centers</td>
<td>60,829</td>
<td>900,844</td>
<td>62,456</td>
</tr>
<tr>
<td>Residential care</td>
<td>3,821,528</td>
<td>2,320,157</td>
<td>107,669</td>
</tr>
<tr>
<td>Personal services</td>
<td>152,295</td>
<td>432,916</td>
<td>1,129,000</td>
</tr>
<tr>
<td>Funeral services</td>
<td>1,400,345</td>
<td>1,657,855</td>
<td>34,069</td>
</tr>
<tr>
<td>Research labs</td>
<td>199,684</td>
<td>138,865</td>
<td>812,266</td>
</tr>
<tr>
<td>Fire &amp; rescue</td>
<td>34,559</td>
<td>884,076</td>
<td>0</td>
</tr>
<tr>
<td>Corrections</td>
<td>217,062</td>
<td>54,586,738</td>
<td>0</td>
</tr>
<tr>
<td>Police</td>
<td>577,313</td>
<td>1,573,951</td>
<td>0</td>
</tr>
</tbody>
</table>
### Table VII-19-C.—Summary of Compliance Costs—Initial Costs—Continued

<table>
<thead>
<tr>
<th>Industry</th>
<th>Infection control plan</th>
<th>Vaccination/post exposure follow-up</th>
<th>Training</th>
<th>Housekeeping</th>
<th>Recordkeeping</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health units in industry</td>
<td>20,622,316</td>
<td>9,064,197</td>
<td>923,299</td>
<td>304,081</td>
<td>507,830</td>
<td>31,441,723</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>276,050</td>
<td>113,880</td>
<td>15,497</td>
<td>0</td>
<td>3,503</td>
<td>409,909</td>
</tr>
<tr>
<td>Total</td>
<td>20,898,366</td>
<td>9,278,077</td>
<td>938,796</td>
<td>304,081</td>
<td>511,333</td>
<td>31,851,629</td>
</tr>
</tbody>
</table>

*Includes $59,015 for signs.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

### Table VII-19-D.—Summary of Compliance Costs—Recurring Costs

<table>
<thead>
<tr>
<th>Industry</th>
<th>PPE</th>
<th>Vaccination/post exposure follow-up</th>
<th>Training</th>
<th>Housekeeping</th>
<th>Recordkeeping</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office of physicians</td>
<td>$36,594,622</td>
<td>$7,171,473</td>
<td>$53,461,639</td>
<td>$41,418,796</td>
<td>$364,646</td>
<td>$139,011,177</td>
</tr>
<tr>
<td>Office of dentists</td>
<td>181,765,977</td>
<td>3,081,289</td>
<td>10,800,131</td>
<td>27,145,148</td>
<td>1,512,509</td>
<td>418,988,605</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>60,627,753</td>
<td>11,144,498</td>
<td>9,182,353</td>
<td>27,145,148</td>
<td>1,671,414</td>
<td>117,742,689</td>
</tr>
<tr>
<td>Hospitals</td>
<td>30,338,514</td>
<td>18,533,346</td>
<td>30,937,388</td>
<td>38,337,002</td>
<td>1,569,104</td>
<td>179,715,953</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>1,250,981</td>
<td>1,487,519</td>
<td>1,339,543</td>
<td>1,512,509</td>
<td>40,223</td>
<td>3,628,775</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>17,961,080</td>
<td>2,657,894</td>
<td>5,577,474</td>
<td>7,465,886</td>
<td>31,455</td>
<td>43,994,600</td>
</tr>
<tr>
<td>Blood/plasma/tissue centers</td>
<td>6,044,858</td>
<td>146,905</td>
<td>842,874</td>
<td>1,671,414</td>
<td>14,255</td>
<td>8,720,306</td>
</tr>
<tr>
<td>Residential care</td>
<td>7,347,071</td>
<td>1,066,699</td>
<td>1,870,840</td>
<td>9,731,649</td>
<td>120,037</td>
<td>12,610,227</td>
</tr>
<tr>
<td>Personal services</td>
<td>0</td>
<td>1,596,511</td>
<td>8,377,986</td>
<td>0</td>
<td>370,368</td>
<td>10,328,865</td>
</tr>
<tr>
<td>Funeral services</td>
<td>0</td>
<td>231,656</td>
<td>817,280</td>
<td>1,553,772</td>
<td>0</td>
<td>3,048,540</td>
</tr>
<tr>
<td>Research labs</td>
<td>4,663,091</td>
<td>1,553,772</td>
<td>1,865,468</td>
<td>1,537,020</td>
<td>184,004</td>
<td>9,246,027</td>
</tr>
<tr>
<td>Fire and rescue</td>
<td>1,368,577</td>
<td>1,249,020</td>
<td>715,553</td>
<td>457,620</td>
<td>3,732,075</td>
<td>1,737,417</td>
</tr>
<tr>
<td>Corrections</td>
<td>98,861</td>
<td>766,134</td>
<td>1,108,612</td>
<td>1,637,318</td>
<td>91,153</td>
<td>3,372,075</td>
</tr>
<tr>
<td>Police</td>
<td>614,121</td>
<td>385,341</td>
<td>2,042,854</td>
<td>196,360</td>
<td>82,710</td>
<td>3,504,387</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>2,550,640</td>
<td>3,268,626</td>
<td>31,300,520</td>
<td>1,523,176</td>
<td>231,748</td>
<td>39,904,779</td>
</tr>
<tr>
<td>Medical equipment repair</td>
<td>271,255</td>
<td>30,392</td>
<td>23,169</td>
<td>0</td>
<td>3,503</td>
<td>333,453</td>
</tr>
<tr>
<td>Total</td>
<td>400,717,716</td>
<td>53,361,087</td>
<td>160,510,282</td>
<td>177,998,957</td>
<td>4,370,253</td>
<td>786,960,870</td>
</tr>
</tbody>
</table>

*Includes $2,573 for signs.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Total annual incremental costs for the proposed regulation appear in Tables VII-19-A and VII-19-B. Total costs are expected to be $282 million. It is estimated that offices of dentists will incur the largest share of these costs at $224 million. Medical equipment repair establishments will bear the smallest share, $2,573 for signs. The average cost per facility will be $3,397, ranging from $742 per facility for the medical equipment repair sector to $33,035 per facility for hospitals. It is estimated that state and local governments will bear about 3 percent of the costs of the proposed regulation while federally administered facilities will bear about 8 percent. Estimates of average costs per facility for the medical equipment repair sector to $33,035 per facility for hospitals. It is estimated that state and local governments will bear about 3 percent of the costs of the proposed regulation while federally administered facilities will bear about 8 percent of the costs of the proposed regulation while federally administered facilities will bear about 3 percent. The costs of adequate PPE are expected to amount to almost one-half of total compliance costs.

Tables VII-19-C and VII-19-D provide summaries by sector of initial costs and recurring costs, respectively.

**Cost Savings.** As an offset to these costs, there are several areas of potential cost savings. First, cost savings attributable to reduced rates of nosocomial infections are likely after implementation of the OSHA rule. JFA reports that average direct charges for nosocomial infections in the U.S. may be greater than $2.5 billion per year [Ex. 13, p. H-47]. Though most facilities have certainly instituted some kind of infection control program, few are estimated to be at 100% compliance with OSHA’s proposed rule. Most facilities, therefore, should realize some reduction in costs attributable to nosocomial infections. Other evidence in the record indicates that other cost savings will be realized. In one hospital, the cost to the hospital per needlestick is estimated to be $110 [Ex. 6-160]. One commenter felt that reducing needlesticks by 40% would greatly reduce the employee health costs of such injuries which are about $300 per employee [Ex. 11-181, p. 4].

**F. Economic Impacts.** Estimates of the economic impact of the proposed rule are based on the cost figures presented above and on information contained in the public record. Impacts were computed at the industry level and are summarized in Table VII-20. The financial information appearing in columns one and two of the table was obtained from the sources described earlier in the Industry Profile section of this Preliminary Regulatory Impact Analysis. As shown in the table, compliance costs as a percent of profits range up to 12.1%, and 11%, respectively, for firms providing health care personnel services, and dentist offices.

The degree to which affected firms will either incur or shift regulatory burdens depends largely on the competitive environment in which the firms operate and on the price elasticity of demand for the firms’ products. Where the products offered are not very sensitive to price, affected firms can successfully raise prices to offset increased costs. This description characterizes many health care services because consumers (patients) are frequently given little choice in medical decisions and are partially insulated from price increases by the health care financing system. Although recent cost-containment policies tend to moderate these institutional factors, OSHA believes that many of the establishments affected by this standard will eventually pass through a substantial portion of the cost increases to consumers of health care, government units, and third party payers [Ex. 13, p. IV-5]. Based on these data, OSHA preliminarily concludes that no industry sector will experience severe economic disruption due to the impact of the proposed rule.
TABLE VII-20.—SUMMARY OF ECONOMIC IMPACTS

<table>
<thead>
<tr>
<th>Industry</th>
<th>Revenue/ cost/ ($ million)</th>
<th>Profits 1 ($ million)</th>
<th>Annual costs ($ million)</th>
<th>Costs/ revenue (%)</th>
<th>Costs/ profits 1 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offices of physicians</td>
<td>92,000</td>
<td>6,600</td>
<td>148.59</td>
<td>0.161</td>
<td>2.169</td>
</tr>
<tr>
<td>Offices of dentists</td>
<td>25,700</td>
<td>57,500</td>
<td>223.57</td>
<td>0.870</td>
<td>11.013</td>
</tr>
<tr>
<td>Nursing homes</td>
<td>30,600</td>
<td>5,600</td>
<td>122.98</td>
<td>0.402</td>
<td>2.576</td>
</tr>
<tr>
<td>Hospitals</td>
<td>161,000</td>
<td>7,100</td>
<td>961</td>
<td>9.84</td>
<td>0.39</td>
</tr>
<tr>
<td>Medical/dental labs</td>
<td>7,100</td>
<td>2,030</td>
<td>194.91</td>
<td>0.121</td>
<td>2.01</td>
</tr>
<tr>
<td>Outpatient care</td>
<td>33,750</td>
<td>2,033</td>
<td>33.99</td>
<td>0.114</td>
<td>2.23</td>
</tr>
<tr>
<td>Blood/plasma/issue centers</td>
<td>1,420</td>
<td>N/A</td>
<td>9.08</td>
<td>0.038</td>
<td>N/A</td>
</tr>
<tr>
<td>Residential care</td>
<td>8,700</td>
<td>254</td>
<td>21.64</td>
<td>0.249</td>
<td>5.72</td>
</tr>
<tr>
<td>Personnel services</td>
<td>3,200</td>
<td>96</td>
<td>11.50</td>
<td>0.359</td>
<td>11.97</td>
</tr>
<tr>
<td>Funeral services</td>
<td>3,500</td>
<td>30</td>
<td>2.12</td>
<td>0.029</td>
<td>0.54</td>
</tr>
<tr>
<td>Research labs</td>
<td>10,300</td>
<td>3</td>
<td>13.66</td>
<td>0.133</td>
<td>2.01</td>
</tr>
<tr>
<td>Fire and rescue</td>
<td>4,000</td>
<td>N/A</td>
<td>4.95</td>
<td>0.124</td>
<td>N/A</td>
</tr>
<tr>
<td>Corrections</td>
<td>9,900</td>
<td>N/A</td>
<td>4.52</td>
<td>0.084</td>
<td>N/A</td>
</tr>
<tr>
<td>Police</td>
<td>16,600</td>
<td>92</td>
<td>4.12</td>
<td>0.024</td>
<td>N/A</td>
</tr>
<tr>
<td>Health units in industry</td>
<td>18,700</td>
<td>1,000</td>
<td>0.42</td>
<td>0.002</td>
<td>0.94</td>
</tr>
</tbody>
</table>

1 Profit totals reflect proprietary firms only.
2 Profits exclusive of salary.
3 Profits including salaries.
4 Based on profit margin of ambulatory facilities.
5 Based on profit margin of nursing home sector.
6 Medical equipment supply firms only.
7 Ratio reflects private firms only.
8 Health care budgets not estimated.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Hospitals. As shown in Table VII-20, OSHA estimates that the cost of the OSHA standard at 0.12 percent of hospital revenues and 2.6 percent of hospital profits. According to JFA [Ex. 13], hospital profit margins have deteriorated noticeably since 1984, largely due to Medicare's Prospective Payment System (PPS), which sets a predetermined fee for each Diagnostic Rate Group (DRG). To raise prices for these services, hospitals must rely on organizations, such as Medicare, to approve rate increases. Although the added burden of the OSHA standard may eventually be reflected in higher rates for DRGs (which, in turn, would require an increase in federal Medicare/Medicaid budgets), in the short-term, hospitals will bear the cost increases or pass them on to consumers not covered by DRGs. Hospitals which employ temporary nursing personnel may also experience additional cost increases due to personnel service companies attempting to pass forward compliance costs [see below].

Hospitals are now in a period of consolidation, evidenced by increases in the closing of investor-owned facilities, which accounted for over 43 percent of community hospital closures in 1987, and by accelerated growth in the number of hospitals owned or managed by multi-hospital systems [Prospective Payment Assessment Commission, Report to the Congress, June 1988, pp. 50,51]. Nevertheless, JFA concluded that although the costs of the proposed OSHA standard will increase the financial problems of troubled hospitals, they will not necessarily lead to hospital closures. They noted that rural hospitals, which have the greatest financial problems, often survive because of strong community support, and that the standard's costs are a relatively minor part of the expenditures of larger hospitals.

JFA also calculated that, in 1988, 54% of hospital revenues were provided by government, 36% by private insurers, and only 8% by direct patient outlays [Ex. 13, p. IV-11]. With so much of the cost of hospital care borne by third parties, these price increases would not significantly reduce the long run demand for hospital services. Thus, OSHA expects that the average additional cost of $32,000 per facility might support the current consolidation trend in the hospital sector, but will not substantially alter the general industry structure.

Physicians Offices. Prospective compliance costs are estimated to be 0.16% of physician office revenues and 2.2% of profits. This latter ratio, however, may not be a meaningful indicator of economic feasibility for this sector because most physician offices are owner-managed, and current tax laws provide strong incentives for distributing income as salaries or bonuses. Adjusting this ratio by adding an estimate of average physicians' income to the reported office profit shows that expected compliance costs are only 0.3% of total practitioner's income. Although costs of this magnitude would not bring a marked disruption in this industry even if borne entirely by these employers, this sector will not bear the full cost burden. JFA estimated that under the current reimbursement system, the direct consumer contribution to physicians office receipts is only about 26%, with private insurance and government making up the remainder [Ex. 13, p. IV-11]. Thus, it is probable that physicians will be able to pass through some of the increased costs by raising fees.

Dentists. Dental practices will incur compliance costs averaging almost $2,400 per facility, about 0.67% of revenues and 11% of reported profits. After adjusting this ratio to reflect the average income of dentists, the expected compliance costs amount to 1.2% of the total net income. Several factors have reduced dentist incomes in recent years, including fluoride treated water and better tooth decay prevention and, since the early 1980's, a fall in the number of employees covered by private dental insurance plans. JFA calculates that almost two-thirds of dental revenues are paid by direct consumer outlays [Ex. 13, p. IV-11]. As a result, dentists may be less able than most other health care providers to pass forward the costs of compliance and may suffer some income decline, and some patients may choose to defer routine preventive care.

Nursing Homes. Compliance costs for nursing homes are estimated at about
0.4% of revenue and at 9.3% of profits. These facilities may face the same problem as hospitals in passing forward cost increases because state and federal agencies are developing similar cost control measures. At this time, however, at least some price increases would be expected because approximately half of nursing home revenues are from government and insurance programs. Moreover, future conditions should favor nursing home profits since the demand for beds is expected to rise sharply as the population ages.

Residential Care Facilities.

Compliance costs for residential care facilities average about 0.25% of revenues and 5.8% of profits. Many of these facilities, however, are nonprofit or public institutions. Costs incurred by the nonprofit establishments may or may not be fully passed through depending on financing sources. JFA found that only about one-half of the revenue of these facilities consist of direct consumer payments, so it is likely that some increased rates could be supported. Alternatively, The Hospice Association of America reports that 60% to 100% of hospice funding is derived from donations [Ex. 11-302], and that these facilities would have to absorb a large proportion of the costs of compliance. For the facilities that are publicly owned, additional funds would need to be covered by increases in tax rates or by reduced funding to other government programs.

Other Health Care Facilities. As shown in Table VII-20, compliance costs for the other health care facilities will be less than 1% of revenues. For those sectors where profit data were available, the estimated compliance cost-to-profit ratios for the other affected sectors are below 3%. Although a significant burden within this group may be experienced by some medical and research laboratories, pharmaceutical companies, in which many of the larger laboratories are located, generally have strong profits and favorable expectations for future R&D growth.

Health Units in Industry. The national cost total for health units in other industries is substantial, but the costs for these units are spread over so many industries that the estimated annual cost per facility is only $204. Since health units are typically found in large businesses, these costs will have a negligible impact on market structure. Personnel Services. At this time, however, Compliance costs for personnel firms supplying medical care staff are estimated at 0.36% of related revenue and 12.1% of related profits. The impact on this sector is substantial because of the large number of affected employees per firm who must be provided with training and with medical evaluations. The estimated cost-to-profit ratio may be overstated, however, because it assumes that profits of firms providing health care personnel revenue, similar to profits of firms providing other categories of personnel. JFA noted that some of these firms may attempt to defray costs by giving preference to hiring vaccinated workers [Ex. 13, p. IV-15]. In many areas, however, it is likely that the shortage of nursing personnel will permit these firms to shift compliance costs forward to hospitals.

Non-Health Care Facilities.

Compliance costs for corrections, police, and fire and rescue operations amount to less than 0.2% of the budgets of such organizations. JFA calculates that if these costs were passed on by higher taxes, this would increase the average per capita tax burden by 11 cents [Ex. 13, p. IV-14]. Similarly, the costs of compliance for funeral homes would not disrupt the industry as they are estimated at less than 0.1% of revenues and at about 0.5% of profits. As noted above, facilities administered by state and local governments were estimated to incur about 8 percent of the total costs of compliance and federal facilities were estimated to incur about 3 percent. The total impact on government finances, however, will be greater, as some of the costs passed forward by health care providers will be financed through government programs such as Medicare. Assuming that the percentage of health care costs financed by government programs in 1988 is an approximation of future financing patterns [Ex. 13, p. IV-11], costs to the federal government would be expected to be about $200 million, representing 23.5% of the total costs of the rulemaking, and costs to state and local governments would be expected to be about $125 million, representing 14.7% of the total costs of the rulemaking.

Regulatory Flexibility Analysis.

OSHA finds that the impact of the proposed rule on small businesses will be similar to that found for the affected universe as a whole because the vast majority of businesses affected are small. Table VII-21 lists eleven industry sectors (public services, health units in industry, and blood banks are omitted) and provides estimates reported by JFA [Ex. 13, p. IV-17] of the percentage of firms classified as small (reporting less than $3.5 million in revenue) and the percentage of total sector revenue earned by those firms.

It is evident from the table that for all sectors except hospitals, the high percentage of small firms precludes any significant competitive disadvantage based on size. Thus, for all sectors except hospitals, the impacts developed above will be borne relatively uniformly throughout each respective sector.

As shown in the table, small firms make up about 29% of the hospital sector. These facilities may bear a competitive disadvantage in that small hospitals may have lower operating margins than large hospitals [Ex. 13, p. IV-11]; Prospectvie Payment Assessment Commission, Report to the Congress, June 1988, p. 50, and, thus, cost absorption may not be an option for such facilities. This effect will be offset somewhat as smaller hospitals tend to be located in rural areas where there are few competitors.

OSHA concludes that the impact of the proposed standard on small businesses will not differ significantly from that which will be realized by the affected universe as a whole. Also, no differential impact with regard to establishment size is expected, though, as noted earlier in the discussion of overall impacts, the pace of hospital industry consolidation may be accelerated.

<table>
<thead>
<tr>
<th>SIC</th>
<th>Facility type</th>
<th>Percent of firms with revenue of less than $3.5 million</th>
<th>Percent of revenue from small business</th>
</tr>
</thead>
<tbody>
<tr>
<td>801 6 &amp; 7</td>
<td>Offices of MD's &amp; DO's</td>
<td>99.32</td>
<td>88</td>
</tr>
<tr>
<td>802 Offices of Dentists</td>
<td>99.97</td>
<td>88</td>
<td></td>
</tr>
<tr>
<td>805 Nursing Homes</td>
<td>98.47</td>
<td>48</td>
<td></td>
</tr>
<tr>
<td>806 Hospitals</td>
<td>98.64</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>807 Medical and Dental Labs</td>
<td>98.59</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>808 Outpatient Care</td>
<td>90.02</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>836 Residential Care</td>
<td>98.60</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>7362 Personnel Services</td>
<td>90.54</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td>726 Funeral Services</td>
<td>99.61</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>7591 Research Labs</td>
<td>91.63</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

Source: Jack Faucett Associates.

VIII. Environmental Impact

The provisions of the proposed standard have been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 [42 U.S.C. 4321 et seq.], the Council on Environmental Quality (CEQ) NEPA regulations [40 CFR Part 1500], and OSHA’s DOL NEPA Procedures [29 CFR Part 11]. As a result
of this review, OSHA concludes that no
evidence exists to suggest that the
proposed rule will have a significant
environmental impact.
Evidence in the public record
demonstrates that the volume of waste
handled as infectious will increase
somewhat following promulgation of the
OSHA bloodborne pathogens standard.
This is because not all generators of
infectious waste are currently packaging
all types of infectious waste (as defined
in the standard) in the manner required
by the proposed rule [Ex. 13, Tables II-
29, 30]. (The proposed regulation
requires infectious waste to be packaged
in color coded containers or to bear the
universal symbol for infectious waste).
As generators come into compliance,
infectious waste previously entering the
general waste stream will be shifted into
one of the major treatment options used
for the disposal of infectious waste,
namely incineration or autoclaving. Any
potential environmental impact
associated with the proposed rule would
be realized via one of these disposal
techniques. To the extent that infectious
waste in the general waste stream is
currently handled improperly, the
proposed rule may improve
environmental quality as previously
mishandled infectious waste is
redirected toward preferred disposal
alternatives.

The proposed rule will also increase
the volume of waste entering the general
waste stream. This will be due to the
increase in the use of disposable
personal protective equipment. This
waste will be disposed of principally by
landfill and incineration. OSHA
estimates that an increase in tonnage of
approximately 67,000 tons per year will
be disposed by all sectors. Total U.S.
solid waste generation is about 150
million tons per year [1987 Stat.
Abstract]. Thus, the OSHA proposed
regulation is estimated to increase solid
waste tonnage by less than 0.1 percent.

It should also be noted that OSHA is
aware that the Environmental Protection
Agency will publish an interim final rule
on infectious waste early in 1989. When
published, the rule will be incorporated
into the public record for the bloodborne
pathogens standard.

IX. Summary and Explanation of the
Proposed Standard

OSHA believes that the proposed
requirements set forth in this notice are
those, based on currently available data,
which are necessary and appropriate to
provide adequate protection to
employees exposed to blood and other
potentially infectious materials. In the
development of this proposal, OSHA
has carefully considered the comments
from interested parties given in response
to the Advance Notice of Proposed
Rulemaking. In addition, numerous
guidelines, journal articles, and other information
was accumulated by OSHA since the
initiation of this proceeding have been
taken into consideration in the
development of this proposed standard.

Paragraph (a) Scope and Application

The standard applies to all
occupational exposures to blood and
other potentially infectious materials as
defined in paragraph (b) of this
standard. The risk of infection with
bloodborne pathogens is dependent on
the likelihood of exposure to blood and
other potentially infectious materials
wherever that exposure occurs. Any
exposure incident may result in
infection and subsequent illness. The
hazard affects employees in many
industries and is not dependent on the
type of facility in which an employee
works. By conditioning coverage upon
exposure potential rather than
occupation or industry segment, OSHA
wishes to protect all employees at risk
regardless of their job titles or place of
employment.

Blood has long been recognized as a
potential source of pathogenic
microorganisms that may present a risk
to individuals who are exposed during
the performance of their duties. In 1983,
the CDC published guidelines for
controlling infections in hospitals [Ex. 6-
74]. One section, entitled "Blood and
Body Fluid Precautions," recommended
that certain precautions be taken in
handling the blood and body fluids of
patients who were known or were
suspected of being infected with
bloodborne pathogens. Special
precautions were recommended to be
followed with these patients. The
patients were identified using special
placards, and their blood specimens
were labeled in order to alert employees
who had contact with the specimens.

Under this approach, specimens of
blood from patients whose serological
status was unknown were collected and
analyzed using no special precautions to
protect the employee from exposure.

Although some patients could be
identified as infected with HIV or HBV,
allowing employees to be alerted to the
increased risks present, it soon became
apparent that many infected, with these
reference works were collected and
analyzed, were not known to the healthcare
employee. Patients being treated for
unrelated injuries or illnesses; dental
patients; trauma victims; and blood
donors are all examples of individuals
whose infection status may not be
known and whose blood may present a
risk to the employees who come in
contact with it. The possibility of
undiagnosed infection combined with the
increasing prevalence of HIV and
HBV led many infection control
practitioners to recommend that blood
and certain other body fluids from all
patients be considered potentially
infectious and that rigorous infection
control precautions be taken to
minimize the risk of exposure. This
approach is called "universal blood and
body fluid precautions" or "universal
precautions," and the CDC published
this recommendation in its August 1987
guidelines (Ex. 6-153).

"Who is at risk?" and "When?" was the
subject of many comments to the
record. Information submitted
documented both the occupations at risk
and the specific tasks and procedures
that can result in occupational exposure.
Risks associated with certain
occupations or procedures have also
been singled out by CDC in their
guidelines and were mentioned
repeatedly by the commenters to the
ANPR.

The 1985 CDC guideline
recommending HBV vaccination for
personnel at risk included these
examples of occupational groups having
frequent exposure to blood: medical
technologists; operating room staff;
phlebotomists and I.V. therapy nurses;
surgeons and pathologists; oncology and
dialysis unit staff; emergency room staff;
nursing personnel; and staff physicians.
CDC also cites the need for HBV
vaccination of students in schools of
medicine, dentistry, nursing, laboratory
technology and other allied health
professions. This set of
recommendations also included
healthcare workers based outside
hospitals such as dental professionals,
laboratory and blood bank technicians,
dialysis center staff, emergency medical
technicians and morticians. A brief
discussion follows of some additional
types of employees exposed to
bloodborne pathogens and the places
where they are employed.

Individuals who render emergency
medical services are clearly at risk for
blood exposure incidents. One study has
demonstrated that a high percentage (16%) of
male trauma victims between the ages
of 25 and 34 at an urban hospital were
infected with HIV [Ex. 6-131]. The
comments received from the
International Association of Firefighters
included information about a Norwalk,
Ohio firefighter/paramedic, who became
infected with hepatitis B virus when
responding to an emergency call. The
employee's initial exposure incident
occurred while he was treating the victim of a drug overdose whose wound infected with hepatitis B. A painful, debilitating illness followed and he eventually died of renal and hepatic failure seven years after the initial exposure (Ex. 11-125).

Prehospital care is often rendered in a hostile or uncontrolled environment. Conditions beyond the control of the employee's or volunteer's actions pose risks that can be equally hazardous. The CDC has recently completed a set of guidelines for public health care providers that they believe should be included in OSHA rulemaking. They also stated that the provision of the HBV vaccine would be prohibitively expensive (Ex. 11-54).

Since the risk to these providers of emergency medical services is substantial (ANA Ex. 11-86, AAOHN Ex. 11-111, Int. Assn. of Firefighters Ex. 11-125, Merck Ex.11-165), moreover, CDC has issued guidelines for personnel rendering emergency medical service (Ex. 6-153, 6-189, Ex. 15). On the other hand, the American Ambulance Association stated that although its members are voluntarily following some of the CDC guidelines, the evidence did not show a need for first responders/ambulance transport personnel to be included in OSHA rulemaking. They also stated that the provision of the HBV vaccine would be prohibitively expensive (Ex. 11-54).

Employees who work in clinical or diagnostic laboratories which perform a variety of tests to aid in the diagnosis of disease and the management of treatment are at risk for occupational exposure. Although not all laboratory tasks involve blood or other potentially infectious materials, a relatively high potential for exposure exists for employees who analyze and process these substances. Several organizations and groups have devised procedures for reducing risks in the laboratory and these procedures are part of our record (Ex. 11-159, 11-71, 11-280, 6-153). In addition to the traditional hospital clinical laboratory, employees in other laboratories are at potential risk for exposure as well. These include, but are not limited to, free-standing clinical or diagnostic labs, labs in dentists' or physicians' offices, blood and plasma centers, cemeteries, and laboratories preparing reagents from human blood or blood components.

The housekeeping and laundry workers in healthcare facilities may also be at risk for occupational exposure to bloodborne pathogens. (Ex. 11-18).

Individuals who perform housekeeping duties, particularly in patient care and laboratory areas, are at risk for occupational exposure when they perform certain tasks such as cleaning blood spills and handling infectious wastes. Laundry workers may be exposed to laundry contaminated with blood or to contaminated sharps inadvertently left in the laundry. Most recommendations for minimizing or eliminating these hazards focus on limiting the risk by minimizing handling of soiled laundry. This advice not only reduces the likelihood of skin contact with blood contaminated laundry but also reduces the likelihood of a puncture wound from a needle or other sharp object.

Dentists, dental hygienists, other dental professionals are continually exposed to blood and bloody saliva during almost all dental procedures. Because saliva in dental procedures is so likely to contain blood, the CDC recommends personal protective equipment to practitioners for all dental procedures (Ex. 6-490). Most commenters who considered this issue agreed these workers are at risk and supported a standard for dental operations (Exs. 11-162, 11-177, 11-327). The American Dental Association did not question the risk but opposed an OSHA standard because they believe dentists are already taking precautions (Ex. 11-43).

The physician's office is commonly the scene of blood collection, treatment of wounds, and other invasive procedures. Physicians, nurses, nurse practitioners, physician assistants and related healthcare workers may be exposed in this setting. The office may also contain a laboratory where occupational exposure may occur as blood is analyzed. Employees who perform these tasks have the same risk as their hospital-based colleagues.

Nursing homes or other long-term care facilities were frequently cited by commenters as places of employment where employees are at risk for blood and body fluid exposure (Exs. 11-86 ANA, 11-74, 11-172). The American Health Care Association, which represents more than 9,000 long-term care facilities and allied health care providers, stated:

[long term health care facilities should be included, [in the standard] but we believe that recognition should be given to the differences in both type of care and population served in long term care facilities as opposed to acute care facilities. (AHCA Ex. 11-27)]

The Service Employees International Union urged OSHA not to exclude nursing homes from the standard:

An exclusion of nursing homes based on their current low AIDS population for inappropriate. Nursing home workers are as likely as other health care workers to be exposed to HBV. They also face other infectious diseases such as TB. Moreover, such a policy would be dangerously short sighted. CDC estimates that more than 1.5 million individuals are today infected with the HIV virus. The growing numbers of AIDS patients together with soaring hospital-based health care costs would make alternative healthcare settings such as nursing homes and respite homes. (SEIU Ex. 11-61)

A hospice is one of several alternative health care programs open to the terminally ill, including terminally ill AIDS patients. Employees provide services to these patients that place the employee at risk for occupational exposure. The Hospice Association of America, representing more than 1700 hospice programs, noted the risk and requested OSHA consider giving employees and their volunteers for inclusion in any mandated infection control program (Ex. 11-202).

Another alternative to hospital care is home health care. The National Association for Home Care (Ex. 11-203) expressed the concern that using "health care facility" to define coverage would lead to misunderstanding and indicated that it is the services being rendered rather than the location of those services is connected to the risk. They listed a number of tasks that home health care providers may be expected to perform including collecting a blood specimen, cleaning and dressing wounds, and managing intrathecal, epidural, venous and arterial shunts and catheters. Employees who perform these tasks are clearly at risk for occupational exposure. In blood banks and plasma centers, the potential for occupational exposure begins with the initial finger stick of the donor and continues until contaminated units are identified and destroyed. The blood and blood products in these facilities are regulated by the Food and Drug Administration (FDA), and all plasma and blood collection facilities have extensive written procedures for donor requirements, donor room procedures, and laboratory testing of the blood with blood components (ABRA Ex. 11-71). However, the FDA does not set standards for the health and safety of the employees.

The American Blood Resources Association (ABRA) has argued that workers in a plasma center are at a reduced risk of exposure to bloodborne pathogens because many plasma donors donate frequently, as often twice a week, and therefore their antibody status is known (Ex. 11-71). Similarly,
the American Red Cross stated that “its healthy blood donor population does not present any increased health risks to its employees and volunteers” (ARC Ex. 11-280). However, despite prescreening, both blood banks and plasma centers have donors who are infected with HIV, HBV, and other bloodborne pathogens including hepatitis C. In any discussion of the risk to employees in the processing centers, it is important to note that these facilities dedicate a substantial amount of their resources to identifying these contaminated units and ensuring that they are not released for distribution or for further manufacture. Employees engaged in the collecting and testing of these units are at risk for exposure.

Another potential source of bloodborne pathogens is human tissue that is removed for laboratory analysis or for transplantation. The American Association of Tissue Banks, representing 800 individual and 100 institutional members, strongly supported the implementation of a standard and recommended including the category “tissue bank personnel” in the coverage (Ex. 11-50).

Although the overwhelming majority of cases of HBV and HIV infections occur in adults, one group of children have a high risk for hepatitis B infection. This group consists of mentally retarded children who are or have been institutionalized. Surveys conducted in large state institutions indicate that the risk of a child contracting hepatitis B in one of these institutions ranges from 50% to 80% with 5% to 20% of those infected becoming hepatitis B carriers (11-165 pp 161). The behavior of these children, including scratching, biting, and self-mutilation, may present a risk to those who teach or otherwise care for them. Mentally retarded adults who are or have been institutionalized also have an increased risk for being infected with HBV. In 1985, the CDC recommended the hepatitis B vaccine for both the clients and the staff of institutions for the mentally retarded (Ex. 6-199).

Many commenters made the point that healthcare is also being provided in school health clinics, in states without OSHA approved state plans, see section II—Legal Authority.)

For example:

Mortuary workers are potentially exposed to large quantities of blood during the preparation of cadavers; there is also potential for certain abrasions (SEIU Ex. 11-165).

Embalmers constitute a group of long-ignored non-hospital based health care workers. During the embalming procedure they often come into contact with large amounts of non-anticoagulated blood as the vascular system is drained. Depending on the cause of death and whether an autopsy has been performed, they may be required to handle various body parts and tissues, as well as to make numerous incisions and subsequently suture the incised tissue. These procedures put them at risk of exposure. (AAOHN Ex. 11-111)

Only one commenter, The National Funeral Home Directors, questioned whether there was a significant risk of occupational exposure to HIV and HBV in the industry. Nevertheless, they stated that “Funeral directors are not taking precautions regarding known HBV and HIV cases” (NFDA 11-280).

Several commenters pointed out the potential risk to employees who service or repair medical instruments or other types of equipment that may be contaminated with blood or body fluids such as dialysis pumps, pacemakers, liquid chromatographs, and centrifuges (Exs. 11-3, 11-43, 11-97, 11-282). These devices are often contaminated both externally and internally (Ex. 11-43 ADA, 11-7 YSI). An occupational exposure may occur when the equipment is serviced on site (Ex. 11-282) or at the factory or service center prior to decontamination (Ex. 11-7).

Other employees who may be exposed to blood and other potentially infectious materials include firefighters, law enforcement personnel and corrections officers. These employees would be covered under the proposed standard if they have occupational exposure to blood or other potentially infectious materials and if they are employed by the private sector, the federal government, or a state or local government in a state that has an OSHA approved state plan. Employees of state and local governments, including those employed in public hospitals and health clinics, in states without OSHA approved state occupational safety and health plans are not covered by OSHA regulations. (For more information on states and territories with OSHA state plans, see section II—Legal Authority.)

Legislation, regulations, or standards exist regarding the potential for exposure to bloodborne pathogens in these other settings, including the potential for a hostile or criminal act.

Many commenters urged OSHA to include firefighters and law enforcement personnel, who they considered to be at increased risk. (Exs. 11-86 ANA, 11-15 AFSCME, 11-74 NY State Dept. of Health, 11-111 AAOHN, 11-165 Mensk, 11-125 Int'l Ass'n. of Firefighters). When these individuals act as emergency first responders their risk is similar to that discussed earlier for emergency medical services. In addition, the potential for a hostile or uncontrolled environment at a fire or crime scene mandates special procedures in devising an adequate program of protection. The combination of broken glass, jagged metal and blood may present a hazard to the public safety officer who is attempting to extricate the victim of a vehicle.
accident. Even after the victim has been removed from the scene, the employee may have to remain in a blood contaminated environment while the investigation and cleanup continues. For law enforcement officers, weapons (including knives, ice picks and razor blades) and drug paraphernalia (including needles and syringes) may have to be collected as evidence. Also, facilities for personal protection may be inadequate or lacking altogether.

OSHA requests specific comments on the protection of employees in the public sector and any circumstances that may be unique to these individuals. One example would be the need to protect the hands from both blood exposure and from cuts by broken glass and jagged metal during the extrication of a victim from an automobile accident. There are a number of circumstances that place corrections officers at risk of exposure. Some examples are body cavity searches and exposure as a result of the violent behavior of the inmates, a group with a high prevalence because of past and present high risk behavior, for example, intravenous drug use.

OSHA's preliminary conclusion is that all employees who have occupational exposure to blood or other potentially infectious materials [as defined in paragraph (b) of the standard] as the result of performing their duties are at risk for infection by bloodborne pathogens. This risk has been most thoroughly documented in healthcare facilities such as hospitals; however, the risk is not confined to hospitals but is present whenever blood or other potentially infectious materials are present. Exposures do occur in a number of industries outside the healthcare industry and to employees who are not necessarily engaged in the direct delivery of healthcare (e.g. medical equipment repair). Therefore, the scope of the standard includes occupational activities that occur both in healthcare and non-healthcare facilities and in permanent and temporary worksites. Examples of health care facilities include, but are not limited to: hospitals, clinics, dentist's and physicians' offices, blood banks and plasma centers, occupational health clinics, nursing long term care) homes, hospices, urgent care centers, clinical laboratories, mortuaries and funeral homes, and institutions for the mentally retarded. Examples of non-healthcare operations include, but are not limited to the service and repair of equipment, infections waste disposal, virus research laboratories and production facilities, and correctional institutions. In addition, examples of mobile (temporary) operations where there may be occupational exposure to blood and other potentially infectious materials include mobile blood banks, crime scenes, and scenes of accidents or other trauma.

OSHA believes that under the proposed scope each employee who has occupational exposure to blood or other potentially infectious materials will be provided the necessary protection afforded by the proposed standard. The Agency requests comment on the breadth of the scope and application of the standard.

Paragraph (b) Definitions

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health or a designated representative of the Assistant Secretary.

"Blood" is defined in this standard as human whole blood; human blood components such as plasma or platelets; and human blood products such as clotting factors.

"Bloodborne Pathogens" means pathogenic microorganisms that are present in human blood and that can infect and cause disease in persons who are exposed to blood on other potentially infectious materials containing these pathogens. In addition to hepatitis B virus (HBV), human immunodeficiency virus (HIV), and non-A, non-B hepatitis virus(es), further examples of such microorganisms include, but are not limited to, the pathogens which cause syphilis, malaria, viral hemorrhagic fever, and babesiosis.

"Clinical Laboratory" is defined as a workplace where diagnostic procedures or other screening procedures are performed on blood or other potentially infectious materials. These laboratories may be located within hospitals and clinics, in medical or dental offices, or may be free-standing facilities. Laboratories that perform antibody and antigen screening, such as laboratories in blood and plasma centers, are also considered "clinical laboratories".

"Director" means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or a designated representative of the Director.

"Disinfect" is defined, for the purpose of this standard, as a procedure which inactivates virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g. bacterial endospores) on inanimate objects. This definition is identical to that found in Chapter 13 of the Manual of Clinical Microbiology of the American Society for Microbiology. (Ex. 6–343)

"Engineering Controls" are defined as controls that isolate or remove a hazard from a workplace. Biosafety cabinets are examples of engineering controls since they not only remove air contaminants through a local exhaust system but provide the added protection of confining the contaminant within an enclosed cabinet thereby isolating it from the worker. Other examples of engineering controls are sharps disposal containers which are designed to contain sharps, such as needles or other sharps from employees and plexiglass shields on hematomas to prevent blood spattering into the operator's face during tube segmentation.

"Exposure Incident" means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties. Examples of an exposure incident include blood spattering into the eyes or splashing into the mouth or an injury involving a blood-contaminated needle.

"Infectious Waste" incorporates those items about which there is some agreement of expert opinion that they may present an exposure risk. In July of 1988, the Office of Technology Assessment (OTA) conducted a workshop with hospital, regulatory, and environmental experts at which the status of medical waste management nationwide was discussed. The background paper emanating from that meeting, Issues in Medical Waste Management notes that Dr. Nelson Slavik states in his report on the proceedings of the EPA meeting of experts on infectious wastes held in November 1987:

Not withstanding the risk perceptions and anxieties associated with the fear of contracting AIDS, those categories of infectious wastes that possess the greatest potential to transmit disease are contaminated sharps, human blood and blood products, pathological wastes (primarily body fluids), and laboratory wastes (Slavik, 1987).

The paper goes on to say that since these wastes are consistently recognized as presenting a potential hazard of either disease association or accidental injection, proper handling and disposal are warranted. (Ex. 6–339). Therefore, OSHA has defined "Infectious Waste", to be blood and blood products, contaminated sharps, pathological wastes, and microbiological wastes.

"Occupational exposure" is one of the key terms upon which this proposed standard rests. It contains the criteria
which trigger application of the provisions of the proposed standard. As proposed, occupational exposure is:

"reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties. This definition excludes incidental exposure that may take place on the job, and that are neither reasonably nor routinely expected and that the worker is not required to incur in the normal course of employment."

Actual contact would be expected during an autopsy or surgery. In these cases, the blood or other potentially infectious materials come in direct contact with the employee's skin, gloves or other protective clothing. Even though actual exposures may not occur, reasonably anticipated exposures occur in procedures where blood or other potentially infectious materials are an integral part of the task being performed but the procedure does not always result in actual contact. Examples of potential contacts include phlebotomy and changing a surgical dressing.

The occupational exposure must be reasonably anticipated. For example, the employer would reasonably anticipate that exposure to blood either may occur or will occur when an employee is performing dentistry and certain surgical, medical, or laboratory procedures. On the other hand, the employer would not reasonably anticipate that exposure to blood would occur when an employee is processing insurance claims in an office setting.

As indicated these are exposures that the employee is required to incur in the performance of the employee's duties. There are many examples of employees whose jobs require them to come into contact with blood or other potentially infectious materials—most physicians, nurses, dentists, and embalmers. An example of an exposure that an employee is T3not required to incur (i.e., an incidental exposure) happens when an employee takes it upon himself or herself to help another employee, a "Good Samaritan Act." For example, one employee may assist another employee who has a nosebleed or who is bleeding as the result of a fall. This would not be considered an occupational exposure unless the employee who provides assistance is a member of a first aid team or is otherwise expected to render assistance as one of his or her duties. Under the latter circumstance, the exposure would be considered occupational. OSHA seeks comment on whether this definition includes all situations that should be considered occupational exposures.

"Other Potentially Infectious Materials" consists of three primary categories of material which have the potential to transmit bloodborne pathogens. OSHA has used the term "potentially" to acknowledge that body fluids and tissues may or may not contain bloodborne pathogens. However, the provisions of the proposed standard must be followed in any case. Under this definition OSHA has included the body fluids specified by the CDC in their June 1988 update of guidelines to healthcare workers (Ex. 6-316). The fluids covered by this definition are: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, saliva in dental procedures, and any other body fluid that is visibly contaminated with blood. Semen and vaginal fluid have been shown to transmit HIV and HBV. In support of utilizing universal precautions when contacting other fluids, CDC states:

Universal precautions also apply to tissues and to the following fluids: cerebrospinal fluid (CSF), synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. The risk of transmission of HIV and HBV from these fluids is unknown. Epidemiologic studies in the health-care and community setting are currently inadequate to assess the potential risk to health-care workers from occupational exposures to them. However, HIV has been isolated from CSF, synovial, and amniotic fluid, and HBsAg has been detected in synovial fluid, amniotic fluid and peritoneal fluid. One case of HIV transmission was reported after a percutaneous exposure to bloody pleural fluid obtained by needle aspiration (12). Whereas aseptic procedures used to obtain these fluids for diagnostic or therapeutic purposes protect health workers from skin exposures, they cannot prevent penetrating injuries due to contaminated needles or other sharp instruments. (Ex. 6-316)

While universal precautions do not generally apply to saliva, exception is made in the case of saliva in dentistry. Addressing this situation, the CDC states:

Special precautions, however, are recommended for dentistry. Occupationally acquired infection in dental workers has been documented, and two possible cases of occupationally acquired HIV infection involving dentists have been reported. During dental procedures, contamination of saliva with blood is predictable, trauma to health-care workers' hands is common, and blood splattering may occur. Infection control precautions for dentistry minimize the potential for nonintact skin and mucous membrane contact of dental health-care workers to blood-contaminated saliva of patients (Ex. 6-316).

The CDC guidelines for public safety officers state:

The unpredictable and emergent nature of exposures encountered by emergency and public-safety workers make differentiation between hazardous body fluids and those which are not hazardous very difficult and often impossible. For example, poor lighting may limit the worker's ability to detect visible blood in vomitus or feces. Therefore, when emergency medical and public-safety workers encounter body fluids under uncontrolled, emergency circumstances in which differentiation between fluid types is difficult, if not impossible, they should treat all body fluids as potentially hazardous.

OSHA seeks comment on whether the proposed definition of "other potentially infectious materials," should be amended to make it consistent with the guidelines.

The second category of "other potentially infectious materials" is any unixed tissue or organs from a human (living or dead). These pose a risk because they may be contaminated with bloodborne pathogens. One example is human bone which has transmitted HIV infection as the result of transplantation (Ex. 6-357). In the same document, CDC also notes reported transmission of HIV through "transplantation of kidney, liver, heart, pancreas, possibly by skin, and by artificial insemination.* * *". Although tissues and organs may contain blood and body fluids, which may be the reason for the transmission hazard, they are not in reality "fluids". Therefore, to avoid confusion OSHA has listed them as a separate category. Since casual contact, including touching and hugging, does not pose a risk of transmission, intact skin is not considered to be "other potentially infectious materials."

The third group under "other potentially infectious materials" relates to the culture and propagation of HIV and HBV in laboratory cultures and experimental animals. The group contains HIV- or HBV-containing cell or tissue cultures, organ cultures, and culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV. This definition applies to research activities and to production activities where concentrations of virus can be expected to exceed that in blood.

The Case Reports Section of HIV Health Effects in this document discusses in detail the infection of two workers that resulted from occupational exposure to high concentrations of HIV virus in a production facility.
"Parenteral" exposure is exposure which occurs through a break in the skin barrier. Examples of parenteral exposure include self-inoculation through an accidental needlestick or a cut with HIV-contaminated glass that may occur when a laboratory technician is picking up a broken centrifuge tube that contained an HIV culture.

"Patient" means any individual (living or deceased) whose blood or other potentially infectious materials may be a source of exposure to the employee. This term includes a wide spectrum of people when one considers both the need for universal precautions and the multitude of healthcare and non-healthcare settings in which occupational exposure may occur. Examples of such individuals include, but are not limited to, hospital and clinic patients; clients of drug and alcohol treatment facilities; accident, gunshot, stabbing, or other trauma victims; residents of nursing homes or hospices; individuals who donate or sell blood, plasma, or blood components; and human remains prior to embalming.

"Personal Protective Equipment" is specialized clothing or equipment worn by an individual to protect him/her from a hazard. For the purposes of this standard, this term includes, but is not limited to, equipment such as (a) gloves; (b) gowns, fluid-proof aprons, laboratory coats, head and foot coverings; (c) face shields, protective eyewear and masks; and (d) mouthpieces, resuscitation bags, or other ventilation devices. 

"Production Facility" and "Research Laboratory" are derived from CDC's 1988 Agent Summary Statement for Human Immunodeficiency Virus. (Ex. 6-312) "Production Facility" means a facility engaged in activities such as production of industrial-scale, large-volume quantities of HIV or HBV or high concentration and manipulation of concentrated HIV or HBV. In comparison, "Research Laboratory" is defined as a facility engaged in activities such as producing research-laboratory-scale amounts of HIV or HBV, manipulating concentrated virus preparations, and conducting procedures that may produce aerosols or droplets.

"Sharps" means any object that can penetrate the skin including, but not limited to, needles, lancets, scalpels, and broken capillary tubes.

"Sterilization" follows the American Society of Microbiology's definition for the term to mean a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores. (Ex. 6-343).

"Universal Precautions" is a method of infection control in which all human blood and certain other potentially infectious materials are considered infectious for HIV, HBV, and other bloodborne pathogens. In reference to the basis for utilization of universal precautions, the CDC states:

Since medical history and examination cannot reliably identify all patients infected with HIV or other bloodborne pathogens, blood and body-fluid precautions should be consistently used for all patients. This approach, previously recommended by CDC, and referred to as "universal blood and body-fluid precautions" or "universal precautions" should be used in the care of all patients, especially including those in emergency-care settings in which the risk of blood exposure is increased and the infection status of the patient is usually unknown. (Ex. 6-133).

Universal precautions may be a part of a broader program of infection control, such as body substance isolation (BSI), designed to prevent the transmission of many other pathogens in addition to bloodborne pathogens.

"Work Practice Controls" are controls that reduce the likelihood of exposure by altering the manner in which a task is performed. As they relate to this standard, examples of some work practice controls include (1) adherence to the practice of universal precautions in situations of possible exposure; (2) prohibiting the shearing, bending, or breaking of needles and other sharps and not permitting recapping or manipulation of needles or other sharps by hand; and (3) prohibiting pipetting or suctioning by mouth. In each of these instances, the possibility for exposure to blood or other potentially infectious materials has been eliminated or minimized simply by altering the way in which the employee performs the task.

Paragraph (c) Infection Control

Employees incur risk each time they are exposed to bloodborne pathogens. Any exposure incident may result in infection and subsequent illness. Since it is possible to become infected from a single exposure incident, exposure incidents must be prevented whenever possible. It is the goal of the proposed standard to reduce significant risk by minimizing or eliminating exposure incidents.

In order to determine what measures can be taken to minimize or eliminate exposure incidents, the employer must know which tasks or procedures involve occupational exposure. Therefore paragraph (c)(1)(iii) requires each employer having employees with occupational exposures to identify and document the tasks and procedures where occupational exposures may occur.

The requirement to perform an exposure determination is similar to the approach taken by the DOL/HHS Joint Advisory Notice (JAN) (52 FR 43183, October 30, 1987) which calls for identifying three categories of tasks: those with actual blood exposure (Category I), those with no blood exposure (Category III), and Category II tasks which, by themselves, entail no blood exposure, though the individual assigned to the task may be called upon to perform an unplanned Category I task. For example, a nurse completing medical records in an emergency room would be expected to immediately assist in the care of a bleeding accident victim who arrives in the emergency room.

Therefore, while the paperwork task has no inherent blood exposure, the patient's arrival requires the nurse to perform a Category I task. In addition to categorizing tasks, the JAN calls for development of Standard Operating Procedures (SOPs) for each Category I and II task. These SOPs include mandatory work practices and protective equipment for each task.

In the proposed standard, the employer is responsible only for identifying the tasks equivalent to Category I tasks, and is not required to develop SOPs for all tasks equivalent to Categories I and II. Nevertheless, while SOPs are not required by the proposed standard, some employers may find their development beneficial both for use in training employees in performing routine tasks and procedures in a manner that minimizes or eliminates occupational exposure and as a reference for unusual or infrequently conducted tasks.

The second part of the exposure determination is the identification and the documentation of the positions whose duties include the tasks identified above. This is necessary in order to assure that the employees who hold these positions are included in the training programs, are provided with personal protective equipment, and where appropriate, are provided with post-exposure follow-up and are included in the HBV vaccination program.

Paragraph (c)(1)(iii) requires the exposure determination be made without taking into consideration the use of personal protective clothing or equipment. In other words, a task or procedure that would result in occupational exposure if the employee were not wearing personal protective equipment, must be identified and documented by the employer for
paragraph (e)(1)(i). The reason for this is that several conditions must be met for personal protective equipment to effectively lessen exposures. First, the employee must be trained to use the equipment properly. Second, the personal protective equipment must be used each time the task is performed. Third, the equipment must be appropriate for the task. Fourth, it must be free of physical flaws that could compromise safety. If even one of these conditions is not fully met, protection cannot be assured. For example, if blood covered gloves are not removed correctly, the hands may become contaminated. If utility gloves are torn or cracked, they will not provide protection. Therefore, these tasks need to be included in the exposure determination so that the workers who perform them will receive training.

The Infection Control Plan that would be required by paragraph (c)(2) is a key provision of the proposed standard. It must contain the exposure determination discussed above. In addition, it must state when and how the employer will implement the other provisions of the standard in a manner appropriate to the circumstances in the employer’s workplace. An annotated copy of the final standard would be sufficient to meet this requirement. The requirement is in performance language, so that each employer can structure the plan to cover the circumstances in the employer’s workplace. The time frame for completion of the Infection Control Plan would be within 120 days of the effective date of the standard [see paragraph (j)(2)].

The Infection Control Plan would have to be reviewed and updated to reflect significant changes in tasks or procedures. The purpose of this proposed requirement would be to assure that all new tasks and procedures are evaluated in order to determine whether they will result in occupational exposure. The employer would also have to amend the Infection Control Plan when there are significant changes in tasks or procedures. For example, if a medical center plans to open an HIV research laboratory where none existed before, then the Infection Control Plan would have to be amended to include the provisions specified by paragraph (e).

**Paragraph (d) Methods of Compliance**

It is generally acknowledged that protection of the employee is most effectively attained by elimination or minimization of the hazard at its source, which engineering controls and work practices are both designed to do. Industrial hygiene doctrine also teaches that control methods which depend upon the vagaries of human behavior are inherently less reliable than well-maintained mechanical methods. For these reasons, OSHA has preferred engineering and work practice controls and required they be used where feasible. Nevertheless, OSHA recognizes that in some situations neither of these control methods is feasible and in these circumstances employee protection must be achieved through the use of personal protective equipment. In other situations, personal protective equipment may have to be utilized in conjunction with engineering controls and/or work practices to obtain a further reduction in employee exposure.

The need to implement and comply with infection control procedures is recognized by nearly all the commenters to the ANPR and is illustrated by the epidemiologic studies on HIV. The CDC has concluded that case reports of healthcare workers who seroconverted to HIV following parenteral, mucous membrane or non-intact skin exposure to blood or concentrated virus provide strong evidence for the transmission of HIV from patients to healthcare workers and that infection control practices, emphasizing universal precautions, need to be implemented and strictly followed (Ex. 6-365). Marcus and coworkers (Ex. 6-372) and McCray and co-workers (Ex. 4-39) concluded that approximately 37-40% of the exposures in their study cohort would probably not have occurred if the workers had followed recommended infection control procedures. Klein and co-workers (Ex. 6-366) concluded that to minimize the risk of contracting HIV, dental professionals must adhere to recommended infection control procedures. Weiss and co-workers (Ex. 6-167) recommended that laboratories working with HIV and related agents promote continuing educational programs for all employees regarding precautions necessary for working in a laboratory. They concluded that employees must be proficient in and strictly adhere to the recommended infection control procedures and that employee proficiency and compliance with these precautions should be periodically monitored. Gerberding and coworkers (Ex. 6-375) (Ex. 6-383) concluded that although "special infection-control precautions for HIV-infected patients are not required to prevent occupational transmission of HIV * * * it would seem prudent to implement and enforce standard infection-control guidelines designed to reduce exposure to body fluids from all patients, regardless of the probability of HIV infection, to prevent nosocomial transmission of blood-borne pathogens." Henderson and coworkers (Ex. 6-377) (Ex. 6-382) concluded the risk of occupationally acquiring HIV is very small. Kuhl and coworkers (Ex. 6-355) concluded that with the practice of recommended hospital infection control procedures the risk of healthcare workers occupationally contracting HIV infection appears low. Ramsey and coworkers (Ex. 6-373) (See CASE REPORTS, CASE 16) concluded that "almost half of the exposures (41%) were a result of non-compliance with recommended precautions * * * results confirm that needlestick injuries place health-care workers at risk of acquiring HIV-1 infections."

One of the most important methods of compliance is the implementation of "universal precautions" as recommended by CDC. "Universal precautions" requires the employer and employee to assume that all blood, and other potentially infectious materials are, indeed, infectious and must be handled accordingly. The Centers for Disease Control (CDC) bases the rationale of universal precautions on the following:

Since medical history and examination cannot reliably identify all patients with HIV or other blood-borne pathogens, blood and body fluid precautions should be consistently used for all patients. This approach, previously recommended by CDC, and referred to as "universal blood and body-fluid precautions" or "universal precautions"
should be used in the care of all patients, especially including those in emergency-care settings in which the risk of blood exposure is increased and the infection status of the patient is usually unknown. (Ex. 6-153)

This approach is advocated by the majority of the ANPR commenters including the American Hospital Association (Ex. 11-233), the American Dental Association (Ex. 11-43), and the National Committee for Clinical Laboratory Standards (Ex. 11-159).

OSHA agrees that universal precautions is necessary to prevent workers from contacting blood or other materials that may be infectious.

As previously stated, universal precautions is a concept of infection control which, in addition to treating blood and other potentially infectious materials as being infectious, encompasses a variety of associated practices other than medical procedures as such, to prevent occupational exposure such as use of personal protective equipment, disposal of sharps in sharps containers, housekeeping, and so forth. Throughout the Methods of Compliance section, OSHA has taken care to specifically provide flexibility. See, for example, the sections on handwashing (d)(2)(ii), disposable gloves (d)(3)(v)(A), and decontamination (d)(4)(ii)(A).

In addition, paragraph (d)(1) of the proposed standard states: "Universal precautions shall be observed to prevent contact with blood and other potentially infectious materials, unless those precautions would interfere with the proper delivery of healthcare or public safety services, in a particular circumstance, or would create a significant risk to the worker's personal safety."

Since flexibility in following the other practices required under universal precautions is specifically addressed elsewhere in paragraph (d), OSHA expects that the exemption to observing universal precautions stated in the latter portion of paragraph (d)(1), will serve as an exemption to the use of personal protective equipment in appropriate cases and is not intended to provide an excuse for complete non-adherence to the overall concept of universal precautions.

The Agency recognizes that on occasion particular circumstances arise in which the use of personal protective equipment may interfere with the proper delivery of health care or public safety services or create a significant risk to the personal safety of the worker. These "particular circumstances" shall be taken to mean extraordinary situations which are unexpected and threaten the life or safety of the patient or worker.

The following examples illustrate several scenarios to which, OSHA believes, the exemption may apply.

(1) A surgeon's glove tears in the midst of critical surgery?
(2) A sudden change in patient status such as when an apparently stable patient unexpectedly begins to hemorrhage profusely, putting the patient's life in immediate jeopardy?
(3) A firefighter rescues an individual who is not breathing from a burning building and discovers that his/her resuscitation equipment is lost/damaged and he/she must administer CPR; and
(4) A suspect who is bleeding unexpectedly attacks a officer with a knife threatening the safety of the officer and/or co-workers.

The first three scenarios are examples of situations which may be immediately life-threatening to the patient while the latter illustrates circumstances in which the personal safety of the worker could be placed at significant risk. In evaluating each of the above situations it may be judged that the time required to don personal protective equipment is critical to saving the patient's life or preventing significant risk to the worker's personal safety. However, use of the exemption is meant to be limited in extent and time. The employee who takes advantage of this exemption in a particular circumstance must continue to take steps to reduce his or her risk.

Those practices associated with universal precautions which can be used are to be implemented whenever possible. Moreover, as soon as the situation changes as, for example, when a properly-protected co-worker is available to relieve the employee, the criticality of the patient's condition decreases, or the violent patient/prisoner is subdued, the employee is expected to return to use of full universal precautions.

It is the intent of the Agency that the decision not to utilize personal protective equipment in these types of situations rests with the employee, not the employer. Employees must exercise their professional judgment in making such a decision and should be aware that they may be asked to explain the reasons for their course of action. For example, OSHA believes that disregarding use of personal protective equipment because there is concern that the appropriate personal protective equipment may be alarming to the patient or that the size of the population is perceived to be "low risk" are not legitimate reasons. Also, a concern that employees may not be able to properly perform their jobs because, for instance, gloves dull their sense of feeling or goggle become fogged is not considered a legitimate reason to not use such exemption for routine procedures. These issues are dealt with elsewhere in this preamble.

While "interfere with" may be construed to encompass a broad range of intrusions into one's task performance, OSHA intends for this term to be interpreted in the strictest sense, that is, the prevention of proper delivery of healthcare or public safety services. Therefore, the Agency does not feel that concerns about appearance, perceived low-risk, or personal perception of "interferences" are acceptable reasons for not using personal protective equipment.

Some employers may express the concern that gloves, because they do not fit properly, increase their risk of injury. Since the proposed standard requires that personal protective equipment be provided in "appropriate sizes," the employer would be obligated, under paragraph (d)(3)(ii), to provide gloves and other equipment that fit. Therefore, a general concern that the use of gloves, for instance, increases risk to the personal safety of the worker cannot be a basis for an exemption.

It should also be understood that the decision not to use personal protective equipment is to be made by the employee on a case-by-case basis. Also, no work area with the potential for occupational exposure would be exempt from following universal precautions and its associated practices. Therefore, the employer must assure that proper personal protective equipment is readily accessible to employees at all times.

In summary, employees may on occasion find themselves in extraordinary circumstances in which, based upon their professional judgment, they feel that utilizing personal protective equipment will prevent proper delivery of healthcare or public safety services or will create a significant risk to their personal safety. The decision not to use personal protective equipment is to be made by the employee on a case-by-case basis and must be prompted by legitimate and truly extenuating circumstances. In such cases, the employee may temporarily abandon use of personal protective equipment. However, this does not mean that the circumstances surrounding such a decision should not be scrutinized, and it does not relieve the employer of the responsibility to assure that personal protective equipment is readily accessible at all times. The employer shall not discourage adherence to universal precautions or the appropriate use of personal protective equipment.
OSHA seeks comment on whether the exemption from using universal precautions is appropriate, and, if so, is it clearly stated? Are there situations which require employees to suspend universal precautions as a whole or are the situations that require professional judgment limited to times when personal protective equipment cannot be used? Should the exemption be available to all employees or only those in certain professions? Would it be more appropriate to state the exemption under paragraph (d)(3)(ii) “Provision and Use” of personal protective equipment? For example, would the limitations of this exemption be made more clear with the following language:

(3) Personal Protective Equipment

(i) Provision

(ii) Use. The employer shall assure that the employee uses appropriate personal protective equipment unless doing so in a specific instance would, in the professional judgment of the employee, prevent the proper delivery of healthcare or public safety services or pose a greater hazard to the safety of the employee or co-workers.

OSHA believes employees can be fully protected only when the language of the exemption is strictly interpreted to limit the instances in which it applies. Do some of the terms (e.g., “interfere with,” “proper delivery,” “significant risk”) lack precision and clarity? If so, how could the Agency better delineate the particular circumstances? Would substitution of “prevent” for “interfere with” or “greater hazard” for “significant risk” be more easily understood? Is there a generally accepted definition for “proper” delivery of healthcare or public safety services? OSHA seeks comment on whether an exemption is needed, to what situations it should apply, and how it can best be drafted to afford employees the flexibility which may be necessary while assuring adequate protection against occupational exposures.

Engineering and Work Practice Controls. Engineering controls serve to reduce employee exposure in the workplace by either removing the hazard or isolating the worker from exposure. These controls encompass personal protective designs (e.g., self-shielding needles), process or equipment enclosure (e.g., biosafety cabinets), and employee isolation. In general, engineering controls act on the source of the hazard and eliminate or reduce employee exposure without reliance on the employee to take self-protective action. Once implemented, engineering controls protect the employee permanently, subject only, in some cases, to periodic replacement or preventive maintenance. Examples of engineering controls that would protect employees from exposure to bloodborne pathogens include sharps disposal containers, biosafety cabinets, and splashguards, such as might be placed over the segmenting unit of a Hematron to prevent blood spattering into the operator’s face. Relative to this, section (3)(2)(i) of the proposed standard requires that engineering controls be examined and maintained or replaced on a regular schedule to ensure their effectiveness. Regularly scheduled inspections are required to confirm that engineering controls such as protective shields have not been removed or broken; that ventilation systems such as those in biosafety cabinets are operating properly; that filters, sharps disposal containers, and so forth are being replaced on a sufficiently frequent interval; and that any other physical, mechanical, or replacement-dependent controls are functioning as intended. In comparison, work practice controls reduce the likelihood of exposure through alteration of the manner in which a task is performed. While work practice controls also act on the source of the hazard, the protection they provide is based upon employer and employee behavior rather than installation of a physical device such as a protective shield. In many instances these two control methodologies work in tandem as it is often necessary to employ work practice controls to assure effective operation of engineering controls. For example, a sharps disposal container provides no protection if an employee persists in recapping needles by hand and disposing of them in the waste basket. Proper work practices and engineering controls must both be utilized to ensure safe, acceptable sharps disposal. In developing the methods of compliance section for this proposal, OSHA recognized the uniqueness of many of the work environments which have the potential for producing occupational exposures. Since the source of the hazard is frequently a living person or tissue, typical industrial methods of reducing or eliminating the hazard—the source are often not feasible. For example, in an industrial operation a process may be entirely enclosed and operated/monitored by an employee at a remote location. Clearly, this is not possible in patient-care settings, in circumstances of violence in correctional institutions, and so forth. The Agency believes, therefore, that protection of exposures to blood or other potentially infectious materials can require use of a combination of control methods to achieve adequate protection of employees.

Returning to the previous example of using a Hematron (a device for segmenting blood-containing tubing in plasmapheresis centers, blood collection sites, etc.), methods of exposure control could include a plexiglass shield over the segmenting/sealing unit to prevent blood spattering into the operator’s face—an engineering control, positioning of the employee’s face over the shield during operation—a work practice; and use of personal protective equipment such as gloves, a lab coat, and/or other personal protective equipment depending on where blood could spatter onto the employee. In the above example, engineering controls, work practice controls, and personal protective equipment were necessary to provide proper protection. Each control method plays a part in reducing and/or protecting against exposure; however, none of them taken singly can be said to eliminate or significantly lessen the need for other methods of control.

When dealing with primary hazard sources that are often living persons, transplant tissues, and so forth, use of engineering controls may not always be feasible. However, OSHA would like to know about situations where engineering controls alone or in combination with work practices will sufficiently protect workers so that personal protective equipment would not be necessary.

OSHA recognizes that the conditions of exposure to bloodborne pathogens are substantially different from those of exposure to other hazards which OSHA regulates. Considering the primary hazard sources involved in this proposal, it is OSHA’s belief that combinations of controls (varying greatly in task) are best used to prevent exposure incidents. OSHA seeks comment on how the Agency can best assure employers institute the appropriate combinations of controls. In paragraph (d)(2)(ii) OSHA proposes to require employers to assure that employees wash their hands immediately or as soon as possible following activities that may result in exposure. OSHA has recognized that a major precept of infection control is thorough handwashing. A number of commenters supported the requirement that hands be washed immediately or as soon as possible 1) after removal of gloves or protective clothing (Exs. 6-153, 11-71, 11-159, 11-239(d), 11-280), and 2) after hand contact with blood or other potentially infectious materials (Exs. 6-153, 6-318, 11-71, 11-111, 11-159, 11-239(d)). This frequency of handwashing...
needles and other sharp instruments are used. In view of this, the AHA and a number of other commentators recommend that hands be washed upon leaving the work area. While this requirement has not been included in the proposal, OSHA seeks comment as to whether there are instances in which an employee would not be wearing gloves in a work area presenting the potential for hand contamination. Will requiring washing of hands upon leaving the work area serve to reduce contaminant migration and/or better protect employees? Should it be a stated requirement?

With regard to managing and further limiting the possible spread of contamination, OSHA proposes to require that all personal protective equipment be removed immediately upon leaving the work area or as soon as possible if overtly contaminated (Exs. 6-153, 6-338, 11-159, 11-260). The former requirement will prevent migration of contamination beyond the work area to such places as lunchrooms and offices. The latter will limit contact contamination within the work environment and reduce the possibility for contaminant soak-through which would result in contamination of the employee's underlying garments and/or skin.

Placement of the contaminated equipment in an appropriately designated area or container for storage, washing, decontamination, or disposal will help ensure that the potentially contaminated clothing and equipment will only be handled by employees who have been properly trained in the safe handling of this material. One of the greatest hazards to workers is from needles and other sharp objects contaminated with blood or other potentially infectious materials. Of the 25 Case Reports presented in the HIV Health Effects section of this proposal, 15 of the seroconversions are associated with needlestick injuries (Cases 1,2,6,7,9-16,19,22,23). In addition, as stated previously in the hepatitis B Health Effects section, the chance of becoming infected after a single needlestick from a hepatitis B source patient ranges from 7% to 30%. Therefore, handling of needles and sharps must be minimized. The AHA affirmed this hazard in their statement:

As with other blood-borne diseases, the potential for transmission is greatest when needles and other sharp instruments are used in patient care (Ex. 6-75) 

In view of this, the AHA and a number of other commentators recommend that
covering the tube with gauze pad while removing stopper. (Ex. 11-159)

It is the responsibility of the employer to evaluate such tasks and institute the measures necessary to minimize splashing, spraying, and production of aerosols.

In paragraph (d)(2)(viii), OSHA proposes to adopt the good laboratory and infection control practice of prohibiting pipetting or suctioning by mouth. The use of cotton plugs or other barriers does little to reduce the hazards of mouth pipetting. Even a technician who is skilled in mouth pipetting may inadvertently suck blood or other potentially infectious materials into the mouth which could result in bloodborne pathogens coming in contact with the mucous membranes of the mouth as well as any blisters, cuts, abrasions or other lesions in the mouth or on the lips.

Personal Protective Equipment

OSHA’s proposed requirements for personal protective equipment, paragraph (d)(3), have been set to assure adequate protection based upon the type of exposure expected during task performance. In their response to the ANPR, the National Institute for Occupational Safety and Health (NIOSH) stated:

The purpose of personal protective clothing and equipment is to prevent or minimize the entry of materials into the worker’s body. This includes entry via apparent or inapparent skin lesions or entry through the membranes of the eye, nose or mouth. Appropriate protective clothing and equipment should be selected based on the specific work and exposure conditions that will be encountered and the anticipated level of risk. (Ex. 11-167)

This approach to the selection of protective barriers is echoed by CDC in their June 1988 guidelines:

The type of protective barrier(s) should be appropriate for the procedure being performed and the type of exposure anticipated. (Ex. 6-316)

The proposed standard requires the employer to provide personal protective equipment to employees who have the potential for occupational exposure. Examples of such personal protective equipment are gloves, gowns, fluid-proof aprons, laboratory coats, head and foot coverings, face shields, eye protection, masks, and respiratory ventilation devices such as mouthpieces, pocket masks, or resuscitation bags.

While the reasons for providing protective clothing such as gowns, gloves, and face shields should be obvious, some question may arise as to the necessity of emergency ventilation devices. OSHA bases this requirement on the possibility of employee exposure to blood or other potentially infectious materials in the mouth or in fluids that may be expelled by the patient during resuscitation. As little as one cubic centimeter of blood positive containing one hundred million infectious doses of hepatitis B virus (see Hepatitis B Health Effects section). In their August 1987 guidelines, the CDC states:

Although saliva has not been implicated in HIV transmission, to minimize the need for emergency mouth-to-mouth resuscitation, mouthpieces, resuscitation bags, or other ventilation devices should be available for use in areas in which the need for resuscitation is predictable. (Ex. 6-153)

The American Federation of State, County, and Municipal Employees (AFSCME) expressed a similar, but more detailed justification in their comments:

Resuscitation devices should be included with other types of required personal protective equipment, although there is no evidence of transmission of bloodborne pathogens from administering Cardiopulmonary Resuscitation, such transmission remains a theoretical possibility and other pathogens can definitely be transmitted in this way. CDC also recommends the use of such devices in its August 1987 document. Resuscitation devices are very inexpensive, some models well under $10. Affected employees should be trained in the use of such equipment and the equipment needs to be strategically stationed in order to facilitate its use. Prisons, mental health facilities, and public safety occupations are obvious candidates for such equipment. Anywhere a large group of people are housed, or where there is likelihood that emergency assistance may have to be rendered should have resuscitation devices on hand. (Ex. 11-157)

OSHA agrees with CDC and AFSCME on the need to minimize mouth-to-mouth resuscitation, and believes the most effective way to do so is to require ventilation devices be provided for resuscitation.

In addition, the employer shall assure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or issued to employees who may be exposed to blood or other potentially infectious materials during performance of their work duties. Resuscitation bags, pocket masks, mouthpieces, and other ventilation devices must be readily accessible to employees who can reasonably be expected to resuscitate a patient. (Exs. 6-153, 11-71, 11-111, 11-157, 11-159, 11-223(d)). These devices are to be readily accessible for use at sites where the need for emergency resuscitation is likely or issued to employees for use at mobile non-fixed worksites as required by paragraph (d)(3)(ii). It is of great importance that personal protective equipment is easily accessible and of proper size. The consistent use of such items hinges, in part, upon the employee’s motivation and acceptance. If access to the equipment is difficult, its use may be perceived as too time consuming and burdensome. Proper fit of personal protective equipment also plays a major role in its utilization by employees. If it is too large or small it may be uncomfortable or could interfere with proper task performance, resulting in frustration and non-use. Proper employee protection rests upon utilization of this equipment, therefore provision of proper sizes and accessibility must be maintained to ensure and promote their use.

The Agency is aware that use of gloves as a protective barrier is a major part of this proposal’s methods of preventing occupational exposure. In addition, it is known that some employees may exhibit an allergic dermal reaction to the gloves normally provided to workers or the powder they contain. To prevent exacerbation of such allergic dermatitis and thereby permit these individuals to continue working, the proposed standard requires that employers make hypoallergenic gloves readily accessible to those employees who are allergic to the gloves normally provided.

The employer’s responsibility to assure accessible personal protective equipment for employees at non-fixed worksites, such as emergency medical technicians, cannot be over emphasized. Adequate planning and reinventory should assure that the necessary equipment is present on the response vehicle in a portable “kit” or on the employee’s person.

The proposed standard also requires that the employer shall provide for the cleaning, laundering, or disposal of personal protective equipment required by paragraphs (d) and (e). This is to insure that these items remain within the control of the employer and, therefore, will be properly disposed of, cleaned, or laundered consistent with that employer’s infection control program. This will prevent contamination outside of the work area (e.g. non-work areas such as the employee’s home) and insures that only those personnel trained in proper work practices will handle potentially contaminated equipment during cleaning or repair.

In paragraph (d)(3)(iv), the proposed standard requires that the employer repair or replace personal protective equipment required by this standard as
The requirement to repair or replace the protective equipment is needed to insure proper functioning of these items and, thereby, proper employee protection. Moreover, requiring that the employer be responsible for this activity provides further insurance that the items will remain under the control of the employer who will make this a part of his or her infection control program.

OSHA proposes to require that the employer assure that the employee wear gloves whenever the employee has the potential for direct skin contact (of the hand) with blood or other potentially infectious materials, mucous membranes or non-intact skin of patients, and when handling items or surfaces soiled with blood or other potentially infectious materials. Glove use in these situations is associated in whole or in part by a number of factors. The factors and sources including the American Hospital Association (Exs. 6—75, 11—233(d)), the American Dental Association (Ex. 11—43), the National Committee on Clinical Laboratory Standards (Ex. 11—159), the American Red Cross (Ex. 11—260), and the American Blood Resources Association (Ex. 11—71).

Examples of tasks which require the use of gloves include dentistry, surgery, phlebotomy, laboratory analysis of blood or body fluids, clean-up of blood or body fluid spills, and rendering emergency medical assistance to individuals with traumatic injury.

Along with the provisions for glove usage discussed above, certain work practices are necessary concerning when gloves are to be replaced in order to insure adequate protection for the employee and limit contamination, paragraphs (d)(3)(v) (A) and (B).

Disposable gloves must be changed as soon as possible when they are visibly soiled to reduce inadvertent contamination of items throughout the work area such as doorknobs, telephones, computer keyboards, and so forth (Exs. 6—344). Since the glove acts as the primary physical barrier between potentially infectious materials and the employee’s skin, any tear, puncture, or similar defect compromises the integrity of this barrier, dictating replacement to insure maintenance of protection (Exs. 6—153, 11—71, 11—230).

Disposable gloves, often called surgical or examination gloves, shall not be washed or disinfected for re-use. The CDC in its June 24, 1988, Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings (Ex. 6—316) states that disinfecting agents may cause deterioration of the glove material while washing with surfactants could result in “wicking” or enhanced penetration of liquids into the glove via undetected holes, thereby transporting potentially infectious materials into contact with the hand. Utility gloves, often called “rubber” gloves, such as those which may be used for housekeeping chores are of more substantial construction than surgical or examination gloves. OSHA agrees with CDC’s recommendation permitting decontamination and reuse of utility gloves but requires that they be discarded if they are cracked, peeling, discolored, torn, punctured, or exhibit other signs of deterioration. (Ex. 6—319)

Paragraph (d)(3)(vi) of the proposed standard states that masks and eye protection or chin-length face shields shall be worn whenever splashes, spray, splatter, or droplets of blood or other potentially infectious material (e.g., bone chips) may be generated and there is a potential for mucous membrane (eye, nose, mouth) contamination. If protective eyewear is chosen over use of a face shield, the eyewear must be worn in conjunction with a face mask since the aim of this requirement is to provide protection for the eyes, nose, and mouth. A number of commenters expressed support for this requirement (Exs. 6—153, 10, 11—43, 11—71, 11—111, 11—159, 11—233(d), 11—280). For example, the American Hospital Association stated:

The use of protective eyewear, such as goggles in connection with masks, is recommended in situations in which splatter of blood, body secretions, or body fluids is possible. This is particularly recommended in the performance of procedures such as endotracheal intubation, bronchoscopy, or GI endoscopy. Precautions during other procedures should be judged on an individual basis. (Ex. 6—75)

Mucous membrane and skin exposures are recognized routes of transmission of HBV (see the Hepatitis B Health Effects section) and HIV. In fact, the CDC (Ex. 6—109) has documented a phlebotomist’s HIV seroconversion after blood spattered on her face and in her mouth when the top flew off of a 10 ml vacuum tube of blood. The individual lacked other identified risk factors and the case is considered the result of occupational exposure. Although she had no open wounds, facial acne was present. While it is uncertain if mouth or skin exposure was the direct route of transmission, facial protection would have eliminated the hazard of infection via mucous membrane. In paragraph (d)(3)(vii), OSHA proposes to require that appropriate protective clothing be worn when the employee has a potential for occupational exposure. The type of clothing (e.g., lab coat, gown, apron) and its associated characteristics (e.g., fluid-resistance) will depend upon the task being performed and the degree of exposure anticipated (e.g., soiling, splashing, soaking). In this portion, the proposed standard gives the employer flexibility in complying. Rather than requiring complete barrier protection in all situations, the proposed standard allows the employer to evaluate the task and the exposure expected to be associated with its performance and, based upon this determination, select protective clothing and equipment appropriate to the task. In order to fulfill the requirement of “appropriate” for this standard, the clothing selected shall form an effective barrier under the anticipated conditions of exposure. In their comment to the ANPR, Kimberly-Clark Corporation submitted results of their research and development efforts in the area of blood strike-through potential of various types of protective clothing materials (Ex. 11—353). Kimberly-Clark emphasized the importance of design, breathability, and fluid resistance of the garments. The Agency seeks comment on whether the performance oriented approach will provide adequate protection to employees or whether OSHA should specify characteristics of construction or fabric for particular tasks.

In paragraph (d)(3)(viii)(A), OSHA proposes to require gowns, labcoats, aprons, or similar clothing shall be worn if there is a potential for soiling of clothes with blood or other potentially infectious materials (Exs. 4—25, 6—75, 6—338, 11—71, 11—159). These items are commonly made of tightly woven or fused materials that will prevent the employee’s underlying clothing from becoming contaminated. The contaminated overgarment can be easily removed at the end of the work shift or when access to a non-work area is required and will remain within the work area for cleaning, laundering, or disposal.

If splashing or spraying of blood or other potentially infectious liquids is possible, the proposed standard requires the employee to wear clothing such as gowns, aprons, or coveralls that is fluid-resistant (Exs. 4—25, 6—153, 11—111, 11—159, 11—233(d)). Since a larger volume of blood and other potentially infectious materials (and consequently a greater chance of soak-through and skin contact) accompanies these modes of exposure, a more protective type of barrier clothing is dictated. If extreme splashing or spattering is anticipated, surgical caps or hoods are required to...
prevent potentially infectious materials from reaching the scalp (Exs. 6-75, 11-159).

In some situations, such as autopsies, there is a possibility of clothing becoming soaked with blood or other potentially infectious materials. When a potential for soaking is anticipated, the proposed standard requires that fluid-proof clothing such as gowns, aprons, sleeve covers, or coveralls, be worn (Exs. 6-153, 10, 11-159, 11-233d, 11-260, 11-283). Fluid-proof shoe covers are required to be worn if there is a potential for shoes becoming contaminated or soaked with blood or other potentially infectious materials to prevent possible contact exposure of the foot (Exs. 6-75, 11-159, 11-283). Shoe covers, like all personal protective equipment, must be removed prior to leaving the work area thereby limiting migration of contamination via shoes into other areas.

Some employees may feel that personal protective equipment interferes with their ability to perform their routine duties. OSHA seeks comments on how these concerns can be addressed without compromising the safety provided by barrier protection.

In paragraph (d)(4)(i), OSHA proposes to require that employers assure that the worksite is maintained in a clean and sanitary condition. The term “worksite” refers not only to permanent fixed facilities such as hospitals, dental/medical offices, clinics, and so forth but also covers temporary non-fixed workplaces. Examples of such facilities include, but are not limited to, ambulances, bloodmobiles, temporary blood collection centers, and any other non-fixed worksites which have a reasonable possibility of becoming contaminated with blood or other potentially infectious materials. OSHA recognizes that different types of surfaces and soiling exist throughout a workplace and that the employer is in the best position to evaluate the condition of his or her facility. Therefore, the standard requires that the employer determine and implement the appropriate written schedule of cleaning and method of disinfection based upon the location within the facility, type of surface to be cleaned, type of soiling present, and tasks or procedures being performed (Exs. 11-263, 11-71, 6-153).

The proposed standard also requires that employers ensure that all equipment and environmental and working surfaces are properly cleaned and disinfected after contact with blood or other potentially infectious materials (Exs. 11-159, 11-283). Though there exist a broad range of work environments and circumstances where a work surface may become contaminated, OSHA has preliminarily concluded that there are certain common circumstances where decontamination procedures must be implemented to maintain cleanliness and minimize migration of potentially infectious materials (Exs. 6-153, 6-159). The proposed standard requires that work surfaces shall be decontaminated with an appropriate disinfectant 1) after completion of procedures (Exs. 6-338, 11-159); 2) when surfaces are overtly contaminated (Ex. 11-159); 3) immediately after any spill of blood or potentially infectious materials (Exs. 6-153, 6-338) and; 4) at the end of the work day (Exs. 6-153, 6-312, 11-159, 11-280). With reference to hepatitis B, these requirements are supported by the following statement from Laboratory Safety: Principles and Practices:

The primary mode of transmission is by direct contact with blood and serum specimens and environmental surfaces which are contaminated. The presence of blood or serum on hands, whether from direct or indirect sources, can result in the HBV gaining access to the vascular system subcutaneously by needle sticks or contamination of lesions or by nasal, oral, or ocular exposure (Ex. 6-344). The above are minimum requirements and additional decontamination may be performed any time that it is deemed necessary.

Paragraph (d)(4)(ii)(B) of the proposed standard allows equipment and environmental surfaces to be covered with protective coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper (Exs. 6-153, 6-338, 9-7e, 11-43, 11-159). Examples of such an instance would be covering dental light handles with foil or a dental x-ray unit head with plastic film (Ex. 6-153). The standard requires that if these covers are used, they must be removed and replaced when they become overtly contaminated and at the end of the work shift.

The proposed standard also requires that equipment (e.g. blood gas analyzers, mechanical pipettors, suctioning devices, centrifuges, liquid chromatographs) which may become contaminated with blood or other potentially infectious materials shall be checked routinely for contamination and decontaminated as necessary. The NCCLS (Ex. 11-159) pointed out that automated analyzers with sampling probes that move rapidly can generate a fine mist which can accumulate on the equipment, necessitating periodic inspection and decontamination.

In their comments, Waters Corporation (Ex. 11-3) and YSI Incorporated (Ex. 11-7), both of whom are involved with instrument servicing, address the potential for exposure of repair personnel. In addition, several sources recommend the decontamination of instruments and equipment before being repaired in the laboratory or shipped to the manufacturer for servicing (Exs. 6-153, 11-71, 11-159). On the basis of these recommendations, OSHA has proposed to require that employers check all equipment which may be contaminated with blood or other potentially infectious materials prior to servicing or shipping and decontaminate as necessary. OSHA anticipates that this requirement will minimize the possibility of servicing and shipping personnel becoming exposed due to leakage of potentially infectious fluids from the equipment or contact with interior/exterior contamination.

In some cases bins, pails, cans, and so forth, which are intended for re-use may be utilized in a manner which presents the potential for their becoming contaminated with blood or other potentially infectious materials. For example, a reusable metal trash can may be lined with a disposable plastic infectious waste bag. By virtue of a plastic bag’s construction, the possibility of leakage is inherent and the can could become contaminated. If the can is not cleaned and disinfected the contamination may be spread by leakage or spillage from the can or by fouling the outside of succeeding bags. Therefore, paragraph (d)(4)(ii)(D) of the standard requires that all bins, pails, cans, and similar receptacles intended for re-use and which have the potential for becoming contaminated with blood or other potentially infectious materials must be inspected, cleaned, and disinfected on a regularly scheduled basis and cleaned and disinfected immediately or as soon as possible upon visible contamination. This is consistent with OSHA’s current standard regarding maintenance of waste disposal containers 29 CFR 1910.141 (a)(4)(i).

The case studies portion of the preamble’s HIV Health Effects section (Case 8) describes the HIV seroconversion of an NIH worker as a result of viral inoculation through a cut from a broken glass vial containing HIV-infected blood. This provides an example of the relationship between infection and breaks in the skin barrier caused by contaminated, broken glass. The Agency concludes that broken glass and other potentially infectious materials shall not be handled directly by employees. In the 1988 Agent Summary Statement for
Human Immunodeficiency Virus, the CDC states:

In the laboratory, the skin (especially when scratches, cuts, abrasions, dermatitis, or other lesions are present) and mucous membranes of the eye, nose, mouth, and possibly the respiratory tract should be considered as potential pathways for entry of virus. Needles, sharp instruments, broken glass, and other sharp objects must be carefully handled and properly discarded. (Ex. 6-921)

Accordingly, this standard requires that broken glassware which may be potentially contaminated shall not be cleaned up with the hands. Since gloves do not provide adequate protection against cuts, OSHA proposes to require that all clean-ups be accomplished using mechanical means. Various mechanical means can be used. For example, the Red Cross states that clean-up may be performed with a brush and dustpan or a vacuum cleaner (Ex. 11-260). Pieces in difficult to reach places, such as sinks, can be removed by using tongs for large pieces and cotton swabs or forceps for chips and slivers.

Several sources made a number of recommendations concerning the handling of specimens (Exs. 6-75, 6-153, 11-159, 11-233(d)). After reviewing these recommendations in conjunction with the current OSHA regulations on labelling, this proposed standard requires that specimens of blood or other potentially infectious materials shall be placed in a closable, labeled or color-coded, leakproof container prior to being stored or transported. If outside contamination of the container is likely a second closable, labeled or color-coded, leakproof container shall be placed over the outside of the first and closed to prevent leakage during handling, storage, and transport. This requirement is supported by several sources (Exs. 4-25, 6-35, 11-71, 11-159, 11-283).

A leakproof container or bag is required to prevent leakage of the contents into the work area while closability is necessary to ensure that the waste is contained in the event of the container or bag becoming tipped or upended. If outside contamination is anticipated, as would occur if potentially infectious materials were spilled on the exterior of the bag as it is being filled, then a second bag placed over the first will contain the contamination. This prevents an employee's handling the contaminated exterior and limits spread of contamination throughout the work area as the bag is handled, stored, and transported. The outside bag must also be labeled or color-coded to assure that a warning of biohazardous contents is readily observable to employees.

The National Solid Wastes Management Association sums up the logic for proper containment of sharps and infectious waste in their statement:

- The essential elements to control the risk posed by this waste stream are to create a physical barrier around the waste until it has been treated. This includes double-bagging for “soft” wastes and containment in rigid containers for “sharps” (Ex. 11-60).

- It should be remembered that anything which complicates the physical barrier, such as torn bags resulting from rough handling or compaction or punctures caused by pointed or sharp objects being placed in plastic waste bags, also compromises the benefit which would be gained by proper infectious waste handling and increases the chance of employee exposure and work area contamination.

The CDC recommends that facilities which produce the aforementioned wastes, such as hospitals, blood banks, and clinical or research laboratories, develop an infectious waste management plan which includes identification, collection, proper handling, transport, infectious waste pre-treatment, and disposal of the treated infectious waste (Ex. 6-395).

While the proposed standard puts forth minimum requirements for containing potentially infectious waste to protect employees against exposure, it is not the intent of the proposal to set rigid regulations regarding infectious waste handling and disposal. OSHA is aware that additional requirements may apply to this waste under the jurisdiction of other governing bodies. Therefore, the standard requires that disposal of all infectious waste shall be in accordance with applicable Federal, state, and local regulations (Exs. 4-25, 11-71, 11-187, 11-283).

As with other bloodborne diseases, the potential for transmission is greatest when needles and other sharp instruments are used in patient care. Therefore, needles and syringes should be disposed of in rigid, puncture-resistant containers (Ex. 6-75). Several CDC documents also address disposal of sharps and needles (Exs. 6-27, 6-153, 6-312) including The Centers for Disease Control’s Recommendations on Infective Waste which says:

Disposable syringes with needles, scalpel blades, and other sharp items capable of causing injury should be placed intact into puncture-resistant containers located as close as is practical to the area in which they were used. If predisposable autoclaving is performed, the container should maintain its impermeability after autoclaving in order to avoid subsequent physical injuries (Ex. 6-395).

In addition, the American Federation of State, County, and Municipal Employees (AFSCME) commented:

Currently, one of the most important work practices for preventing needlesticks is the disposal of uncapped unbroken needles and other sharps into puncture resistant needle boxes. In order to facilitate adherence to this practice, adequate numbers of needle boxes must be supplied in convenient locations. All patient rooms and other patient care areas where needles or other sharps are used should be supplied with needle boxes. In
Further required by paragraph (d)(4)(iii)(B) in order to assure that contaminated sharps remain inside the disposal unit while it is being transported and handled prior to terminal disposal. In addition, the containers must be leakproof on the sides and bottom. This requirement is aimed at preventing residual liquid draining from the syringes and pooling in the container from leaking out onto countertops, floors, cart tops, and so forth, thereby spreading contamination. It also prevents employee hand contact with liquids which could otherwise leak through and contaminate the outside of the container. The design of the tops of a number of sharps disposal containers will permit leakage if the container is tipped on its side or turned upside down. This is acceptable if the container meets all other requirements (puncture-resistance, closability, etc.) and will not be tipped or turned over in normal use. If leakage is a possibility during disposal of these containers (i.e. handling, storage, transport) they shall be disposed of as outlined in paragraph (d)(4)(iii)(A). A proper closing will ensure that if the container should become tipped or overturned employees will not be exposed to needles or other sharps which may otherwise spill out. Also, the containers must be labeled or color-coded as described in paragraph (g)(1)(ii) of this proposed standard. This requirement essentially serves two purposes: (1) it allows the containers to be easily identified by employees having needles/sharps to dispose of by clearly distinguishing the containers from others in the area, and (2) it gains the attention of other staff, such as housekeepers, by virtue of the readily recognizable label or color thereby warning them of the potential hazard and signaling that special handling precautions may be necessitated.

A number of commenters and sources made recommendations on disposal of needles and sharps which closely follow (or support) OSHA's proposed standard. (Exs. 4-25, 6-153, 6-75, 6-111, 11-111, 11-157, 11-159, 11-233(d). 11-259, 11-280). Laundry from workplaces with employees covered under paragraph (a) of this section that is contaminated with blood or other potentially infectious materials or may contain sharps shall be treated as if it were contaminated and shall be handled as little as possible with a minimum at agitation. Minimizing handing and agitation of the laundry will not only reduce contact-acquired contamination of the employee and the work area but will also decrease mechanical injuries such as needlesticks, cuts and scratches from sharps accidentally left in linens. Paragraph (d)(4)(iv)(A)(2) of the proposed standard requires that all contaminated laundry shall be bagged at the location where it was used and shall not be sorted or rinsed in patient-care areas. Contaminated laundry is required by paragraph (d)(4)(iv)(A)(2) to be placed and transported in bags that are labeled or color-coded as described in paragraph (g)(1)(ii) in order to indicate contents which are contaminated. Whenever this laundry is wet and presents the potential for soak-through of or leakage from the bag, it shall be placed and transported in leakproof bags (Exs. 4-25, 6-153, 6-75). By requiring bagging of laundry at its location of use and prohibiting sorting and rinsing in patient-care areas, the amount of manual handling of laundry by staff, other than laundry personnel, is limited to only that which is necessary for removal and bagging. Contamination of additional surfaces such as sinks and floors is also reduced in comparison to that which may occur if sorting and rinsing were permitted in areas other than the laundry. The intent of labeling or color-coding the bags is to inform employees who may handle the bags of their contaminated contents and that special handling procedures may be in order. This labeling/color-coding system is supported by the AHA in their recommendations Management of HIV-
This paragraph addresses additional requirements that must be met by research laboratories and production facilities engaged in the culture, production, concentration, and manipulation of HIV and HBV. The risks associated with direct and routine work with pathogens have long been recognized:

Microbiology laboratories are special, often unique, work environments that may pose special infectious disease risks to persons in or near them. Personnel have contracted infectious hepatitis B.

HIV and HBV research laboratories and production facilities are no exceptions, and the risks associated with work in such facilities warrant additional protective measures.

Prior to 1984, no single code of practice, standards, guidelines or other publication providing detailed descriptions of techniques or equipment for laboratory activities involving pathogens was available. In that year, the Centers for Disease Control (CDC) and the National Institutes of Health (NIH) published guidelines entitled "Biosafety in Microbiological and Biomedical Laboratories" (Ex. 6-330). These biosafety guidelines were based on combinations of standard and special practices, equipment, and facilities recommended for use when working with various infectious agents in laboratory settings.

The basic format for the biosafety guidelines categorizes infectious agents and laboratory activities into four classes or levels denoted as biosafety levels 1 through 4. These biosafety levels (BSL) are comprised of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and the hazard posed. The Guidelines indicate the BSL to be used when working with various infectious agents and infected animals. Recommended BSL for working with HIV were not included in the original biosafety guidelines.

In 1988, CDC issued an "Agent Summary Statement for Human Immunodeficiency Virus" (Ex. 6-312) which outlined biosafety levels for various activities involving HIV. Activities performed in clinical laboratories were categorized at BSL 2 which covers standards and practices for handling all clinical specimens. For HIV research laboratories and production facilities, Agent Summary statement states:

Activities such as producing research-laboratory scale amounts of HIV, manipulating concentrated virus preparations, and conducting procedures that may produce aerosols or droplets should be performed in a BSL 2 facility with the additional practices and containment equipment recommended for BSL 3.

Activities involving industrial-scale, large-volume production or high concentration and manipulation of concentrated HIV should be conducted in a BSL 3 facility using BSL 3 practices and equipment (Ex. 6-312).

These recommendations with some modifications were adopted by OSHA to cover HIV/HBV research laboratories and production facilities. Accordingly, the Guidelines's BSL 3 text for standard microbiological practices, special practices, and containment equipment was converted to regulatory language and comprises paragraph (e)(2) of the standard. Requirements for the facilities for research laboratories [paragraph (e)(3)] were derived from the text for BSL 2, while those for production facilities [paragraph (e)(4)] were derived from the text for BSL 4.

While general training requirements for employees working with pathogens are given in paragraph (g), OSHA feels that additional specialized training should be provided for employees of the research laboratories and production facilities covered by paragraph (e). HIV infection of a worker in an HIV production facility as a result of "undiagnosed skin contact with virus culture supernatant" was attributed to inexperience coupled with "on-the-job training in a setting in which episodes of contamination may have occurred frequently" (Ex. 6-312). Therefore, the training recommendations of the NIH committee convened to investigate the incident were incorporated into paragraph (g)(2)(v) of this standard as special training requirements.

OSHA recognizes the valuable contribution that is being made by research laboratories that are studying the human immunodeficiency virus and the hepatitis B virus. The Agency also understands the need to produce extremely high concentrations of these viruses to prepare reagents and other products needed for research, diagnosis and, if an HIV vaccine is developed, prevention. The Agency has no desire to impede these efforts. However, there is clearly documented risk to individuals working with blood containing HIV and HBV. When the concentration of these viruses is increased as the result of growing virus in cell culture or artificial concentrate on, then the risk to employees increases.

The two cases of HIV infection that occurred in HIV production facilities are discussed in the Health Effects section of this preamble. The requirements in
paragraph (e) are derived primarily from the CDC/NIH recommendations found in "Biosafety in Microbiological and Biomedical Laboratories" (Ex. 6-338). Only those provisions that relate to the health and safety of the employee are required by the standard. Since the employer is responsible for following the entire standard, the requirements stated elsewhere in the standard (e.g., the prohibition of mouth pipetting) are not repeated. The special training requirements in paragraph (g)(2)(v) are based on the conclusions and recommendations of an expert team convened by the Director of the National Institutes of Health.

This section applies to two types of facilities that we have designated "research laboratories" and "production facilities." For the purpose of this standard, "research laboratories" means a facility in which HIV or HBV is being grown in cell, tissue or organ culture in the laboratory or in animal model. Although attempts to grow HBV in this manner have not been successful in the past, researchers are attempting to culture HBV and the in vitro culture of HBV may soon be possible. This proposed standard does not require research laboratories such as laboratories using unvaccinated or infected blood or blood components as the source of HIV or HBV to follow these additional requirements. However, they must follow the other provisions of the standard and avoid the production of aerosols.

For purposes of the standard, facilities that are engaged in the concentration of large quantities of or high concentrations of HBV or HIV are called "production facilities." These facilities reduce many liters of plasma or culture fluid into a concentrate of a few milliliters. These concentrated preparations are used for a number of purposes including as testing reagents and for the past for HBV and perhaps in the future for HIV, for vaccines. In many cases, the production of concentrated virus is a byproduct of the process and not the goal, for example, in the production of HbsAg.

Paragraph (e)(2)(i) describes standard microbiological practices, most of which are found in other provisions of the standard. The single requirement listed here, the decontamination of infectious liquid or solid waste, is to prevent the accidental exposure of other employees to the concentrated virus.

Paragraph (e)(2)(ii) describes special practices to be followed and paragraph (e)(2)(iii)(A), (C), and (D) serve to further limit access to the laboratory and would warn of the hazards associated with bloodborne pathogens. These paragraphs ensure that unauthorized individuals are not placed at risk, and that they do not distract or otherwise interfere with the activity of the authorized employees. This works in concert with the requirements for signs in paragraph (g). This ensures that only those individuals who meet special requirements, such as training, clothing and/or immunization, would enter the area. The requirement proposed in paragraph (e)(2)(ii)(B) that contaminated material removed from the work area be placed in a durable, leakproof container that is closed before being removed from the work area is to assure there are no accidental spills or other contamination that may place other employees at risk.

The requirement in paragraph (e)(2)(ii)(E) that all activities involving infectious materials be conducted in a biological safety cabinet or equivalent containment is to ensure that material containing virus will be contained and away from the worker's mucous membranes, unprotected skin, and breathing zone (in the case of aerosols). Paragraphs (e)(2)(iii)(F) and (G) specify personal protective clothing to be worn to prevent contact of the infectious materials with the employee's skin.

The requirements for decontamination of wastes (paragraph (e)(2)(iii)(H)) and the use of HEPA filters and traps on vacuum lines, paragraph (e)(2)(ii)(I), are to prevent the spread of contamination to other work areas.

Since needlestick injury is one of the most efficient methods of accidental infection, paragraph (e)(2)(iii)(J) requires that the use needles and other sharp objects be kept to a minimum, handled carefully and disposed of in containers that prevent accidental injury.

Exposure incidents must be reported (paragraph (e)(2)(iii)(K)) so that post exposure follow-up required by paragraph (f)(3) can be initiated.

The requirement for a biosafety manual, paragraph (e)(2)(iii)(L), ensures that any necessary additional procedures are developed to address situations that are unique to a particular facility and to provide appropriate protection to potentially exposed employees.

Paragraph (e)(2)(iii) specifies that specific containment equipment (engineering controls) are required to minimize or eliminate exposure to the viruses. Biological safety cabinets must be certified to ensure that they will provide the proper protection.

Paragraph (e)(3) contains requirements specific for HIV and HBV research facilities. This paragraph requires a sink for hand washing and an autoclave. Hand washing reduces both the likelihood of infection and the contamination of environmental surfaces, and the availability of a handwashing sink near the work area is essential. The availability of an autoclave is required for inactivating or destroying HIV or HBV in or on a variety of media, including culture fluids, plastic ware, and equipment.

The specific requirements for HIV and HBV production facilities are found in paragraph (e)(4). Paragraph (e)(4)(i) would require that in production facilities work areas be separated from other areas by two sets of doors. This reduces the likelihood of accidental entry into the work area and means that entry into the area is a deliberate action. This further reduces the likelihood that untrained individuals will enter the work area as does the requirement that the doors be self-closing (paragraph (e)(4)(iv)).

The requirement for an autoclave in or very near the work area (paragraph (e)(4)(iii)) is necessary because of the high concentration of the virus that may be present and the need to decontaminate the work area to reduce the possibility of infection.

The requirement for a handwashing sink (paragraph (e)(4)(iii)) is to allow for handwashing prior to exiting the work area and to keep environmental contamination to a minimum by requiring that the sink be foot, elbow and automatically operated.

The requirement for an autoclave in or very near the work area (paragraph (e)(4)(iv)) is necessitated because of the very high concentration of virus in these facilities. Transporting contaminated fluids, plastic ware and other equipment would result in a high potential for accidental exposure to other employees.

The requirement that production facilities have a directional airflow into the work area (paragraph (e)(4)(v)) is to ensure air is drawn into the work area in order to maintain the containment of the facility.

Paragraph (e)(5) alerts the employees to the special, additional training requirements found in paragraph (g)(3)(v) for employees in research laboratories and production facilities.

OSHA seeks comments on its designations "research laboratory" and "production facility." Should there be additional requirements or should any of the proposed requirements be modified? Could alternative provisions provide equivalent protection?
Paragraph (f) HBV Vaccination and Post Exposure Follow-up

The provisions in this paragraph of the proposed standard are designed to protect employees from infection caused by bloodborne pathogens by requiring the employer to (1) make the HBV vaccination available to employees to prevent HBV infection and subsequent illness and death and (2) ensure that the employee receives appropriate medical follow-up after an exposure incident. Early intervention, including testing, counseling and appropriate prophylaxis can reduce the risk of infection, in the case of HBV, and prevent further transmission if an infection should occur.

The proposed standard calls for a hepatitis B vaccination and post-exposure follow-up program to be made available to all employees who are covered by paragraph (a) of this section. Since a single exposure may result in an infection, the Agency believes its coverage is reasonably related to achieving benefits to the health of these employees as well as being technologically and economically feasible.

The proposed standard requires all medical evaluations and procedures to be performed by or under the supervision of a licensed physician. Although a licensed physician must supervise and interpret a medical evaluation(s), certain parts of the evaluation(s) do not necessarily require the physician's expertise, and these may be conducted by other suitably qualified health care personnel under the supervision of the physician.

The proposed standard requires that all laboratory tests be performed by an accredited laboratory. Accreditation by a national accrediting body or its state equivalent means that the laboratory has participated in a recognized quality assurance program. This accreditation process is required to ensure a measure of quality control so that employees receive accurate information concerning their laboratory tests and tends to assure long-term stability and consistency among laboratory test procedures and interpretations of results.

The proposed standard requires all evaluations, procedures, vaccinations, and post-exposure prophylaxis to be provided at a reasonable time and place, and according to standard recommendations for medical practice. In order to increase the likelihood that employees receive the benefits provided by the standard, the evaluations must be convenient to them and the above requirements ensure that they will be.

Moreover, OSHA has included this provision in other standards (e.g., EIO, 49 FR 22757 (1984) and Asbestos, 51 FR 22737 (1986)). The requirement for adherence to standard recommendations for medical practice assures that employees are afforded the benefit of receiving all procedures according to currently accepted medical standards.

The requirements for the hepatitis B vaccination and post exposure follow-up program are sufficiently detailed to ensure the employees will receive appropriate protection from bloodborne pathogens, while affording the treating physician flexibility to exercise professional judgment in the management of particular cases. The physician will be able to determine whether the employee has any condition that would prevent the employee from receiving the hepatitis B vaccination and will have access to information such as the documentation required following an exposure incident in order to evaluate, counsel and provide appropriate prophylaxis to employees who have experienced an exposure incident.

HBV Vaccination. The proposed standard requires that the vaccine shall be offered to all employees occupationally exposed on average one or more times per month unless it has been determined through antibody testing that an employee is immune or has previously received the vaccine. In addition, the vaccine shall be provided to any such employee who initially declines HBV vaccination but later, while still covered under the standard, decides to accept the HBV vaccine. Should booster dose(s) be recommended at a future date, they shall be provided. An employee who is exposed to potentially infectious materials such as concentrated preparations of HIV concentrate, that do not contain HBV and who has no exposure to blood has no reason, on the basis of employment, to receive HBV vaccine. Therefore, it is not required that HBV vaccine be offered to these employees.

In the past, the CDC has published lists of occupations identified by epidemiologic studies as placing employees at risk for hepatitis B infection and has recommended the vaccination of these groups. If this approach were to be followed for regulatory purposes, some occupations with routine exposure to blood may be excluded because epidemiologic studies may not be available to quantify the risk. Since this standard seeks to minimize or eliminate exposure to blood and other potentially infectious materials, the mechanism for occupational transmission of bloodborne pathogens. OSHA proposes to base HBV vaccination on frequency of exposure rather than occupation. This allows greater flexibility and provides protection for those individuals whose occupation may not be included on the recommended list but may nonetheless have frequent occupational exposure.

OSHA is proposing that employers offer the vaccine to those employees who are occupationally exposed on average one or more times per month. If, for example, once a month or twice every other month, an employee dons gloves to perform a phlebotomy procedure, then for the purpose of paragraph (f)(2)(i) the requisite occupational exposure has occurred and the employee must be offered the vaccine. Since the basis for specifying the frequency of this occupational exposure is lifetime risk, an employee who has 12 occupational exposures in a day or in a week but has no additional exposures for several months is eligible to receive the vaccine.

The requirement that the HBV vaccine be administered “according to standard recommendations for medical practice” refers to such considerations as dosage, route, site and technique of immunization (Ex. 6-409). It does not refer to any recommendation that conflicts with OSHA’s proposed requirement that the employer make the HBV vaccine available to employees occupationally exposed on average one or more times per month.

Since OSHA is charged with protecting a worker over his or her entire working lifetime (45 years), an exposure frequency of once a month means that the employee will have potential exposure to the blood of 540 different individuals over a working lifetime. Although it is not possible to predict exactly how many of these exposures involve blood or body fluids from HBV infected individuals, estimates of the prevalence of HBV carriers are available in the literature. For example, approximately 0.2% of the white population, 1% of hospital patients, and 13% of immigrants from areas of high endemicity are infected (HBsAg positive) and capable of transmitting the virus (Ex. 6-390, 6-427, 6-199). Using these figures, one can estimate that a hospital employee who is exposed once a month for 45 years (540 exposures) will be exposed to the blood of an HBV infected individual approximately 5 to 6 times over a working lifetime. The actual number of exposures to blood or other potentially infectious materials containing HBV could be higher if the contact population consists of individuals from high risk
groups or those with a higher HBV carrier rate. If these exposures are by needlestick, then the probability of infection would be expected to range from 7% to 30% for each exposure. Exposure by other routes would have a lower probability of infection. For additional estimates of lifetime risk to workers with an average of one exposure per month, see Exhibit 6-49.

The objective of this proposal is to encourage employees to be vaccinated under this proposal should be for those employees who would receive the vaccine under this proposal should be expanded and upon what criteria the exposure be based.

The requirement that employers make the vaccine available to employees who initially decline vaccine but who later decide to accept the vaccine, assures that employees who initially are reluctant to accept vaccine but who later change their minds as the result of information or experience are accorded the opportunity to receive such vaccine. The signing of a waiver by the employee eliminates the need for the employer to provide the vaccine to a later date of the employee understands the vaccine. This is consistent with OSHA's goal of encouraging employees to be vaccinated.

Since the plasma-derived HBV vaccine has been available in the U.S. only since 1982, with the recombinant DNA HBV vaccine licensed in 1986, future follow-up of vaccines may demonstrate that HBV antibody levels fall to a level at which they are no longer protective. At that time, booster doses of vaccine may be recommended to ensure protection. Should such doses be recommended, the provision for booster doses assures that employees will be available to be protected.

HBV vaccination has been endorsed in an ANPR comment by NIOSH (Ex. 11-187) and recommended by CDC (Ex. 6-200). The Departments of Labor and Health and Human Services endorsed HBV vaccination in the Joint Advisory Notice (Ex. 10). In addition, the ADA has recommended that all dental health care workers with possible exposure to blood or direct contact with obtain HBV vaccination (Ex. 11-43), and AFSCME has recommended that HBV vaccine be offered (Ex. 11-157). The ANA (Ex. 11-86) and AANCN (Ex. 11-117) have endorsed provision of HBV vaccination by the employer, and the American College of Obstetricians and Gynecologists (Ex. 11-158) has recommended that health care workers be vaccinated against HBV.

The proposed standard requires that HBV antibody testing shall be made available to an employee who desires such testing prior to deciding whether to receive HBV vaccination. OSHA believes that it is the right of employees to have such information so that they can make a fully informed choice regarding HBV vaccination. The manufacturer of the vaccine has stated that antibody screening prior to vaccine is not warranted (Ex. 11-165). However, the agency believes that employees who are already immune to HBV should have the opportunity to obtain that information so that they can choose whether or not to be vaccinated based on knowledge of their HBV immune status. In addition, if adequate HBV antibody titer is demonstrated in an employee, there is no reason for the employer to offer the HBV vaccine to that employee. In addition, in many cases, the employer will find it cost effective to prescreen prior to vaccination (Ex. 6-196).

OSHA seeks to gather additional information related to hepatitis B vaccination during the written comment period and the public hearing. Since the employee's participation in the hepatitis B vaccination program is voluntary, OSHA will also be interested in existing HBV vaccination programs that have achieved a high degree of voluntary employee compliance. The Agency will attempt to identify those elements that are common to successful programs and will provide this information to all employers. In addition, we are also seeking information on availability, cost and any potential distribution problems that may be associated with initiating the vaccination of large numbers of employees within the 150 day period following the effective date of the standard.

The Agency intends to designate several days of the Washington, DC hearing to focus on the issues surrounding HBV vaccination. We encourage hearing participants who are concerned about this matter or who have pertinent information to participate either by requesting to testify on one of the designated days or by submitting a statement to be entered into the record on the days set aside to focus on Hepatitis B vaccination. Specific information on this matter can be found in Section X. Public Participation.

Post Exposure Evaluation and Follow-up

Following a report of occupational exposure, medical evaluation and monitoring are to be made available to the employee. Such evaluation and monitoring, as well as maintaining the required medical records, are to be done in a manner which protects the confidentiality of the employee's identity and test results. OSHA believes that medical evaluation and monitoring following an exposure incident are necessary to provide appropriate prophylaxis to prevent HBV infection, to take appropriate precautions to prevent possible perinatal transmission, and to ensure that such employees are able to take necessary precautions to ensure that sexual contacts are protected from infection. Post-exposure medical evaluations have been recommended by NIOSH (Ex. 11-187), NCCLS (Ex. 11-159), AHA (Ex. 6-75), NIH/CDC (Ex. 6-312), AAHOH (Ex.11-356), and AFSCME (Ex. 11-157). The ADA has stated that CDC guidelines should be followed (Ex. 11-43).

Determination of and Documentation of exposure incident. The route of exposure, the source patient's antibody status (if known), and the circumstances under which the exposure occurred are to be documented. Such determinations enable the employer to discharge further responsibilities in providing information to the physician by determining the infection status of the source patient. In addition, through documentation of such exposure the employer can receive feedback regarding the most prevalent circumstances and routes of exposure of employees so that efforts can be focused on decreasing or eliminating the circumstances involved (e.g., providing protective equipment that is acceptable to employees and that they will more likely use, increasing training efforts regarding certain procedures which seem to be associated with exposure incidents). Such determination of and documentation of exposure incidents and circumstances has been recommended by ABRA (Ex. 11-71) and the Hospital Association of Greater Des Moines (Ex. 11-23). Additionally, NCCLS (Ex. 11-159) and NIH/CDC (Ex. 6-312) have recommended that institutions develop and maintain post-exposure documentation.

Testing of source patient. If the source patient of an employee's occupational
exposure can be determined, permission for antigen or antibody testing of the source patient’s blood shall be obtained, if possible, and testing shall be performed to determine HBV and HIV infection status. In any case, management of the exposed employee shall be according to standard recommendations for medical practice. OSHA believes that testing of source patient(s) for infection status provides exposed employees with information that will assist them in their decisions regarding testing of their own blood, complying with other elements of post-exposure management, and using precautions to prevent possible infection in others. The American Red Cross has recommended that the employer make an early attempt to evaluate the infectivity of the implicated material after an employee exposure (Ex. 11-280). SEIU has stated that it is the right of workers to know the HIV and HBV status of patients if exposed to their blood or body fluids (Ex. 11-161). The need to obtain the consent of the source patient prior to testing is recognized. Many organizations and associations support testing of source patient(s) only after obtaining consent of such patient(s). These associations and groups include CDC (Ex. 6-153), NIOSH (Ex. 11-161), AAOHN (Ex. 11-358), NCCLS (Ex. 11-159), AHA (Ex. 6-75), ABRA (Ex. 11-71), and SEIU (Ex. 11-161). The American Red Cross has recommended that employee blood samples be held until the employee requests testing and that samples not tested be held for at least 5 years (Ex. 11-280). The American Dental Association has recommended that blood of exposed employees be tested only if the source patient has AIDS or is HIV infected (Ex. 11-43). OSHA seeks comments on whether this provision will increase the likelihood that the employee will be willing to participate in a post exposure follow-up program.

Further follow-up of the exposed employee includes counseling and illness reporting. OSHA believes that further follow-up of an exposure incident is vital to assure that employees are afforded further information and counseling regarding their condition as a result of exposure. The American Blood Resources Association (Ex. 11-71) has recommended that follow-up testing be encouraged and that the employer be referred, if a test is positive for infection, for further evaluation and follow-up. The American Red Cross (Ex. 11-280) has recommended referral to a physician of an exposed employee if the source material is infectious. The Centers for Disease Control and the National Institutes of Health (Ex. 6-312) have currently recommended measures to protect employees in laboratories and production facilities. The American Association of Occupational Health Nurses (Ex. 11-358) has recommended follow-up antibody tests at 6 weeks and 6 to 12 months post exposure. A number of commenters including NIOSH (Ex. 11-187), AFSCME (Ex. 11-157), the Hospital Association of Greater Des Moines (Ex. 11-23), Joint Advisory Notice (Ex. 10), AAOHN (Ex. 11-358), NCCLS (Ex. 11-159), AHA (Ex. 6-75), ABRA (Ex. 11-71), and SEIU (Ex. 11-161). The American Dental Association has recommended that blood of exposed employees be tested only if the source patient has AIDS or is HIV infected (Ex. 11-43). OSHA seeks comments on whether this provision will increase the likelihood that the employee will be willing to participate in a post exposure follow-up program.

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The requirement for the employer to advise employees to report illness to the responsible physician assures that such employees will have the benefit of early medical evaluation and can accept in a timely manner any currently recommended treatment of such disease. This illness reporting provision has been recommended by CDC (Ex. 6-153) and is supported by ABRA (Ex. 11-71), CDC/NIH (Ex. 6-312), AMA (Ex. 11-163), AAOHN (Ex. 11-358), and NCCLS (Ex. 11-159).

OSHA believes that counseling of exposed employees is a vital component of the post-exposure follow-up procedures. Counselling concerning the infection status (results and interpretation of all tests) will assist the employee in understanding the potential risk of infection and in making decisions regarding the protection of personal contacts. Post exposure counseling has been recommended by CDC (Ex. 6-153), DOL/CDC (Ex. 10), NIOSH (Ex. 11-167), ARC (Ex. 11-280), AAOHN (Ex. 11-358), SEIU (Ex. 11-161), AHA (Ex. 6-75), ABRA (Ex. 11-71), AMA (Ex. 11-163), NCCLS (Ex. 11-159), and AFSCME (Ex. 11-187). OSHA believes that it is essential that exposed or infected employees be offered post-exposure follow-up according to standard recommendations for medical practice. This provision guarantees employees the benefit of currently recommended measures to help prevent infection and disease immediately after occupational exposure. The offering of such measures in a timely manner assures that maximum effectiveness is achieved. Post exposure follow-up for exposed employees has been recommended by SEIU (Ex. 11-161). The American Federation of State, County and Municipal Employees (Ex. 11-157) and AAOHN (Ex. 11-111) have endorsed prophylaxis for HBV as recommended by CDC, and the ACIP has recommended HBIG, along with HBV vaccine, for unvaccinated exposed employees (Ex. 6-199). In addition to treatment of the exposed employee,
AAOHIN has recommended that if a pregnant employee is exposed, the baby should be treated if necessary (Ex. 11-111).

Information Provided to the Physician. The proposal requires that the employer provide the evaluating physician with certain information [paragraph(f)(4)]. This information includes:

(i) A copy of this regulation and its appendices, and
(ii) A description of the affected employee's duties as they relate to the employee's occupational exposure.

The purpose of making this information available to the physician is to inform the physician of the requirements of the standard and to aid the physician in understanding the employee's assigned duties.

Physician's Written Opinion

For each evaluation required under this section the employer shall obtain and provide the employee with a copy of the evaluating physician's written opinion within 15 working days of the evaluation. The written opinion shall be limited to the following information:

(i) The physician's recommended limitations upon the employee's ability to receive the HBV vaccination.
(ii) A statement that the employee has been informed of the results of the medical evaluation and that the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.
(iii) Specific findings or diagnoses, which are related to the employee's ability to receive the HBV vaccine. Any other findings and diagnoses shall remain confidential.

The purpose of requiring the evaluating physician to supply the employee with a written opinion is to provide the employer with a documentation of a medical assessment of the employee's ability and need to receive HBV vaccination. The requirement that the employee be provided with a copy of the physician's written opinion within 15 working days ensures that the employee is informed in a timely manner of the results of the evaluation and the need for any additional follow-up, and of the receipt by the employer of the information contained in the physician's written opinion. The purpose of limiting the information the employee receives is to encourage employees to participate in the medical evaluation by removing concern that the employer will obtain information about their physical condition and specific findings or diagnoses that are unrelated to the employee's ability to receive vaccine.

Hepatitis B Vaccination and Post Exposure Follow-up Recordkeeping.

Medical records shall be maintained in accordance with paragraph (b)(1) of this section. The above notation is included in this discussion so that the employer and interested parties reviewing this discussion of the proposed medical surveillance requirements are made aware that there are requirements for medical surveillance recordkeeping elsewhere in the standard. These records must remain confidential.

Paragraph (g) Communication of Hazards to Employees

This proposed standard includes paragraph (g) entitled: "Communication of Hazards to Employees." This paragraph addresses the issue of transmitting information to employees about the hazards of bloodborne pathogens through the use of signs, labels, and information and training. This paragraph of the proposed standard on bloodborne pathogens would apply to all operations where there is potential for exposure to blood and other potentially infectious materials. OSHA's primary intent in this paragraph of the proposed standard is to ensure that employees will receive adequate warning (signs and labels) and training necessary to minimize or eliminate exposure to bloodborne pathogens.

Signs and labels

Paragraph (g)(1) of the proposed bloodborne pathogens standard provides the specific labeling and sign requirements that would have to be used to warn employees of the hazards to which they are exposed. The requirements for signs and labels are consistent with Section 6(b)(7) of the OSH Act, which prescribes the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed. There was also strong support in fee laboratorv director or other responsible individual be posted on the sign will ensure that, in the event of an emergency or other unforeseen event, a trained and knowledgeable individual will be available to provide guidance and ensure that procedures are followed to minimize or eliminate exposure.

The provisions for signs in paragraph (g)(1)(i) are virtually identical to the recommendations for signs found in Special Practices for Biosafety Levels 2 and 3 in "Biosafety in Microbiological and Biomedical Laboratories" (Ex. 6-338). The only exception is the additional requirement that the word "biohazard" be used. OSHA has added this requirement based on the likelihood that some individuals who are present in the general work area may be unfamiliar with the meaning of the biohazard symbol.
The hazard warning signs are intended to supplement the training which employees are to receive under the other provisions of paragraph (g)(2), since even trained employees need to be reminded of the location of regulated areas and of the precautions to be taken before entering these hazardous areas.

Paragraph (g)(1)(ii) would require that labels or other appropriate forms of warning be provided on containers of infectious waste; on refrigerators or freezers that are used to store blood or other potentially infectious materials and on other containers used to store or transport either blood or other potentially infectious materials. The only exception would be substitution of red bags or red containers for infectious waste and the use of containers of blood or blood components that are labeled as to their contents and have been released for distribution. (The reasons for these exemptions are discussed below.)

This is to alert employees of possible exposure since the nature of the material or contents will not always be readily identified as blood or other potentially infectious materials. The proposed labeling requirement reads as follows: BIOHAZARD, followed by the universal biohazard symbol in the color black, and any other appropriate designation, e.g., Infectious Waste. The purpose of the term “Biohazard” and the universal biohazard symbol are as described above for signs. Any “other appropriate designation” is also required because this would ensure that employees know the contents of the bag or container without opening it and risking possible exposure.

One result of the implementation of universal precautions is that, in most facilities, signs and labels that indicate the patient’s HIV or HBV infection status are no longer used. Under this method, for example, blood from all patients is treated as if it contains HBV or HIV, and there is no need for these particular signs and labels. In addition, the labeling of some blood specimens and not others may set up a dual system in which employees take fewer precautions with unlabelled specimens than with those labeled “HIV” or “HBV.” On the other hand, some employees may feel that if they are required to provide care to a patient who is known to be infected with HIV or HBV, the employee has a right to know that the patient is infected.

The proposed standard would neither require nor prohibit the posting of signs or labels of specimens to specify the patient’s HIV or HBV infection status as long as the employer has implemented universal precautions. Should OSHA continue to leave the decision to use labels and signs designating the patient’s infection status to the employer? Should OSHA prohibit the use of signs and labels stating the patient’s HIV or HBV infection status? Should OSHA require the use of these particular signs and labels?

The proposed standard would allow the substitution of red bags for labels on bags or containers of infectious wastes. OSHA recognizes the accepted current practice of “red bagging” infectious wastes. Paragraph (g)(2)(iv)(k) of the proposed standard would require that employees be trained to understand the meaning of all symbols used on signs and labels. This would include information on the meaning of red bags, thus assuring that OSHA’s intent, to inform employees of hazards present at their worksite, would be achieved by the use of red bags.

Although some products are available that have biohazard labels as an integral part of the container, the proposed standard would allow a label to be affixed to the container. This flexibility is particularly important since objects, such as refrigerators or freezers, would have to be labeled under certain circumstances.

The proposed standard would exempt containers of blood and blood components, labeled as to their contents and released for distribution, from the labeling provision of this standard. This exemption is justified because the standard would require the implementation of universal precautions as defined in paragraph (h) so that containers bearing a specific label which identifies blood or blood components would provide sufficient information to ensure that employees will know to take appropriate infection control measures. For example, the labeling requirements of the Food and Drug Administration for blood and blood products provide sufficient warning for a trained employee so that no additional labeling would be necessary. The Agency specifically seeks additional comments from the public on the appropriateness of this exemption.

Employee Information and Training

According to paragraph (g), the employer would be required to provide all employees exposed to bloodborne pathogens with training about the hazards associated with blood, and potentially infectious materials and the protective measures to be taken to minimize the risk of occupational exposure. Effective training is a critical element of any overall infection control program. It will ensure that employees understand hazards associated with bloodborne pathogens, the modes of transmission, the infection control plan, and the use of engineering controls, work practices, and personal protective clothing. Employees would also be trained in the appropriate actions to take in an emergency, and they would be informed of the reasons that they should participate in medical surveillance programs. This training would help reduce the risk of occupational exposure, consequently reducing exposure-related infection, illness, and death.

The proposed standard would require the employer to provide an explanation of the contents of the final standard on bloodborne pathogens including appendices. This ensures the employee will know the standard exists and will become familiar with its provisions. The proposed provisions for employee training are performance oriented, listing categories of information that must be provided to employees. This ensures that important information is communicated to employees while allowing employers the most flexible approach to providing training.

Training of employees would have to be accomplished at the time of initial assignment or within 150 days of the effective date of the final standard for bloodborne pathogens, whichever comes later. Employee training would be repeated and updated at least annually thereafter.

It is OSHA’s position, in general, that it is essential for employees to understand the nature of the hazards they may face in the course of their employment and the procedures to follow to minimize or eliminate the risks associated with their exposure to these hazards. This is particularly important in the case of bloodborne pathogens because a single exposure incident may result in an infection, illness or death. Because of the severity of the diseases and the potential to contact them from a single event, it is also important to retrain workers exposed to bloodborne pathogens on an annual basis. Annual retraining reinforces initial training and
provides an opportunity to present new information that had not been available at the time of initial training. In the November 27, 1987 ANPR, OSHA requested public comment and other pertinent information on how employees are currently informed of the occupational hazards associated with HBV and HIV; how employees should be trained to ensure that they understand the nature of HIV and HBV infections and the ways to reduce the likelihood of occupational exposure to these viruses; the number of employees who already have received training; how often training should be repeated; any model training programs available and whether employee training should address occupational exposures only or whether it should address personal behavior that increases risks as well. The more than 350 comments OSHA received comprise a record that strongly supports the need for employee training programs and endorses the conclusion that employee training should be mandated as an integral part of OSHA's standard on bloodborne pathogens. The comments also provided many suggestions regarding the types of information that should be included in a specific requirement for training, and OSHA has relied heavily on these comments in developing the proposed training requirements listed below. (See, for example, Exs. 11-1, 11-7, 11-51, 11-57, 11-58, 11-60, 11-111, 11-156, 11-181, 11-195, 11-199, 11-187, 11-233, 11-280, 11-327.) Typical of the comments received is that of the American Federation of State, County and Municipal Employees (AFSCME) (Ex. 11-157) which addresses the need for training as follows:

A critically important part of preventing injuries or illnesses in the workplace is training workers about potential hazards and safe working conditions. Workers shall have the same right to know about communicable disease hazards to their health that they now have for chemical hazards (Ex. 11-157).

The American Dental Association (ADA) noted that such training is already received as part of a dental education. "Dental professionals are already mandated as part of a dental education background, will receive adequate training in infection control procedures. Many commenters suggested such a provision, as seen in the citations below:

Training materials shall be of professional quality that is appropriate in content and vocabulary to education level, literacy and language background of employees. This would ensure that all employees, regardless of their cultural or educational background, will receive adequate training on infection control procedures. Many commenters suggested such a provision, as seen in the citations below:

Training materials shall be of professional quality and may involve a variety of media (Merck, Sharpe & Dohme, Ex. 11-365). Education must be appropriate to education level, literacy and language background; * * * clarify materials to workers at all levels with varying cultural, ethnic and language background (American Association of Occupational Health Nurses (AAOHN), Ex. 11-111). Program depth, content and frequency might vary widely depending on audience characteristics (such as prior training, educational background, job duties, nature and degree of risk) (American Hospital Association (AHA), Ex. 11-233).

The Service Employees International Union (SEIU) provided similar suggestions in recommending that the following factors be taken into consideration for training employees exposed to bloodborne pathogens:

(Employee) attitudes and knowledge about these diseases; educational level of workers and potential barriers to training (i.e., language difficulties of non-English speaking workers, limited literacy on the part of some workers * * * ) (Ex. 11-161).

The proposed standard would require that the training program include an explanation of the epidemiology, symptomatology, and modes of transmission of the diseases. This ensures a basic understanding of the diseases and the need to observe precautions to prevent disease transmission. There is general agreement in the record that such information would be needed in a training program for bloodborne pathogens. For example, the SEIU envisioned a training program where "there will be sessions on the general epidemiology of diseases as well as a clinical explanation of the disease" (Ex. 11-161). As a more general statement of the same principle, the National Institute of Occupational Safety and Health (NIOSH) commented that "[w]orkers require complete understanding of the modes of transmission of HBV and HIV to observe properly the protective measures required of them" (Ex. 11-187). Similarly, the State of Maryland (Ex. 11-283), AFSCME (Ex. 11-157), and the American Red Cross (ARC) (Ex. 11-280) endorsed the need for training workers to understand the diseases that could be transmitted by exposure.

Certain individuals, for example, infection control practitioners and some virologists, might be expected to be thoroughly familiar with some of the material in the training program. Is it appropriate to substitute some measure of competency in lieu of training for these individuals? OSHA seeks comment on this matter.

OSHA believes it is important for each worker to recognize how he or she specifically might be occupationally exposed to bloodborne pathogens and under which circumstances infection control precautions will be necessary. The proposed standard, therefore, would require employee training to include an explanation of the infection control program and of the appropriate methods for recognizing tasks that may involve exposure to blood, and other potentially infectious materials.

Several groups who have commented to OSHA's record on bloodborne pathogens stressed the need for workers to be able to recognize when they may be at risk of exposure. For example, the ARC (Ex. 11-280) commented:

Descriptions of staff duties must indicate whether duties routinely involve potential for exposure to infectious agents * * * whether such exposure might occasionally occur due to extra-ordinary circumstances * * * or whether duties do not include potential for exposure.

Likewise, AFSCME (Ex. 11-157) pointed out that "[*]raining should ensure that all workers * * * can identify tasks that may involve exposure to blood or other potentially infectious body fluids." In suggesting a specific training program, the SEIU (Ex. 11-101)
proposed that "... workers will learn the exposure associated with specific occupations and tasks in health care facilities."
The proposed standard would require that employees be provided information on appropriate methods for recognizing tasks and other activities that could involve exposure to blood or potentially infectious materials. This would ensure that workers will be prepared for unusual or extraordinary circumstances that include the potential for exposure to bloodborne pathogens. Typical of the support in the record for this provision is the following comment from the ARC (Ex. 11-280):

Staff must understand * * * actions to be taken when confronted with a situation of potential exposure that had not been anticipated by the employee. Such training might include knowledge of the existence of safety procedures applicable to the situation and availability of assistance.

To ensure that employees will be able to identify and implement methods of reducing or preventing occupational exposure to bloodborne pathogens, the proposed training requirements would require an explanation of the use and limitations of appropriate engineering controls, work practice controls, and personal protective equipment.

The proposed standard would require that employees have access to a variety of critical knowledge about the proper use of protective equipment and clothing. This would ensure that employees are knowledgeable about the proper use of personal protective equipment to achieve appropriate barrier protection.

Comments in the record support inclusion of information on personal protective equipment and clothing in the training program for employees. For example, AFSCME (Ex. 11-157) suggested the following:

Training should ensure that all workers * * * know where all protective equipment is kept, how to remove, handle, decontaminate and dispose of contaminated equipment.

The ARC (Ex. 11-280) noted that:

Staff must understand * * * protective clothing and equipment (e) available and their proper use * * * all proper practices and pertinent Standard Operating Procedures, including handling, decontamination, and disposal of contaminated clothing and equipment.

NIOSH (Ex. 11-167) stressed the need for employee training on measures to control exposure to bloodborne pathogens, recommending that "[a]ll workers * * * receive detailed training on engineering controls, personal protective clothing and equipment and work practices required for their duties." According to NIOSH, this training would have to cover not only the proper use of protective devices, but also the inherent limitations of those devices.

The proposed standard would require that employees be provided with information on the hepatitis B vaccine to ensure that they are aware of its efficacy and safety as well as its benefits. The vaccine is the best available means of preventing HBV in the vast majority of workers. Nevertheless, a disappointingly large percentage of employees at risk remain unvaccinated, many because of a lack of knowledge about the vaccine including an unfounded fear of contracting HBV or HIV from the vaccine. According to the vaccine's manufacturer, a number of studies on worker acceptance attribute the "underutilization of the vaccine" to a "lack of information about the disease and the vaccine safety and effectiveness" (Ex. 11-165). In fact, a study conducted at three teaching hospitals found that "the amount of information received concerning the need for and safety of the vaccine correlated significantly with the level of vaccination among employees. Approximately 50% of employees who reported receiving adequate information were vaccinated, whereas fewer than 20% who indicated they did not receive adequate information requested the vaccine (Ex. 11-165)." Merck (Ex. 11-165) concluded that successful vaccination programs combined "proper education about the disease and the vaccine, [with] * * * active support for employee vaccinations from the managerial staff, and * * * vaccine(s) without cost to the employees."

OSHA believes informing employees about the HBV vaccine is a critical component of any training program. The Agency seeks comment on how this can best be achieved and requests interested parties to inform OSHA of specific methods that have proven successful in encouraging employees to accept the vaccine.

It is important that employees understand the actions to be taken if an occupational exposure occurs as well as what medical follow-up is available for exposed individuals to ensure that they seek appropriate medical treatment, prophylaxis and/or post-exposure follow-up. Therefore, the proposed standard would require an explanation of the procedure to follow if an occupational exposure to bloodborne pathogens occurs, including the method of reporting the incident and a description of the medical follow-up that would be made available.

Support for including training about exposure reporting and post-exposure follow-up after an exposure incident was given by several commenters to the record, such as the ARC (Ex. 11-280) who stressed that "[t]he staff must understand * * * proper procedures to be followed in case of an incident or exposure." Elaborating on this position, AFSCME (Ex. 11-157) stated:

Training should ensure that all workers * * * know the corrective actions to take in the event of * * * personal exposure to fluids or tissues, the appropriate reporting procedures and the medical monitoring recommended in cases of suspected parenteral exposure.

The AAOHN (Ex. 11-111) took an even more explicit position regarding training on the need for follow-up medical care in stating that:

All health care workers should receive education about the counseling of occupationally exposed individuals, monitoring and surveillance activities, current management of the disease process and legal, ethical issues.

The proposed standard would require an explanation of the required signs and labels, including color codings and "red bagging", to ensure that employees understand the warning messages presented and the need for appropriate infection control procedures.

Employees in HIV/HBV research laboratories and HIV/HBV production facilities may be at especially high risk of infection following occupational exposure because they handle concentrated preparations of these viruses. OSHA has concluded that the risk is sufficiently high to warrant a requirement for additional training in the handling of HIV/HBV. The proposed standard, therefore, would require that employees in such facilities who have occupational exposures be trained in and demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV/HBV.

The proposed rule would also require employees in HIV/HBV research laboratories and HIV/HBV production facilities to be experienced in the handling of human pathogens or tissue cultures prior to working with HIV or HBV. Employees with no prior experience in handling human pathogens would have to participate in an on-the-job training program where initial work activities would not include the handling of infectious agents. A progression of work activities would be...
permitted as techniques are learned and proficiency is developed. An employee would be permitted to participate in work activities involving infectious agents only after proficiency has been demonstrated to ensure that the worker is able to handle HIV or HBV as safely as possible, thereby minimizing the risk of occupationally related infection and illness.

OSHA's provisions proposing to require additional training for employees in HIV/HBV research laboratories and HIV/HBV production facilities are patterned after the recommendations made by an expert team convened by the Director of the National Institutes of Health (Ex. 6-312). This expert team made the following recommendations to help assure a safe and healthful work environment for employees who handle concentrated preparations of HIV:

A. Strictly adhere to standard microbiologic practices and techniques:

The most important recommendation is to adhere to standard microbiologic practices and techniques. Persons working with HIV must be aware of potential hazards and must be trained and proficient in practice and techniques necessary for self-protection. Employees must be informed that parental exposure is the most serious potential hazard for causing a laboratory-acquired infection. They must be able to recognize how such exposures occur and how they can be prevented. Although on-the-job training is an acceptable approach for learning techniques and practices, it is imperative that proficiency be obtained before virus is actually handled. Initial work activities should not include the handling of virus. A progression of work activities should be assigned as techniques are learned and proficiency is developed.

B. Assure that workers are proficient in virus-handling techniques:

Selection criteria for employees who will work in production operations or with concentrated preparations of HIV should require experience in the handling of human pathogens or tissue cultures. If an employee has not had such experience, s/he should participate in carefully structured, well-supervised on-the-job training programs. The director or person in charge of the laboratory or production facility must ensure that personnel are appropriately trained and are proficient in practices and techniques necessary for self-protection. Initial work activities should not include the handling of virus. A progression of work activities should be assigned as techniques are learned and proficiency is developed. Virus should only be introduced into the work activities after the supervisor is confident it can be handled safely.

Paraphrase (h) Recordkeeping

The proposed rule would require that employers maintain records related to hepatitis B vaccination and post exposure follow-up and training. These requirements are in accordance with section 8(c) of the Act which authorizes the promulgation of regulations requiring an employer to keep necessary and appropriate records regarding activities to permit the enforcement of the Act, or to develop information regarding the causes and prevention of occupational illnesses. OSHA has determined that, in this context, requiring employers to maintain medical and training records is necessary and appropriate. In addition, medical records are necessary for the proper evaluation of the employee's immune status and for proper medical management following an exposure incident.

The proposed standard would require employers to maintain medical records which include: (1) The name and social security number of the employee; (2) a copy of the employee's hepatitis B vaccination record and medical records relative to the employee's ability to receive the HBV vaccine or the circumstances of an exposure incident; (3) a copy of all results of physical examinations, medical testing and follow-up procedures as they relate to the employee's ability to receive vaccination or post-exposure evaluation following an exposure incident; (4) the employer's copy of the physician's written opinion; and (5) a copy of the information provided to the physician as required by paragraph (f) of this proposed standard.

The proposed standard requires that the employer keep the employee's medical record confidential. OSHA has attempted to reduce barriers to exposure reporting by requiring that medical records, including all test results, be kept confidential except as otherwise required by law. Fear that coworkers or others may see test results may discourage the reporting of exposure incidents and seeking follow-up care. OSHA recognizes the sensitive nature of HIV testing and the possible repercussions should that test be positive. Unfortunately, some individuals have suffered the loss of their jobs, homes, medical and life insurance, and have been otherwise stigmatized as a result of testing positive for antibody to HIV. This provision would assure that testing results would not be disclosed and would encourage exposure reporting.

The time period for retention of medical records is the duration of employment plus thirty years which is consistent with 29 CFR 1910.20. The transfer of employee medical records is to be in accordance with the provisions of paragraph (h) of 29 CFR 1910.20. If an employer ceases to do business and there is no successor employer, the employer is to notify NIOSH at least three months prior to the disposal of the records and to transmit them to the Director for retention, if requested. The employer may cease to do business before or during this time period. However, the records must be retained for at least 3 months after NIOSH is notified.

The proposed rule would require employers to maintain training records which include: (1) The dates of the training sessions; (2) the contents or a summary of the training session; (3) the names of the persons conducting the training; and (4) the names of all persons attending the training sessions. The time period for retention of training records is five years. Maintaining these training records for five years will facilitate review of the content, consistency, and completeness of the training program by OSHA and the employer. The transfer of training records is to be in accordance with the provisions of paragraph (h) of 29 CFR 1910.20. OSHA believes that these records are necessary and appropriate to the enforcement of the standard.

The access provisions of this proposed standard are consistent with 29 CFR 1910.20. Employees and their designated representatives are, in general, allowed unrestricted access to training records. Access to medical records is also provided for employees and, if the employee has given specific written consent, for the employee's designated representative. OSHA retains unrestricted access to both these medical and training records, but the Agency's access to personally identifiable medical records is subject to regulations designed to protect privacy which have been published at 29 CFR 1913.10 (see 45 FR 35584).

Paraphrase (i) Dates

As proposed, the final rule would become effective thirty (30) days after publication in the Federal Register. This will allow time for public distribution and give employers time to familiarize themselves with the standard. The various provisions have phased-in effective dates.

The employers initial duty under the standard is the exposure determination required by paragraph (c)(1) of this section and would have to be completed within ninety days of the effective date of the standard. The employer would then have an additional 30 days (120 days after the effective date) to complete the infection control plan required by paragraph (c)(2).
Thirty days later, 150 days after the effective date of the standard, paragraphs (d)(2) engineering controls and work practice controls, (d)(3) personal protective equipment, (d)(4) housekeeping, (e) HIV and HBV research laboratories and production facilities, (f) hepatitis B vaccination and post-exposure follow-up, and (g) communication of hazards to the employee, and (h) recordkeeping would take effect. Since many employers have many of these provisions already in effect through current infection control plans and the implementation of universal precautions, OSHA believes that these dates provide adequate time for compliance.

X. Public Participation—Notice of Hearing

Pursuant to section 6(b)(3) of the Act, an opportunity to submit oral testimony concerning the issues raised by the proposed standard including economic and environmental impacts, will be provided at three informal public hearings scheduled to begin at 16:00 p.m. at places and on dates as follows:


Chicago, IL: October 17, 1989. Palmer House, 17 East Monroe Street, Chicago, IL 60603.


Notice of Intention to Appear

All persons desiring to participate at the hearing must file in quadruplicate a Notice of Intention to Appear, postmarked on or before August 14, 1989, addressed to Mr. Tom Hall, OSHA Division of Consumer Affairs, Docket H-370, Room N-3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 523-8615. A Notice of Intention to Appear also may be transmitted by facsimile to (202) 523-5046 or (for FTS) to 8-523-5046, provided the original and 4 copies of the Notice are sent to the above address thereafter.

The Notices of Intention to Appear, which will be available for inspection and copying at the OSHA Technical Data Center Docket Office, Room N-2625, 200 Constitution Avenue NW., Washington DC 20210; telephone (202) 523-7894; must contain the following information:

(1) The name, address, and telephone number of each person to appear;

(2) The capacity in which the person will appear;

(3) The approximate amount of time requested for the presentation;

(4) The specific issues that will be addressed;

(5) A statement of the position that will be taken with respect to each issue addressed;

(6) Whether the party intends to submit documentary evidence, and if so, a brief summary of that evidence; and

(7) Whether the party wishes to testify on the days set aside to focus on hepatitis B vaccination.

At which hearing or hearings the party wishes to testify.

Filing of Testimony and Evidence Before Hearing

Any party requesting more than 10 minutes for a presentation at the hearing, or who will submit documentary evidence, must provide in quadruplicate the complete text of his testimony, including any documentary evidence to be presented at the hearing, to the OSHA Division of Consumer Affairs. This material must be received by August 31, 1989, for the Washington, DC hearing and September 29, 1989, for the Chicago, IL, and San Francisco, CA hearings, and it will be available for inspection and copying at the Technical Data Center Docket Office. Each such submission will be reviewed in light of the amount of time requested in the Notice of Intention to Appear. In those instances where the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact.

Any party who has not substantially complied with this requirement may be limited to a 10-minute presentation. Any party who has not filed a Notice of Intention to Appear may be allowed to testify, as time permits, at the discretion of the Administrative Law Judge. OSHA emphasizes that the hearing is open to the public, and that interested persons are welcome to attend. However, only persons who have filed proper notices of intention to appear at the hearing will be entitled to ask questions and otherwise participate fully in the proceeding.

Conduct and Nature of Hearing

The hearing will commence at 10 a.m., on September 12, 1989. At that time any procedural matters relating to the proceeding will be resolved. The nature of the informal rule making hearings to be held is established in the legislative history of section 6 of the Act and is reflected by the OSHA hearing regulations (see 29 CFR 1911.15(a)). Although the presiding officer is an Administrative Law Judge and questioning by interested persons is allowed on crucial issues, it is clear that the proceeding shall remain informal and legislative in type. The essential intent is to provide an opportunity for effective oral presentation by interested persons which can be carried out expeditiously and in the absence of rigid procedures which might unduly impede or protract the rulemaking process.

The hearings will be conducted in accordance with 29 CFR Part 1911. The hearing will be presided over by an Administrative Law Judge who will have all the powers necessary and appropriate to conduct a full and fair informal hearing as provided in 29 CFR 1911 including the powers:

1. To regulate the course of the proceedings;

2. To dispose of procedural requests, objections and comparable matters;

3. To confine the presentation to the matters pertinent to the issues raised;

4. To regulate the conduct of those present at the hearing by appropriate means;

5. In the Judge’s discretion, to question and permit the questioning of any witness and to limit the time for questioning; and

6. In the Judge’s discretion, to keep the record open for a reasonable, stated time to receive written information and additional data, views, and arguments from any person who has participated in the oral proceedings.

Written Comments

Interested persons are invited to submit written comments on the issues raised in the proposal and summarized in this notice. Written comments must be postmarked on or before August 14, 1989, and submitted in quadruplicate to the Docket Office, Docket Number H-370, Room N-2625, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC 20210. The telephone number of the Docket Office is (202) 523-7894, and its hours of operation are 8:15 a.m. to 4:45 p.m. Monday through Friday except Federal holidays. Comments limited to 10 pages or less in length may also be transmitted by facsimile to (202) 523-5046 or (for FTS) to 8-523-5046, provided the original and 4 copies of the comment are sent to the Docket Officer thereafter. Written submissions must clearly identify the provisions of the proposal which are addressed and the position taken on each issue.

All materials submitted will be available for inspection and copying at
XI. Authority and Signature

This document was prepared under the direction of Alan C. McMillan, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

Accordingly, pursuant to sections 6(b), 6(c) and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655, 657), 29 CFR Part 1911 and Secretary of Labor's Order No. 9-83 (48 FR 35736), 29 CFR Part 1910 is proposed to be amended as set forth below.

List of Subjects in 29 CFR Part 1910


Signed at Washington, DC on this 19th day of May, 1989.

Alan C. McMillan,
Acting Assistant Secretary of Labor.

XII. The Proposed Standard

PART 1910—[AMENDED]

Subpart Z—[Amended]

1. The general authority citation for Subpart Z of 29 CFR Part 1910 continues to read as follows and a new citation for § 1910.1030 is added:

Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657, Secretary of Labor's Orders Nos. 12-71 (36 FR 8754), 8-76 (41 FR 25059), or 8-85 (48 FR 35736), as applicable; and 29 CFR Part 1911.

Section 1910.1030 also issued under 29 U.S.C. 655.

2. Section 1910.1030 is added to read as follows:

§ 1910.1030 Bloodborne pathogens.

(a) Scope and application. This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

(b) Definitions. For purposes of this section, the following shall apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

Blood means human blood, human blood components and products made from human blood.

Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

"Disinfect" means to inactivate virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial endospores) on inanimate objects.

"Engineering Controls" means controls that isolate or remove the hazard from the workplace.

"Exposure Incident" means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

"Infectious Waste" means blood and blood products, contaminated sharps, pathological wastes, and microbiological wastes.

"Occupational Exposure" means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties. This definition excludes incidental exposures that may take place on the job, and that are neither reasonably nor routinely expected and that the worker is not required to incur in the normal course of employment.

"Other Potentially Infectious Materials" means:

(1) The following body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, and any body fluid that is visibly contaminated with blood.

(2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead) and

(3) HIV- or HBV-containing cell or tissue cultures, organ cultures, and culture medium or other solutions; and blood, organs or other tissues from experimental animals infected with HIV or HBV.
"Parenteral" means exposure occurring as a result of piercing the skin barrier (e.g., subcutaneous, intramuscular, intravenous routes). "Patient" means any individual, living or dead, whose blood, body fluids, tissues, or organs may be a source of exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the mentally retarded; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains prior to embalming; and individuals who donate or sell blood or blood components.

"Personal Protective Equipment" is specialized clothing or equipment worn by an employee to protect him/her from a hazard.

"Production Facility" means a facility engaged in industrial-scale, large-volume production of HIV or HBV or in high concentration production of HIV or HBV.

"Research Laboratory" means a laboratory producing research-laboratory-scale amounts of HIV or HBV.

"Sharps" means any object that can penetrate the skin including, but not limited to, needles, scalpels, and broken capillary tubes.

"Sterilize" means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

"Universal precautions" is a method of infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV and other bloodborne pathogens.

"Work Practice Controls" means controls that reduce the likelihood of exposure by altering the manner in which a task is performed.

(c) Infection control—(1) Exposure Determination. (i) Each employer who has employees with occupational exposure as defined by paragraph (b) of this section shall identify and document those tasks and procedures where occupational exposures may take place.

(ii) Each employer shall identify and document all positions with occupational exposure.

(iii) This exposure determination shall be made without regard to the use of personal protective equipment.

(2) Infection Control Plan. (i) Each employer having employees whose reasonably anticipated duties may result in occupational exposure shall establish a written infection control plan designed to minimize or eliminate employee exposure.

(ii) This infection control plan shall contain the following as a minimum: (A) The exposure determination required by paragraph (c)(1) and (B) The schedule and method of implementation for each of the applicable paragraphs of this standard.

(iii) This infection control plan shall be reviewed and updated as necessary to reflect significant changes in tasks or procedures.

(iv) The infection control plan shall be made available to the Assistant Secretary and the Director for examination and copying.

(c) Methods of Compliance—(1) General. Universal precautions shall be observed to prevent contact with blood and other potentially infectious materials, unless those precautions would interfere with the proper delivery of health care or public safety services in a particular circumstance, or would create a significant risk to the personal safety of the worker.

(2) Engineering and work practice controls. (i) Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

(ii) Employees shall wash their hands immediately or as soon as possible after removal of gloves or other personal protective equipment and after hand contact with blood or other potentially infectious materials.

(iii) All personal protective equipment shall be removed immediately upon leaving the work area or as soon as possible if overtly contaminated and placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

(iv) Used needles and other sharps shall not be sheared, bent, broken, recapped, or reassembled by hand. Used needles shall not be removed from disposable syringes.

(v) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a potential for occupational exposure.

(vi) Food and drink shall not be stored in refrigerators, freezers, or cabinets where blood or other potentially infectious materials are stored or in other areas of possible contamination.

(vii) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, and aerosolization of these substances.

(viii) Mouth pipetting/suctioning is prohibited.

(3) Personal protective equipment—(i) Provision and Use. When there is a potential for occupational exposure, the employer shall provide and assure that the employee uses appropriate personal protective equipment such as, but not limited to, gloves; goggles; shoe- and foot-proofer aprons, laboratory coats, and head and foot coverings; face shields or masks and eye protection; and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices.

(ii) Accessibility. The employer shall assure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or issued to employees. Hypoallergenic gloves shall be readily accessible to those employees who are allergic to the gloves normally provided.

(iii) Cleaning. The employer shall provide for the cleaning, laundering or disposal of personal protective equipment required by paragraphs (d) and (e) of this standard.

(iv) Repair and replacement. The employer shall repair or replace required personal protective equipment as needed to maintain its effectiveness.

(v) Gloves. Gloves shall be worn when the employee has the potential for the hands to have direct skin contact with blood, other potentially infectious materials, mucous membranes, non-intact skin, and when handling items or surfaces soiled with blood or other potentially infectious materials.

(A) Disposable (single use) gloves, such as surgical or examination gloves, shall be replaced as soon as possible when visibly soiled, torn, punctured, or when their ability to function as a barrier is compromised. They shall not be washed or disinfected for re-use.

(B) Utility gloves may be disinfected for re-use if the integrity of the glove is not compromised, however they must be discarded if they are cracked, peeling, discolored, torn, punctured, or exhibit other signs of deterioration.

(vi) Masks, Eye Protection, and Face Shields. Masks and eye protection or chin-length face shields shall be worn whenever splashes, spray, sputter, droplets, or aerosols of blood or other potentially infectious materials may be generated and there is a potential for eye, nose, or mouth contamination.

(vii) Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing shall be worn when the employee has a potential for occupational exposure. The type and characteristics will depend upon the task and degree of exposure anticipated; however, the clothing selected shall form an effective barrier.

(A) Gowns, lab coats, aprons, or similar clothing shall be worn if there is a potential for soiling of clothes with blood or other potentially infectious materials.
(B) Fluid-resistant clothing shall be worn if there is a potential for splashing or spraying of blood or other potentially infectious materials. (C) Surgical caps or hoods shall be worn if there is a potential for splashing or splattering of blood or other potentially infectious materials on the head. (D) Fluid-proof clothing shall be worn if there is a potential for clothing becoming soaked with blood or other potentially infectious materials. (E) Fluid-proof shoe covers shall be worn if there is a potential for shoes to become contaminated and/or soaked with blood or other potentially infectious materials.

(4) Housekeeping—(i) General. Employers shall assure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement the appropriate written schedule for cleaning and method of disinfection based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed. (ii) Cleaning and Disinfection. All equipment and environmental and working surfaces shall be properly cleaned and disinfected after contact with blood or other potentially infectious materials. (A) Work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; when surfaces are overtly contaminated; immediately after any spill of blood or other potentially infectious materials; and at the end of the work shift. (B) Protective coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper may be used to cover equipment and environmental surfaces. These coverings shall be removed and replaced at the end of the work shift or when they become overtly contaminated. (C) Equipment which may become contaminated with blood or other potentially infectious materials shall be checked routinely and prior to servicing or shipping and shall be decontaminated as necessary. (D) All bins, pails, cans, and similar receptacles intended for reuse which have a potential for becoming contaminated with blood or other potentially infectious materials shall be inspected, cleaned, and disinfected on a regularly scheduled basis and cleaned and disinfected immediately or as soon as possible upon visible contamination. (E) Broken glassware which may be contaminated shall not be picked up within the facility, typed. It shall be cleaned up using mechanical means, such as a brush and dust pan, a vacuum cleaner, tongs, cotton swabs or forceps. (F) Specimens of blood or other potentially infectious materials shall be placed in a closable, leakproof container labeled or color-coded according to paragraph (g)(1)(ii) prior to being stored or transported. If outside contamination of the primary container is likely, then a second leakproof container that is labeled or color-coded according to paragraph (g)(1)(ii) shall be placed over the outside of the first and closed to prevent leakage during handling, storage, or transport. If puncture of the primary container is likely, it shall be placed within a leakproof, puncture-resistant secondary container. (G) Reusable items contaminated with blood or other potentially infectious materials shall be decontaminated prior to washing and/or reprocessing. (iii) Infectious Waste Disposal. (A) All infectious waste destined for disposal shall be placed in closable, leakproof containers or bags that are color coded or labeled as required by paragraph (g)(1)(ii) of this standard. (1) If outside contamination of the container or bag is likely to occur then a second leakproof container or bag which is closable and labeled or color-coded as described in paragraph (g)(1)(ii) shall be placed over the outside of the first and closed to prevent leakage during handling, storage, and transport. (2) Disposal of all infectious waste shall be in accordance with applicable Federal, state, and local regulations. (B) Immediately after use, sharps shall be disposed of in closable, puncture-resistant, disposable containers which are leakproof on the sides and bottom that are labeled or color-coded according to paragraph (g)(1)(ii). (1) These containers shall be easily accessible to personnel and located in the immediate area of use. (2) These containers shall be replaced routinely and not allowed to overfill. (iv) Laundry. (A) Laundry from workplaces with employees covered under paragraph (a) of this section that is contaminated with blood or other potentially infectious materials or may contain contaminated sharps shall be treated as if it were contaminated and shall be handled as little as possible and with a minimum of agitation. (1) Contaminated laundry shall be bagged at the location where it was used and shall not be sorted or rinsed in patient-care areas. (2) Contaminated laundry shall be placed and transported in bags that are labeled or color-coded as described in paragraph (g)(1)(ii). Whenever this laundry is wet and presents the potential for soak-through of or leakage from the bag, it shall be placed and transported in leakproof bags. (B) The employer shall ensure that laundry workers wear protective gloves and other appropriate personal protective equipment to prevent occupational exposure during handling or sorting. (e) HIV and HBV Research Laboratories and Production Facilities. (1) This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard. (2) Research laboratories and production facilities shall meet the following criteria: (i) Standard microbiological practices. All infectious liquid or solid waste shall be decontaminated before being disposed of. (ii) Special practices. (A) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress. (B) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof container that is closed before being removed from the work area. (C) Access to the work area shall be limited to authorized persons only. Policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms. (D) When potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with the provisions outlined in paragraph (g)(3)(i) of this standard. (E) All activities involving potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work shall be conducted in open vessels on the open bench. (F) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area.
area and shall be decontaminated before being laundered.
(C) Special care shall be taken to avoid skin contamination with potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with potentially infectious materials is unavoidable.
(H) All waste from work areas including animal rooms shall be decontaminated before disposal.
(I) Vacuum lines shall be protected with high-efficiency particulate air (HEPA) filters and liquid disinfectant traps.

(W) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and intraperitoneal bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of potentially infectious fluids. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. A needle shall not be bent, sheared, replaced in the syringe or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before being discarded or reused.

(K) Spills and accidents that result in overt exposures of employees to potentially infectious materials shall be immediately reported to the laboratory director or other responsible person.

(I) A biosafety manual shall be prepared or adopted. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(ii) The employer shall assure that all employees with an occupational exposure on average one or more times per month to blood or other potentially infectious materials, unless the employee has a previous HBV vaccination or unless antibody testing has revealed that the employee is immune. If the employee initially declines HBV vaccination but at a later date while still covered under the standard decides to accept the HBV vaccine, the employer shall provide the vaccine at that time. Should a booster dose(s) be recommended at a future date, such booster dose(s) shall be provided according to standard recommendations for medical practice.

(ii) HBV antibody testing shall be made available to an employee who desires such testing prior to deciding whether or not to receive HBV vaccination. If the employee is found to be immune to HBV by virtue of adequate antibody titer, then the employer is not required to offer the HBV vaccine to that employee.

(3) Post-exposure evaluation and follow-up. Following a report of an exposure incident, the employer shall make available to each employee covered by paragraph (a) a confidential medical evaluation and follow-up, including at least the following elements:

(i) Documentation of the route(s) of exposure, HBV and HIV antibody status of the source patient(s) (if known), and the circumstances under which the exposure occurred.

(ii) If the source patient can be determined and permission is obtained, collection of and testing of the source patient’s blood to determine the presence of HIV or HBV infection.

(iii) Collection of blood from the exposed employee as soon as possible after the exposure incident for the determination of HIV and/or HBV status. Actual antibody or antigen testing of the blood or serum sample may be done at that time or at a later date if the employee so requests.

(iv) Follow-up of the exposed employee including antibody or antigen testing, counseling, illness reporting, and safe and effective post-exposure...
prophylaxis, according to standard recommendations for medical practice.

4. Information provided to the physician. The employer shall provide the following information to the evaluating physician:

(i) A copy of this regulation and its appendices and

(ii) A description of the affected employee's duties as they relate to the employee's occupational exposure.

5. Physician's written opinion. For each evaluation under this section, the employer shall obtain and provide the employee with a copy of the evaluating physician's written opinion within 15 working days of the completion of the evaluation. The written opinion shall be limited to the following information:

(i) The physician's recommended limitations upon the employee's ability to receive hepatitis B vaccination.

(ii) A statement that the employee has been informed of the results of the medical evaluation and that the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

(iii) Specific findings or diagnoses, which are related to the employee's ability to receive HBV vaccination. Any other findings and diagnoses shall remain confidential.

6. Medical recordkeeping. Medical records required by this standard shall be maintained in accordance with paragraph (b)(1) of this section.

7. Communication of Hazards to Employees—(1) Signs and Labels—(ii) Signs. The employer shall post signs at the entrance to work areas specified in paragraph (e) of this standard which shall bear the following legend:

**BIOHAZARD**

![BIOHAZARD Symbol]

[Name of the Infectious Agent]

[Special requirements for entering the area]

8. Communication of Hazards to Employees—(2) Labels—(i) Labels. (A) Warning labels shall be affixed to containers of infectious waste, refrigerators and freezers containing blood and other potentially infectious materials; and other containers used to store or transport blood or other potentially infectious materials except as provided in paragraph (g)(1)(ii)(E) and (F).

(B) Labels required by this section shall include the following legend:

**BIOHAZARD**

(C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering or symbols in a contrasting color.

(D) Labels required by paragraph (g)(1)(ii) shall either be an integral part of the container or shall be affixed as close as safely possible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

(E) Red bags or red containers may be substituted for labels on containers of infectious waste.

(F) Containers of blood or blood components that are labeled as to their contents and have been released for distribution are exempted from the labeling requirements of paragraph (g).

9. Information and Training. (1) Employers shall ensure that all employees with occupational exposure participate in a training program.

(ii) Training shall be provided at the time of initial employment or within 90 days after the effective date of this standard and at least annually thereafter.

(iii) Material appropriate in content and vocabulary to educational level, literacy, and language background of employees shall be used.

(iv) The training program shall contain the following elements:

(A) A copy of this standard and an explanation of its contents;

(B) A general explanation of the epidemiology and symptoms of bloodborne diseases;

(C) An explanation of the modes of transmission of bloodborne pathogens;

(D) An explanation of the employer's infection control program.

(E) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

(F) An explanation of the use and limitations of practices that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

(G) Information on the types, proper use, location, removal, handling, decontamination and/or disposal of personal protective equipment;

(H) An explanation of the basis for selection of personal protective equipment;

(I) Information on the hepatitis B vaccine, including information on its efficacy, safety, and the benefits of being vaccinated.

(J) Information on the appropriate actions to take and persons to contact in an emergency;

(K) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available. Also information on the medical counseling that the employer is providing for exposed individuals; and

(L) An explanation of the signs and labels and/or color coding required by paragraph (g)(1).

(v) Additional training. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following training in addition to the above training requirements:

(A) Employees shall be trained in and demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

(B) Employees shall be experienced in the handling of human pathogens or tissue cultures prior to working with HIV or HBV.

(C) A training program shall be provided to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed.
The employee shall participate in work activities involving infectious agents only after proficiency has been demonstrated.

(h) Recordkeeping—(1) Medical records. (i) The employer shall establish and maintain an accurate record for each employee subject to paragraph (f) of this section, in accordance with 29 CFR 1910.20.

(ii) This record shall include:
   (A) The name and social security number of the employee;
   (B) A copy of the employee's hepatitis B vaccination records and medical records relative to the employee's ability to receive vaccination or the circumstances of an exposure incident;
   (C) A copy of all results of physical examinations, medical testing, and follow-up procedures as they relate to the employee's ability to receive vaccination or to post-exposure evaluation following an exposure incident;
   (D) The employer's copy of the physician's written opinion; and
   (E) A copy of the information provided to the physician as required by paragraphs (f)(4).

(iii) Confidentiality. The employer shall assure that employee medical records required by paragraph (f) are:
   (A) Kept confidential; and
   (B) Are not disclosed or reported to any person within or outside the workplace except as required by this section or as may be required by law.

(iv) The employer shall maintain this record for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.20.

(2) Training Records. (i) Training records shall include the following information:
   (A) The dates of the training sessions;
   (B) The contents or a summary of the training sessions;
   (C) The names of persons conducting the training; and
   (D) The names of persons attending the training sessions.

(ii) These records shall be maintained for 5 years.

(3) Availability. (i) The employer shall assure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, employee representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20.

(iii) Employee medical and training records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, and to the Assistant Secretary in accordance with 29 CFR 1910.20.

(4) Transfer of records. (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.20(b).

(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director if required by the Director to do so within that three month period.

(i) Dates—(1) Effective Date. The standard shall become effective on [insert date 30 days after publication in the Federal Register].

(2) Exposure Determination. The exposure determination required by paragraph (c)(1) of this section shall be completed within 90 days of the effective date of this standard.

(3) Infection Control Plan. The Infection Control Plan required by paragraph (c)(2) of this section shall be completed within 120 days of the effective date of this standard.

(4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping shall take effect 150 days after the effective date of this standard. OSHA expects that the employer will have initiated, but perhaps not completed, the HBV vaccination series within this time period.

[FR Doc. 89-12470 Filed 5-23-89; 8:45 am]
Part III

Department of Labor

Office of the Secretary

29 CFR Part 70
Implementing Freedom of Information Act and Executive Order 12600; Final Rule
The Department will consider all comments before deciding whether to change or adopt these rules. If any comments are received which suggest that further action is necessary, a subsequent notice may be published in the Federal Register.

ADDRESS: Written comments on the rule adding the provision at § 70.40(d)(4) and modifying the provision at § 70.20(d)(2) may be mailed or delivered to Seth Zinman, Associate Solicitor for Legislation and Legal Counsel, Office of the Solicitor, U.S. Department of Labor, Room N–2428, 200 Constitution Avenue NW., Washington, DC 20210.


SUPPLEMENTARY INFORMATION:
Publication in Final of § 70.20(d)(2) and 70.40(d)(4)

On February 23, 1988, the Department of Labor published a proposed rule in the Federal Register implementing the Freedom of Information Reform Act of 1986, Executive Order 12600, and revisions to existing Department of Labor regulations implementing the Freedom of Information Act. The Freedom of Information Reform Act of 1986 requires each agency to promulgate regulations specifying the schedule of fees applicable to the processing of requests, and establishing guidelines for determining when such fees should be waived or reduced. Executive Order 12600 requires agencies to establish procedures for notifying submitters of commercial information when the agency determines that it may be required to disclose the information under FOIA. The revisions to existing Department of Labor regulations implementing the Freedom of Information Act are intended to, among other things, simplify the Department’s regulations and to clarify the description of its procedures for access to records under FOIA.

This document also adds a provision for the assessment of mailing costs. A provision similar to the one set forth below was contained in the Department’s existing regulations but was inadvertently omitted from the proposal published on February 23, 1988 [53 FR 5346]. Therefore, it is being incorporated in the final rule at this time. Section 70.20(d)(2) has also been modified in the final rule to permit charging requesters for not only the direct costs of computer tapes, but also for other types of tape as well when information is made available in that form. As explained below, the Department of Labor is requesting comments on both of these provisions.


For further information, contact Seth D. Zinman, Associate Solicitor for Labor for Legislation and Legal Counsel, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–2428, Washington, DC 20210.
Provide Submitters of Business Information With Hearing in Connection With Opportunity To Object to Disclosure

One commenter suggested that submitters of business information be afforded a hearing in connection with determinations regarding whether business information should be disclosed or afforded Exemption 4 protection. The proposed rule was fashioned after the requirements of Executive Order 12600. That Executive Order contains no requirement to give submitters of business information a hearing. Moreover, as submitters of business information themselves will in most instances be the only persons furnishing the agency with information on the question of whether disclosure is appropriate, cross-examination would appear to be of little, if any, utility. Stated another way, the agency is of the view that it can acquire all the information necessary to issue a proper determination on the disclosability of business information through written submissions. The suggestion, therefore, was not adopted and the final rule is being promulgated as proposed.

Require Determination on Business Submitter Information Be Made Within 10 Days of Receipt of Request (§ 70.26(c))

One commenter suggested that § 70.26(c) be modified to include a requirement that determinations on business submitters information be made within 10 days. The rule, as proposed, provides submitters of business information with a “reasonable period of time” within which to submit their objections, if any, to disclosure. Were the agency to require submitters to furnish their objections within a timeframe that would enable the agency to make its determination within 10 days, many, if not all, agency determinations would be subject to the criticism that they did not provide an adequate opportunity to object to disclosure. Accordingly, in order to insure that the rights of submitters of business information are adequately protected, the suggestion has not been accepted.

Provide Exemption 4 Protection to all Submissions Made Objecting to Disclosure (§ 70.26(e))

One commenter suggested that all submissions made by a business establishment for the purpose of objecting to a disclosure request automatically be afforded Exemption 4 protection. The commenter’s rationale was that information submitted by an establishment provides a relatively specific formula of how the information at issue can be used for competitive harm. The rule, as proposed, provides that such materials may be subject to disclosure under FOIA. The agency recognizes that in objecting to the disclosure of purported confidential business information, an establishment might have to submit additional confidential business information in order to explain how disclosure of the former would cause substantial competitive harm. However, that is not likely to always be the case. In fact, based upon this agency’s prior experience with questions of this nature, there will probably be a significant number of instances when it will not be the case. Therefore, it would be both imprudent and unlawful to afford the protection suggested. Instead, the agency has retained the language contained in the proposal and will decide these matters on a case-by-case basis.

Exclude From Definition of “Commercial Use Request” Requests by Public Interest Groups, Labor Unions, Libraries and the News Media (§ 70.38(f))

One commenter suggested that the definition of the term “commercial use request” be revised to exclude all requests from public interest groups, labor unions, libraries and the news media. The merits of this suggestion were reviewed. It was concluded that it would be inappropriate to automatically exclude all requests from the foregoing entities from the definition of “commercial use request” in every instance. Instead, it was considered more prudent to evaluate this question on a case-by-case basis. Accordingly, the proposed definition has been retained in the final rule.

Modify Definition of “Representative of the News Media” (§ 70.38(i))

One commenter criticized the definition of “representative of the news media” because it requires that requests relating to current events or information that would be of current interest to the public. The commenter suggested that with the emphasis on current events, the regulation, as proposed, could be used to exclude requests that concern historical events. This is an overly-narrow construction of the proposed regulation. The Department interprets the regulation as applying to both current events and historical matters of current interest to the public. Therefore, matters of historical significance, in appropriate circumstances, are certainly encompassed within the regulation.

Next, the commenter criticized the requirements to qualify as a freelance journalist. The commenter argued that there is no basis for requiring a freelance journalist to be associated with a specific news organization, noting that many freelance journalists specifically choose not to be associated with one particular news organization, but instead send their articles to many different ones without knowing where they will ultimately be published. The definition, contrary to the commenter’s assertion, does not require association with a specific news organization. A publication contract is but one way of qualifying as a freelance journalist. A person’s past publication record can also qualify the individual for freelance journalist status.

Finally, this commenter suggested that the definition of “representative of the news media” be revised to read as follows: “Any person or organization which regularly publishes or disseminates information to the public, in print or electronically.” As this definition appears to exclude many persons who are covered by the proposed definition, it was considered to be unacceptable.
Another commenter criticized the proposed definition because, in its view, the controlling factor for qualifying under it was not the identity of the requester, but instead, the nature of the information requested. This, in the agency’s view, inaccurately reflects the intent of the definition. A number of factors are considered in the definition including the identity of the requester, the nature of the information requested and how the requester intends to use the information. These matters are all germane to determining whether the requester should be treated as a representative of the news media. For these reasons, the language of the section was not modified.

Free Computer Search Time (§ 70.40(c)(4))

Section 70.40(c)(4) provides that when computer searches are involved, i.e., executing an existing program, the monetary equivalent of two hours of professional search time should be deducted from the total cost of the computer processing time. One commenter objected to this provision suggesting instead that up to two hours of computer processing time be furnished free to the requester. The cost/hour of computer processing time is, of course, considerably more expensive than the cost associated with a search performed by a professional employee. This agency interprets the statute, as does the Office of Management and Budget, to require two free hours of search time at the rate attributable to search by a professional employee, not actual Central Processing Unit (CPU) time. With the cost of CPU time for just one of DOL components' computer facility ranging from $700 to $1,800 per hour, as opposed to $20 per hour for a search by a professional employee, it is unlikely that Congress expected the agency to absorb the foregoing expenses in providing free search time. Accordingly, the suggestion has not been accepted.

Modify Requirements for Fee Waiver (§ 70.41)

The Labor Department regulation set forth at § 70.41 sets out five specific requirements as defined in the Justice Department Guidance, all of which must be satisfied in order to be eligible for a fee waiver. One commenter has suggested that the five foregoing criteria be eliminated and in their place the statutory language simply be inserted. This suggestion has not been accepted for the reason that all the conditions which must be satisfied in order to be eligible for a fee waiver might not be clear to some requesters from just the statutory language. The manner in which the regulation separately treats each of these conditions is intended to better apprise the public of what requirements must exist in order to be eligible for a fee waiver. Consequently, the suggestion that the statutory language replace the proposed regulation was not accepted.

Another commenter suggested that certain categories of requesters, i.e., public interest groups, scholars and journalists, should have the benefit of an across-the-board irrebuttable presumption in their favor under the fee waiver standard—in effect, that they should always receive a complete waiver of fees, regardless of what information is requested or actually disclosed, solely on the basis of their identity. The Department of Labor does not agree that such claims of categorical entitlement to fee waivers are warranted. The interests of those seeking categorical entitlement to fee waivers have already been adequately addressed by Congress in the statutory scheme. The claims of categorical entitlement for any particular group of FOIA requesters cannot be reconciled with the Act's revised fee structure. That is, the approach suggested would render entirely superfluous the particular fee limitation provision specifically established by Congress for such requesters. Accordingly, this suggestion was not accepted.

This requester also suggested that the regulation clearly provide that documents furnished to the government by third party submitters also qualify for fee waivers. The commenter maintains that the Justice Department Guidance precludes fee waiver treatment for these kinds of records. This, however, does not appear to be the case. Instead, the Justice Department Guidance states: "While in most cases records possessed by a federal agency will likely meet the threshold, there are cases in which the requested records do not directly concern government operations or activities and therefore would fail to meet it. A prime example can be records in the agency's possession that were generated by a non-governmental entity, records which often are sought for the intrinsic informational content alone.* The Justice Department Guidance only provides that these types of documents may not in every instance be eligible for fee waiver treatment, it does not declare that these types of documents, as a class, are automatically ineligible for such treatment.

Finally, the commenter proffered five criteria which it proposes to substitute for the requirements set out in § 70.21(a) (the proposed fee waiver regulations). The five criteria proposed by the commenter are as follows: (1) The information is sought: (a) Not for a primarily commercial purpose; (b) not for a primarily personal purpose; (c) in connection with an issue of government accountability, good government or any issue of general government concern; (d) in order to further some kind of civic, political or public activity or communication; and (2) the information is not generally and easily available to the public.

The Labor Department has elected not to adopt the proposed substitution. First, the criteria proposed by the Labor Department are fashioned after the Justice Department Guidance. Contrary to the views of the commenter, this agency believes that the DOJ Guidance correctly reflects the intent of Congress when it enacted the fee waiver provision. In addition, the requirements proposed by the commenter fail to adequately address the statutory requirements, and in addition, are unnecessarily vague.

Additional Comments

A number of technical and editorial comments were received from several components of the Labor Department itself. Some of these suggestions were accepted. However, as none of those accepted addressed substantive considerations, but were essentially of an editorial nature, there appears to be no necessity for reviewing those matters here.

Procedural Matters

This is not a major rule as defined by Executive Order 12291. The rule will have no impact on small entities as described in the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). The rule does not contain any information on collection on recordkeeping requirements as defined in the Paperwork Reduction Act of 1980. (44 U.S.C. 3501 et seq.).

List of Subjects in 29 CFR Part 70

Freedom of Information.

Accordingly, Part 70 of Title 29 of the Code of Federal Regulations is revised as set forth below.

PART 70—PRODUCTION OR DISCLOSURE OF INFORMATION OR MATERIALS

Subpart A—General

Sec.
70.1 Purpose and scope.
70.2 Definitions.
70.3 Policy.
Sec. 70.4 Public access to certain materials.
70.5 Compilation of new records.
70.6 Disclosure of originals.
70.7 Authority of component officials in Department of Labor.
70.8 Supplementary regulations currently in force.

Subpart B—Procedures for Disclosure of Records Under the Freedom of Information Act

70.9 Requests for records.
70.10 Response by components to requests.
70.11 Requester’s appeal.
70.12 Time limits and order in which requests and appeals shall be processed.
70.13 Preliminary notification to submitters of confidential commercial information.
70.14 Preservation of records.

Subpart C—Costs for Production of Documents

70.15 Definitions.
70.16 Statutes specifically providing for setting of fees.
70.17 Charges assessed for the production of records.
70.18 Reduction or waiver of fees.
70.19 Ancillary considerations.

Subpart D—Public Records

70.20 Office of Labor-Management
70.21 Standards
70.22 Pension and Welfare Benefits Administration

Appendix A to Part 70—Disclosure Officers

Subpart A—General

§70.1 Purpose and scope.
This part contains the regulations of the Department of Labor implementing the Freedom of Information Act ("FOIA"), as amended, 5 U.S.C. 552 and Executive Order 12600. It also implements the public information provisions of the Labor Management Reporting and Disclosure Act (LMRDA), 29 U.S.C. 435, 461. Subpart A contains general information about Department of Labor policies and procedures; Subpart B sets forth the procedures for obtaining access to records of the Department; Subpart C contains the Department’s regulations on fees; and Subpart D sets forth the procedures for obtaining access to certain public records. Appendix A contains a list of all Department of Labor disclosure officers from whom records may be obtained.

§70.2 Definitions.
As used in this part:
(a) The terms “agency,” “person,” “party,” “rule,” “order,” and “adjudication” have the meaning ascribed to these terms by the definition in 5 U.S.C. 551.
(b) “Component” means each separate bureau, office, board, division, commission, service or administration of the Department of Labor.
(c) “Disclosure officer” means an official of the Department of Labor who has authority to disclose records under the FOIA and to whom requests to inspect or copy records in his/her custody may be addressed. Department of Labor disclosure officers are listed in Appendix A.
(d) The “Secretary” means the Secretary of Labor.
(e) The “Department” means the Department of Labor.
(f) "Request" means any request for records made pursuant to 5 U.S.C. 552(a) or (b).
(g) "Requester" means any person who makes a request to a component.
(h) “Confidential commercial information” means records provided to the government by a submitter that arguably contain material exempt from release under Exemption 4 of the Freedom of Information Act, 5 U.S.C. 552(b)(4), because disclosure could reasonably be expected to cause substantial competitive harm.
(i) “Business submitter” means any person or entity who provides confidential commercial information to the government. The term “business submitter” includes but is not limited to corporations, labor organizations, state governments, and foreign governments.

§70.3 Policy.
All agency records, except those specifically exempted from mandatory disclosure by one or more provisions of 5 U.S.C. 552(b) shall be held promptly available to any person submitting a written request in accordance with the procedures of this part.

§70.4 Public access to certain materials.
(a) To the extent required by 5 U.S.C. 552(a)(2), each component within the Department shall make the following materials available for public inspection and copying (unless they are published and copies are offered for sale):
(1) Final options, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;
(2) Those statements of policy and interpretation which have been adopted by the agency and are not published in the Federal Register;
(3) Administrative staff manuals and instructions to staff that affect a member of the public, and which are not exempt from disclosure under section (b) of the FOIA.
(b) Each component of the Department shall also maintain and make available current indexes providing identifying information regarding any matter issued, adopted or promulgated after July 4, 1967, and required by paragraph (a) of this section to be made available or published. Each component shall publish and make available for distribution, copies of such indexes and supplements thereto at least quarterly, unless it determines by Notice published in the Federal Register that publication would be unnecessary and impracticable. After issuance of such Notice, the component shall provide copies of any index upon request at a cost not to exceed the direct cost of duplication.
(c) Whenever it is determined to be necessary to prevent a clearly unwarranted invasion of personal privacy, identifying details may be deleted from any record covered by this subsection that is published or made available for inspection.
(d) Certain records of the Department are available for examination or copying without the submission of a formal request under the FOIA, e.g., records maintained in public reference facilities. Information about the availability of records for examination and copying may be obtained by addressing an inquiry to the component which has custody of the records, or if the appropriate component is unknown, to the Assistant Secretary for Administration and Management.

§70.5 Compilation of new records.
Nothing in 5 U.S.C. 552 or this part requires that any agency or component create a new record, either manually from preexisting files or through creation of a computer program, in order to respond to a request for records.

§70.6 Disclosure of originals.
No original document or record in the custody of the Department of Labor, or of any agency or officer thereof, shall on any occasion be given to any agent, attorney, or any other person not officially connected with the Department without the written consent of the Secretary or the Solicitor of Labor.

§70.7 Authority of component officials in Department of Labor.
Each agency of the Department of Labor for which an officer or officers have authority to issue rules and regulations may through such officers
promulgate supplementary regulations not inconsistent with this part. governing the disclosure of particular or specific records which are in the custody of that departmental unit.

§ 70.8 Supplementary regulations currently in force.

Regulations duly promulgated by agencies of the Department and currently in force which govern the disclosure of records in the custody of the affected agency, shall remain in effect, insofar as such regulations are consistent with the provisions of this part, until such regulations are modified or rescinded.

Subpart B—Procedures for Disclosure of Record Under the Freedom of Information Act

§ 70.19 Requests for records.

(a) To whom to direct requests. Requests under this subpart for a record of the Department of Labor must be in writing. A request should be sent to the component that maintains the record at its proper address and both the envelope and the request itself should be clearly marked "Freedom of Information Act Request." (Appendix A of this part lists the components of the Department of Labor and their addresses.) The functions of each component are summarized in the United States Government Manual which is issued annually and is available from the Superintendent of Documents. This initial list of responsible officials has been included for informational purposes only, and the officials may be changed through appropriate designation. Regional, district and field office addresses have been included in Appendix A to assist requesters in identifying the disclosure officer who is most likely to have custody of the records sought. Requesters who need guidance in defining a request or determining the proper component to which the request should be addressed, may write to the Assistant Secretary for Administration and Management, 200 Constitution Avenue, Washington, D.C. 20210.

(b) Description of information requested. Each request shall reasonably describe the record or records sought; i.e., in sufficient detail to permit identification and location thereof with a reasonable amount of effort. So far as practicable, the request should specify the subject matter of the record, the date or approximate date when made, the place where made, the person or office that made it, and any other pertinent identifying details.

(c) Deficient descriptions. If the description is insufficient so that a professional employee who is familiar with the subject area of the request cannot locate the record with a reasonable amount of effort, the officer processing the request will notify the requester and indicate any additional information required. Every reasonable effort shall be made to assist a requester in the identification and location of the record or records sought.

(d) Classified records. Any request for classified records which are in the custody of the Department of Labor shall be referred to the classifying agency under the provisions of § 70.20.

(e) Agreement to pay fees. The filing of a request under this Subpart shall be deemed to constitute an agreement by the requester to pay all applicable fees charged under this part, up to $25.

§ 70.20 Responses by components to requests.

(a) In general. (1) Except as otherwise provided in this section, when a request for a record is received, the component having custody of the requested record shall ordinarily be responsible for responding to the request.

(2) However, when another component or agency is better able to determine the disclosability of a record, that component or agency shall be responsible for responding to the request.

(3) The time for responding to a request begins to run when it is received by the department or component responsible for making the determination on disclosure.

(b) Authority to grant or deny requests. The disclosure officer, or his or her designee, is authorized to grant or deny any request for a record in his or her custody.

(c) Determination that request has been received by the proper component. (1) When a component receives a request for a record, the component shall promptly determine whether another component or another agency of the Government is better able to determine whether the record is exempt from any extent from mandatory disclosure under FOIA.

(2) If the receiving component determines that it is the component and agency better able to determine whether the record is exempt from mandatory disclosure under FOIA, the receiving component shall refer the request to the component or agency that it believes should handle the request.

(4) If the receiving component determines that it is the component and agency better able to determine whether part of the requested records is exempt from disclosure, and another component or agency has primary responsibility with respect to other parts of the requested record, the receiving component shall either:

(i) Respond to the request after consulting with the appropriate component or agency concerning the records for which that component or agency has primary responsibility, or

(ii) Respond to the part of the request for which it has primary responsibility and refer the other portion or portions of the request to the appropriate component or agency.

(d) Notice of referral. Whenever a component refers all or any part of the responsibility for responding to a request to another component or to another agency, it shall notify the requester of the referral and inform the requester of the name and address of each component or agency to which the request has been referred and the portions of the request so referred.

(e) Processing of requests that are not properly addressed. (1) A request that is not properly addressed as specified in § 70.7(a) of this subpart shall be forwarded to the appropriate component, if known, or to the Office of the Assistant Secretary for Administration and Management (OASAM), which shall make reasonable efforts to determine the appropriate component and, if able to do so, shall forward the request to the appropriate component or components for processing. A request not addressed to the appropriate component will be deemed not to have been received by the Department of Labor until OASAM has forwarded the request to the appropriate component and that component has received the request, or until the request would have been so forwarded and received with the exercise of reasonable diligence by Department personnel.

(2) A component receiving an improperly addressed request forwarded by OASAM shall notify the requester of the date on which it received the request.

(f) Date for determining responsive records. In determining records responsive to a request, a component will include only those records existing as of the date of its receipt of the request as that date is determined in accordance with paragraph (c).
§ 70.21 Form and content of component responses.

(a) Form of notice granting a request. After a component has made a determination to grant a request in whole or in part, the component shall notify the requester in writing. The notice shall describe the manner in which the record will be disclosed, whether by providing a copy of the record to the requester or by making a copy of the record available to the requester for inspection at a reasonable time and place. The procedure for such an inspection shall not unreasonably disrupt the operations of the component. The component shall inform the requester in the notice of any fees to be charged in accordance with the provisions of Subpart C.

(b) Form of notice denying a request. A disclosure officer denying a request in whole or in part shall so notify the requester in writing. The notice must be signed by the disclosure officer or his designee, and shall include:

(1) The name and title or position of the disclosure officer, and if applicable, of the designee.

(2) A brief statement of the reason or reasons for the denial, including the FOIA exemption or exemptions which the component has relied upon in denying the request.

(3) A statement that the denial may be appealed under § 70.22 and a description of the requirements of that subsection.

(c) Record cannot be located or has been destroyed. If a requested record cannot be located from the information supplied, or is known or believed to have been destroyed or otherwise disposed of, the component shall so notify the requester in writing.

§ 70.22 Appeals from denial of requests.

When a request for access to records or for a waiver of fees has been denied in whole or in part, where a requester disputes matters relating to the assessment of fees, or when a component fails to respond to a request within the time limits set forth in the FOIA, the requester may appeal the denial of the request to the Solicitor of Labor. The appeal must be filed within 90 days of: (a) the denial, actual or constructive, of the request, including a denial of a request for a fee waiver, (b) an agency's response on a dispute of matters relating to the assessment of fees, or (c) in the case of a partial denial, 90 days from the date the material was received by the requester.

The appeal shall state, in writing, the grounds for appeal, including any supporting statements or arguments. To facilitate processing, the appeal should include copies of the initial request and the response of the disclosure officer.

The appeal shall be addressed to the solicitor of Labor, Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Both the envelope and the letter of appeal itself must be clearly marked: "Freedom of Information Act Appeal."

§ 70.23 Action on appeals.

The Solicitor of Labor, or his designee, shall review the appellant's supporting papers and make a determination de novo whether the denial specified in § 70.22 was proper and in accord with the applicable law.

§ 70.24 Form and content of action on appeals.

The disposition of an appeal shall be in writing. A decision affirming in whole or in part the denial of a request shall include a brief statement of the reason or reasons for the affirmance, including each FOIA exemption relied upon and its relation to each record withheld, and a statement that judicial review of the denial is available in the United States District Court for the judicial district in which the requester resides or has his principal place of business, the judicial district in which the requested records are located, or the District of Columbia. If it is determined on appeal that a record should be disclosed, the record should be provided promptly in accordance with the decision on appeal.

§ 70.25 Time limits and order in which requests and appeals shall be processed.

Components of the Department of Labor shall comply with the time limits required by the FOIA for responding to and processing requests and appeals, unless there are exceptional circumstances within the meaning of 5 U.S.C. 552(a)(6)(C). A component shall notify a requester whenever the component is unable to respond to or process the request or appeal within the time limits established by the FOIA.

§ 70.26 Prediscovery notification to submitters of confidential commercial information.

(a) In general. FOIA requests for confidential commercial information provided to the Department by business submitters shall be processed in accordance with this section.

(b) Designation of confidential commercial information. Business submitters of information to the Department, at the time of submission or within a reasonable time thereafter, may designate specific information as confidential commercial information subject to the provisions of this section. Such a designation may be made for information which the submitter claims could reasonably be expected to cause substantial competitive harm. The designation must be in writing and whenever possible, the submitter's claim of confidentiality shall be supported by a statement or certification by an officer or authorized representative of the submitter that the identified information in question is, in fact, confidential commercial or financial information and has not been disclosed to the public.

(c) Notice to submitters of confidential commercial information. A component shall provide a business submitter with prompt written notice of any request encompassing its business information whenever required under paragraph (d) of this section, and except as is provided in paragraph (g) of this section. Such written notice shall either describe the nature of the confidential commercial information requested or provide copies of the relevant records or portions thereof.

(d) When notice is required. (1) For confidential commercial information submitted to the Department prior to January 1, 1988, the component shall provide a business submitter with notice of a request whenever:

(i) Less than 10 years have passed since the date the information was received by the Department and the information is subject to prior express commitment of confidentiality given by the component to the business submitter, or

(ii) The component has reason to believe that disclosure of the information could reasonably be expected to cause substantial competitive harm.

[2] For confidential commercial information submitted to the Department on or after January 1, 1988, the component shall provide a business submitter with notice of a FOIA request whenever:

(i) The business submitter has in good faith previously designated the information as commercially or financially sensitive information, or

(ii) The component has reason to believe that disclosure of the information could reasonably be expected to cause substantial competitive harm.

Notice of a request for confidential commercial information falling within paragraph (d)(2)(i) of this section shall be required for a period of not more than ten years after the date of submission. The business submitter may request a specific notice period of greater duration. The submitter should provide a justification for such a request. In such a case, the Department may, in its
commercial or financial information that is privileged or confidential. Information provided by a business submitter pursuant to this paragraph may itself be subject to disclosure under the FOIA.

(f) Notice of intent to disclose. A component shall consider a business submitter's objections and specific grounds for nondisclosure prior to determining whether to disclose business information which has been designated by the submitter as confidential commercial information. Whenever a component decides to disclose such information over the objection of a business submitter or designee, the component shall notify the business submitter in writing. Such notice shall include:

(1) A description of the information to be disclosed;

(2) A specified disclosure date;

(3) A statement of why the submitter's objections were not sustained.

Such notice of intent to disclose shall be forwarded a reasonable number of days prior to the specified date upon which disclosure is intended. The requester shall be provided with a copy of the notice of intent to disclose.

(g) Exceptions to notice requirements.

The notice requirements of this section shall not apply if:

(1) The component determines that the information should not be disclosed;

(2) The information has been lawfully published or has been officially made available to the public;

(3) Disclosure of the information is required by law (other than 5 U.S.C. 552); and

(4) The disclosure is required by a rule that:

(i) Was adopted pursuant to notice and public comment; (ii) Specifically classifies records submitted to the agency that are to be released under the Freedom of Information Act; and

(iii) Provides in exceptional circumstances for notice when the submitter provides written justification, at the time the information is submitted or a reasonable time thereafter, that disclosure of the information could reasonably be expected to cause substantial competitive harm.

(5) The information requested has not been designated by the submitter as in accordance with paragraph (b) of this Section, and the submitter had an opportunity to do so at the time of submission of the information or a reasonable time thereafter, unless the component has reason to believe that disclosure of the information would result in substantial competitive harm; or

(6) The designation made by the submitter in accordance with these regulations appears obviously frivolous; except that in such case, the component must provide the submitter with written notice of any final administrative disclosure determination within a reasonable number of days prior to the specified disclosure date.

(h) Notice of FOIA lawsuit. Whenever a requester brings suit seeking to compel disclosure of confidential commercial information covered by paragraph (b) of this section, the component shall promptly notify the business submitter.

(i) Notice requirements. The component shall fulfill the notice requirements of this section by addressing the notice to the business submitter or its legal successor at the last known address. If the notice is returned, the component shall make a reasonable effort to locate the business submitter or its legal successor. Where notification of a voluminous number of submitters is required, such notification may be accomplished by posting and publishing the notice in a place reasonably calculated to accomplish notification.

§ 70.27 Preservation of records.

Each component shall preserve all correspondence relating to the requests it receives under this part, and all records processed pursuant to such requests, until such time as the destruction of such correspondence and records is authorized pursuant to Title 44 of the United States Code. Under no circumstances shall records be destroyed while they are the subject of a pending request, appeal, or lawsuit under the Act.

Subpart C—Costs for Production of Documents

§ 70.38 Definitions.

The following definitions apply to the terms of this subpart:

(a) The term a "statute specifically providing for setting the level of fees for particular types of records" (See 5 U.S.C. 552 (a) (4) (A) (v)), means any statute other than FOIA that specifically requires a agency to establish a fee schedule for particular types of records. An example of such a statute is section 205 (c) of the Labor-Management Reporting and Disclosure Act, as amended, 29 U.S.C. 435 (c).

(b) The term "direct costs" means those expenditures which an agency actually incurs in searching for and duplicating (and in the case of a commercial requester, reviewing) documents to respond to a FOIA request. Direct costs includes the salary of the employee performing the work and the cost of operating duplicating machinery, and when appropriate the cost of the medium in which the information is made available.

(c) The term "duplication" means the process of making a copy of a document necessary to respond to a FOIA request. Such copies can take the form of paper copy, microform, audio-visual materials or machine-readable documentation (e.g., magnetic tape or disk), among others.

(d) The term "search" means the process of looking for material that is responsive to a FOIA request, including page-by-page or line-by-line identification of materials within documents or, when available, use of an existing computer program. Searches do not include the review of material, as defined in §70.38(e), which is performed to determine whether material is exempt from disclosure.

(e) The term "review" means the process of examining documents located in response to a request that is for a commercial use, as defined in §70.38(f), to determine whether any portion of the document located is exempt from disclosure, and accordingly may be withheld. It also includes the act of preparing materials for disclosure, i.e., doing all that is necessary to excise them and otherwise prepare them for release. Review does not include time spent resolving general legal or policy issues regarding the application of exemptions.

(f) The term "commercial use request" means a request from one who seeks information for a use or purpose that furthers the commercial, trade or profit interests of the requester or the person or entity on whose behalf the request was submitted. When a request is
submitted by a commercial entity or its representative and from the nature of the information sought it appears the request is to further the objective of that entity, the request will be treated as a commercial use request unless the requester indicates that the information is being sought for a non-commercial purpose. Where a requester indicates that the information is being sought for a non-commercial purpose, the disclosure officer will evaluate the requester’s submission and determine how the request is to be treated. While requests by non-profit organizations would normally fall outside the commercial use category, when the disclosure officer determines that a request by such an entity or one acting on its behalf does further the entity’s commercial interests, he or she may treat the request as a commercial use request.

(g) The term “educational institution” means:

(1) An institution which is a preschool, a public or private elementary or secondary school, an institution of undergraduate higher education, an institution of graduate higher education, an institution of professional education, or an institution of vocational education, and

(2) Operates a program or programs of scholarly research. To qualify under this definition, the program of scholarly research in connection with which the information is sought must be carried out under the auspices of the academic institution as opposed to the individual scholarly pursuits of persons affiliated with an institution. For example, a request from a professor to assist him or her in writing a book affiliated with an institution. For example, a request from a professor to assist him or her in writing a book

(h) The term “non-commercial scientific institute” means an institution that is not operated on a “commercial” basis as that term is defined in § 70.38(f), and that is operated solely for the purpose of conducting scientific research, the results of which are not intended to promote any particular product or industry.

(i) The term “representative of the news media” means any person actively gathering news for an entity that is organized and operated to publish or broadcast news to the public. Factors indicating such representation status include press accreditation, guild membership, a history of continuing publication, business registration, and/or Federal Communication Commission licensing, among others. For purpose of this definition the term “news” contemplates information that is about current events or that would be of current interest to the public. A freelance journalist shall be treated as a representative of the news media if the person can demonstrate a solid basis for expecting publication of matters related to the requested information through a qualifying news media entity. A publication contract with a qualifying news media entity satisfies this requirement. An individual’s past publication record with organizations of the foregoing nature is also relevant to this determination. Examples of news media entities include:

1) Television or radio stations broadcasting to the public at large, and

2) Publishers of periodicals including newsletters (but only in those instances where they can qualify as disseminators of news) who make their products available for purchase or subscription by the general public.

§ 70.38 Statutes specifically providing for setting of fees.

Nothing in this subpart shall supersede fees chargeable under a statute other than the Freedom of Information Act which specifically provides for setting the level of fees for particular types of records.

§ 70.40 Charges assessed for the production of records.

(a) There are three types of charges assessed in connection with the production of agency records in response to a Freedom of Information Act request: costs associated with

(1) Searching for or locating responsive records (search costs),

(2) Reproducing such records (reproduction costs), and

(3) Reviewing records to determine whether any materials are exempt (review costs).

(b) There are four types of FOIA requesters:

(1) Commercial use requesters,

(2) Educational and non-commercial scientific institutions,

(3) Representatives of the news media, and

(4) All other requesters.

Depending upon the nature of the requester, one or all of the foregoing costs may be assessed. Paragraph (c) of this section sets forth the extent to which the foregoing costs may be assessed against each type of requester. Paragraph (d) of this section establishes the actual rate to be charged in connection with each of the foregoing types of costs. Paragraph (e) delineates the manner in which costs are to be assessed against an individual seeking access to records about himself or herself which are covered by the Privacy Act.

(c) (1) Commercial use requester.

When a commercial use requester as defined in § 70.38(f) makes a request for documents, search costs, reproduction costs and review costs may be assessed in their entirety.

(2) Educational or non-commercial, scientific institution requester. When an educational or non-commercial scientific institution requester, as defined in §§ 70.38(g) and (h), makes a request, only reproduction costs may be assessed, excluding charges for the first 100 pages.

(3) Request by representative of news media. When a representative of the news media as defined in § 70.38(i) makes a request, only reproduction costs may be assessed, excluding charges for the first 100 pages.

(4) All other requesters. Requesters who do not fall within paragraphs (c) (1), (2), and (3) of this section may be charged search costs and reproduction costs, except that the first 100 pages of reproduction and the first two hours of search time shall be furnished without charge. Where computer searches are involved, i.e., executing an existing program, however, the monetary equivalent of two hours of search time by a professional employee shall be deducted from the total costs of computer processing time.

(d) (1) Search costs. When a search for records is performed by a clerical employee, a rate of $2.50 per quarter hour will be applicable. When a search is performed by professional or supervisory personnel, a rate of $5.00 per quarter hour will be applicable. If the search for requested records requires transportation of the searcher to the location of the records or transportation of the records to the searcher, all transportation costs in excess of $5.00 may be added to the search cost. When an existing computer program is employed to locate records responsive to a request, the disclosure officer may charge the actual cost of providing the service.

(2) Reproduction costs. The standard copying charge for documents in paper copy is $.15 per page. When responsive information is provided in a format other than paper copy, such as in the form of computer tapes and discs, the requester may be charged the direct costs of the tape, disc, or whatever medium is used to produce the
information, as well as any related reproduction costs.

(3) Review costs. Costs associated with the review of documents, as defined in §70.38(c), will be applicable at a rate of $5.00 per quarter hour. Except as noted below, charges may only be assessed for review at the initial level, i.e., the review undertaken the first time the documents are analyzed to determine the applicability of specific exemptions to the particular record or portion of the record. Thus a requester would not be charged for review at the administrative appeal level with regard to the applicability of an exemption already applied at the initial level. When, however, a record has been withheld pursuant to an exemption which is subsequently determined not to apply and is reviewed again at the appellate level to determine the potential applicability of other exemptions, the costs attendant to such additional review may be assessed.

(4) Mailing cost. Where requests for copies are made by mail, no postage charge will be made for transmitting by regular mail a single copy of the requested record to the requester, or for mailing additional copies where the total postage cost does not exceed $1. However, where the volume of page copy or method of transmittal requested is such that transmittal charges to the Department are in excess of $1, the transmittal costs will be added, unless appropriate stamps or stamped envelopes are furnished with the request, or authorization is given for collection of shipping charges on delivery.

(c) Privacy Act requesters. Requests from individuals for records about themselves which are contained within agency systems of records shall be treated under the fee provisions of the Privacy Act of 1974 which permit the assessment of reproduction costs only, after providing the first copy of a file at no cost.

§70.42 Ancillary considerations.

(a) Costs assessed when no records are disclosed. The costs of searching for and, in the case of a commercial use request, reviewing records may be assessed even where ultimately no documents are disclosed or located.

(b) Aggregating requests. A requester may not file multiple requests, each seeking portions of a document or documents in order to avoid the payment of fees. When there is reason to believe that a requester or a group of requesters acting in concert, is attempting to break a request down into a series of requests for the purpose of evading the assessment of fees, any such requests may be aggregated and the requesters charged as if there were only a single request.

(c) Advance payments. An advance payment before work is commenced or continued on a request, may not be required unless:

(1) The subject of the requested records concerns the operations or activities of the United States Government;

(2) The disclosure of the requested records is likely to contribute to an understanding of Government operations or activities;

(3) The disclosure is likely to contribute to a public understanding of such operations or activities;

(4) The contribution to public understanding of government operations and activities will be significant; and

(5) The public's interest in disclosure exceeds the requester's commercial interest in disclosure.

(d) De minimis costs. Where the cost of collecting a fee to be assessed to a requester exceeds the amount of the fee which would otherwise be assessed, no fee need be charged. Under normal circumstances, fees which do not exceed $5.00 need not be collected.

(e) Reformulating requests. When the estimated reproduction costs are likely to exceed $25.00, the requester may be notified of the estimated amount of fees. Unless the requester has indicated in advance its willingness to pay fees as high as those anticipated. Such notice may invite the requester to reformulate the request to satisfy his or her needs at a lower cost.

§70.43 Timelines for requests.

(1) To pay the full amount owed plus any applicable interest as provided in §70.41(e), when an outstanding balance is due and owing, and

(2) To make an advance payment of the full amount of the estimated fee before the component begins to process a new request.

(3) In any case, the payment of outstanding fees may be required before responsive materials are actually disclosed to a requester.

(d) Time limits to respond extended when advance payments requested. When an advance payment of fees in accordance with paragraph (c) of this section has been requested the administrative time limits prescribed in subsection (a)(6) of the FOIA, 5 U.S.C. 552(a)(6), will only begin to run after such advance payment has been received by the agency.

(e) Interest charges. Interest charges on an unpaid bill may be assessed starting on the 31st day following the day on which the billing was sent. Interest shall be at the rate prescribed in section 5177 of Title 26 U.S.C. and shall accrue from the date of the billing.

(f) Authentication of copies—(1) Fees. The Freedom of Information Act does not require certification or attestation under seal of copies of records furnished in accordance with its provisions. Pursuant to provisions of the general user-charge statute, 51 U.S.C. §701 and Subchapter II of Title 29 of the United States Code, the following charges may be made where such services are requested:

(i) For certification of true copies, each $1.

(ii) For attestation under the seal of the Department, each $3.

(2) Authority and form for attestation under seal. Authority is hereby given to any officer or officers of the Department of Labor designated as authentication officer or officers of the Department to sign and issue attestations under the seal of the Department of Labor.

(g) Transcripts. All transcripts shall be made available in accordance with the terms set forth in §70.40.

Subpart D—Public Records

§70.53 Office of Labor-Management Standards.

(a) The following documents in the custody of the Office of Labor-
§ 70.54 Pension and Welfare Benefits Administration.

The following documents are in the custody of the Pension and Welfare Benefits Administration at the address indicated below, and the right of inspection and copying provided in this part may be exercised at such offices:

Copies of summary plan descriptions, and annual reports, statements and other documents filed pursuant to the Employee Retirement Income Security Act, Title I, Part I, except that information described in sections 105(a) and 105(c) with respect to a participant may be disclosed only to the extent that information respecting that participant’s benefits under Title II of the Social Security Act may be disclosed under such Act.


Appendix A to Part 70—Disclosure Officers

(a) Offices in Washington, DC, are maintained by the following agencies of the Department of Labor. Field offices are maintained by some of these, as listed in the United States Government Manual (see § 70.5(b)).

(1) Office of the Secretary of Labor
(2) Office of the Solicitor of Labor
(3) Office of the Assistant Secretary for Administration and Management
(4) Office of Information and Public Affairs
(5) Office of the Inspector General
(6) Bureau of Labor-Management Relations
(7) Bureau of Labor-Management Relations and Cooperative Programs
(8) Bureau of Labor Statistics
(9) Employment Standards Administration
(10) Employment and Training Administration
(11) Mine Safety and Health Administration
(12) Occupational Safety and Health Administration
(13) Office of Labor-Management Standards
(14) Pension and Welfare Benefits Administration
(15) Office of Assistant Secretary for Veterans’ Employment and Training
(16) Employees’ Compensation Appeals Board

(b) The titles of the responsible officials of the various independent agencies in the Department of Labor are listed below. This list is provided for information only, to assist requestors in locating the office most likely to have responsive records. The officials may be changed by appropriate designation. Unless otherwise specified, the mailing addresses of the officials shall be:

U.S. Department of Labor
200 Constitution Avenue, NW.
Washington, DC 20210.

Secretary of Labor, ATTENTION: Assistant Secretary for Administration and Management (OASAM)
Deputy Solicitor, Office of the Solicitor
Assistant Secretary for Administration and Management (OASAM)
Deputy Assistant Secretary for Administration and Management (OASAM)
Director, Office of Personnel Management
Services, National Capital Service Center (OASAM)
Director, Office of Procurement Services, National Capital Service Center (OASAM)
Director, Office of Small and Disadvantaged Business Utilization (OASAM)
Deputy Director, National Capital Service Center (OASAM)
Director, Women’s Bureau
Chairperson, Employees’ Compensation Appeals Board
Deputy Assistant Secretary for Policy
Director, Office of Information and Public Affairs
Director, Information, Privacy and Management Investigative Systems, Office of the Inspector General
Associate Deputy Under Secretary for International Affairs

(b)(1) The titles of the responsible officials of the various independent agencies in the Department of Labor are listed below. This list is provided for information only, to assist requestors in locating the office most likely to have responsive records. The officials may be changed by appropriate designation. Unless otherwise specified, the mailing addresses of the officials shall be:

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Deputy Assistant Secretary for Administration and Management (OASAM)
Director, Office of Personnel Management
Services, National Capital Service Center (OASAM)
Director, Office of Procurement Services, National Capital Service Center (OASAM)
Director, Office of Small and Disadvantaged Business Utilization (OASAM)
Deputy Director, National Capital Service Center (OASAM)
Director, Women’s Bureau
Chairperson, Employees’ Compensation Appeals Board
Deputy Assistant Secretary for Policy
Director, Office of Information and Public Affairs
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Services, National Capital Service Center (OASAM)
Director, Office of Procurement Services, National Capital Service Center (OASAM)
Director, Office of Small and Disadvantaged Business Utilization (OASAM)
Deputy Director, National Capital Service Center (OASAM)
Director, Women’s Bureau
Chairperson, Employees’ Compensation Appeals Board
Deputy Assistant Secretary for Policy
Director, Office of Information and Public Affairs
Director, Information, Privacy and Management Investigative Systems, Office of the Inspector General
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Deputy Assistant Secretary for Administration and Management (OASAM)
Director, Office of Personnel Management
Services, National Capital Service Center (OASAM)
Director, Office of Procurement Services, National Capital Service Center (OASAM)
Director, Office of Small and Disadvantaged Business Utilization (OASAM)
Deputy Director, National Capital Service Center (OASAM)
Director, Women’s Bureau
Chairperson, Employees’ Compensation Appeals Board
Deputy Assistant Secretary for Policy
Director, Office of Information and Public Affairs
Director, Information, Privacy and Management Investigative Systems, Office of the Inspector General
Associate Deputy Under Secretary for International Affairs
Director, Office of Equal Employment Opportunity Occupational Safety and Health Administration (OSHA)

Director, Office of Management Accountability and Performance, OSHA

Director, Office of Information and Consumer Affairs, OSHA

Director, Directorate of Federal-State Operations, OSHA

Director, Office of Training and Education, OSHA

Director, Directorate of Policy, OSHA

Director, Directorate of Administrative Programs, OSHA

Director, Office of Personnel Management, OSHA

Director, Office of Administrative Services, OSHA

Director, Office of Management Data Systems, OSHA

Director, Office of Management Systems and Administrative Management, OSHA

Director, Office of Program Budgeting, Planning and Financial Management, OSHA

Director, Directorate of Field Operations, OSHA

Director, Directorate of Technical Support, OSHA

Director, Directorate of Safety Standards Programs, OSHA

Director, Directorate of Health Standards Programs, OSHA

Deputy Assistant Secretary for Labor Management Standards

Associate Director for Program Services, Pension and Welfare Benefits Administration

Deputy Assistant Secretary for Veterans' Employment and Training

Administrative Officer, Veterans' Employment and Training Service

Director, Office of Small and Disadvantaged Business Utilization

Administrator, Office of Financial and Administrative Management, ETA

Administrator, Office of Job Training Programs, ETA

Administrator, Office of Strategic Planning and Policy Development, ETA

Administrator, Office of Regional Management, ETA

Administrator, Office of Employment Security, ETA

Chief, Division of Foreign Labor Certification, ETA

Director, Office of the Comptroller, ETA

Director, Office of Grants and Contract Management, ETA

Chief, Division of Acquisition and Assistance, ETA

Chief, Planning Policy Control and Review Group, ETA

Director, Office of Information Resources Management, ETA

Director, Office of Management Support, ETA

Personnel Officer, Division of Personnel and Administrative Services, ETA

Director, Office of Employment and Training Programs, ETA

Director, Office of Special Targeted Programs, ETA

Director, Office of Job Corps, ETA

Director, Bureau of Apprenticeship and Training, ETA

Director, United States Employment Service, ETA

Regional Director, Employment Service OASAM, Regional Director, ETA

Regional Administrator for Apprenticeship and Training (ETA)

Regional Administrator for Occupational Safety and Health Administration Standards Administration

Assistant Regional Administrator for Wage and Hour, ESA

Assistant Regional Administrator for Federal Contract Compliance Programs, ESA

Assistant Regional Administrator for Workers' Compensation Programs, ESA

Executive Assistant to the Regional Administrator, ESA

State Liaison Advisor, ESA

Office of Workers' Compensation Programs, Deputy Commissioner

Room 1800, J. F. K. Building, Government Center, Boston, Massachusetts 02203

201 Varick Street, Room 750, New York, New York 10014

3535 Market Street, Philadelphia, Pennsylvania 19104

Penn Traffic Building, 319 Washington Street, Johnstown, Pennsylvania 15901 (BLBA only)

South Main Towers, 116 South Main Street, Wilkes-Barre, Pennsylvania 18701 (BLBA only)

Wellington Square, 1235 South Main Street, Greensburg, Pennsylvania 15601 (BLBA only)

31 Hopkins Plaza, Baltimore, Maryland 21201 (LHWCA only)

200 Cranby Mall, Norfolk, Virginia 23502 (LHWCA only)

1020 Quarrier Street, First Floor, Charleston, West Virginia 25301 (BLBA only)

609 Market Street, Parkersburg, West Virginia 26101 (BLBA only)

1100 L Street NW., Room 9101, Washington, DC 20210 (FECA only)

200 Constitution Ave., NW., Room C-4315, Washington, DC 20415 (FECA only)

324 Main Street, Fifth Floor, Pikeville, Kentucky 41501 (BLBA only)

500 Springdale Plaza, Plaza Spring Street, Mt. Sterling, Kentucky 40353 (BLBA only)

311 West Monroe Street, Jacksonville, Florida 32202 (LHWCA only)

400 West Bay Street, Jacksonville, Florida 32202 (FECA only)

230 South Dearborn Street, Chicago, Illinois 60604

1240 East 9th Street, Cleveland, Ohio 44109 (FECA only)

274 Marconi Boulevard, Third Floor, Columbus, Ohio 43215 (BLBA only)

525 Griffin Street, Federal Building, Dallas, Texas 75202

500 Camp Street, New Orleans, Louisiana 70130

12000 North Featherwood Drive, Houston, Texas 77034 (LHWCA only)

601 Rosenberg Avenue, Galveston, Texas 77553 (LHWCA only)

911 Walnut Street, Kansas City, Missouri 64106 (FECA only)

1801 Stout Street, Denver, Colorado 80223 (DCCA)

P.O. Box 2594, Denver, Colorado 80225 (FECA only)

Federal Building, P.O. Box 3789, San Francisco, California 94119
Part IV

Department of Labor

Mine Safety and Health Administration

30 CFR Part 104
Pattern of Violations; Proposed Rule
DEPARTMENT OF LABOR
Mine Safety and Health Administration
30 CFR Part 104
RIN 1219-AA04
Pattern of Violations

AGENCY: Mine Safety and Health Administration. Labor.

ACTION: Proposed rule.

SUMMARY: The Mine Safety and Health Administration (MSHA) is proposing criteria and procedures for identifying mines with a "pattern of violations" of mandatory standards that significantly and substantially contribute to safety or health hazards. The proposed rule would implement section 104(e) of the Federal Mine Safety and Health Act of 1977 (Mine Act). Congress established this provision to bring into compliance mines where operators habitually allow violations of standards to occur, resulting in serious safety or health hazards.

DATES: Comments on the proposed rule must be received by July 31, 1989.

ADDRESSES: Send comments to the Office of Standards, Regulations, and Variances, MSHA; Room 631; Ballston Tower No. 3; 4015 Wilson Boulevard; Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director, Office of Standards, Regulations, and Variances, MSHA: (703) 235-1910.

SUPPLEMENTARY INFORMATION:

I. Background

When enacting the Mine Act, Congress expressed particular concern with mine operations that have a serious safety and health management problem characterized by repeated "significant and substantial" (S&S) violations of mandatory health and safety standards, which are merely abated as they are cited. The enforcement provisions of the Mine Act's predecessor legislation, the Federal Coal Mine Health and Safety Act of 1969 and the Metal and Nonmetallic Mine Safety Act of 1966, were considered inadequate to break such a cycle of violation, citation, and abatement and restore the mine to a safe and healthful work place. As a means to address this situation, Congress added a new provision to the Mine Act, section 104(e), which authorizes MSHA to impose stringent sanctions on mines that develop a "pattern of violations."

Section 104(e) requires that a notice be issued to a mine operator if the mine has a pattern of violations of mandatory standards which could significantly and substantially contribute to health or safety hazards at the mine. Once a section 104(e) pattern notice is issued, any inspection within 90 days which reveals another S&S violation results in an order to withdraw all persons from the affected area of the mine until the violation is abated. Withdrawal orders continue to be issued for subsequent S&S violations until an inspection of the entire mine reveals no S&S violations. A withdrawal order requires all miners to be removed from the area affected by the violation and prohibits entry into the area, with the exception of persons assigned by the operator to eliminate the violation.

The legislative history of the Mine Act emphasizes that the provisions of section 104(e) are intended for use at mines with a record of repeated S&S violations and where the other enforcement provisions of the statute have not been effective in bringing the mine into compliance with Federal health and safety standards. The Mine Act does not define "pattern of violations," but rather authorizes the Secretary to make such rules as necessary to establish criteria for determining when a pattern exists. The Secretary has broad discretion in determining this criteria.

The need for a pattern of violations provision in the 1977 Act became apparent to Congress in its investigation of the Scotia Mine disaster which occurred in March 1976. The Scotia Mine had a chronic history of persistent dangerous violations that were cited by the inspector and abated by the operator. But the operator would then permit the mine to lapse back into violation, exposing the miners to the same risks all over again. The Senate Committee report stated that section 104(e) of the 1977 Act was intended as "an effective tool to protect miners when the operator demonstrates his disregard for the health and safety of miners through an established pattern of violations." (Leg. Hist. at 620). The Committee viewed the pattern notice as an indication "to both the mine operator and the Secretary that there is a need to restore the mine to effective safe and healthful conditions and that the mere abatement of violations is insufficient." [Leg. Hist. at 621]. MSHA believes that Congress intended the pattern sanctions to be directed at abatement rather than the closure of mines.

On August 15, 1980, MSHA published a proposed rule in the Federal Register to establish criteria for identifying mines which have a pattern of violations (45 FR 54636). In response to the proposal, numerous commenters stated that it was then untimely for MSHA to establish pattern of violation regulations because of litigation pending before the Federal Mine Safety and Health Review Commission (Review Commission) that involved how to interpret the S&S provisions of the Mine Act. Prior to the Review Commission's decision, MSHA had cited all violations as S&S, except technical violations and violations that posed only a remote or speculative risk of injury. In April 1981, the Review Commission narrowed the concept of S&S violations by defining them as violations that have a reasonable likelihood of resulting in a reasonably serious injury or illness [Secretary of Labor v. Cement Division, National Gypsum Co., 3 FMSHRC 822, 2 MSHC 1201 (1981)]. MSHA adopted this revised definition as Agency policy in May 1981. The Review Commission has also held that the principles of National Gypsum apply to violations of health standards (Consolidation Coal Co. v. Secretary of Labor, 6 FMSHRC 890 (1986)).

In addition to these concerns, commenters on the 1980 proposal stated that the Agency's then-pending review of the civil penalty regulations could affect provisions of the pattern of violations proposal. In May 1982, MSHA revised its regulations for the assessment of civil penalties. Other criticisms of the proposal were that it was complex, too statistically-oriented and vague.

In February 1985, MSHA announced in the Federal Register (50 FR 5470) that it was withdrawing the 1980 proposal and gave advance notice of a proposed rulemaking (ANPRM) which would address many of the concerns expressed about the 1980 proposal. In that notice, MSHA stated that it intended to develop a regulation that would focus on the safety and health record of each mine, rather than on strictly quantitative comparisons of mines to industry-wide norms. The Agency further stated that it planned to develop simplified criteria to identify the existence of a pattern, coupled with procedures for fair and full notice, including an opportunity for the affected parties to respond to the

Agency's initial evaluation that a pattern of violations may exist at a mine. MSHA received suggestions and views on the ANPRM from commenters representing many segments of the mining community.

This proposed rule is consistent with the concept outlined in the February 1988 ANPRM and contains the following elements: a statement of purposes, procedures for initial identification of mines that may be developing a pattern of violations, criteria for determining whether a pattern of violations exists at a mine, notification procedures which would provide both the mine operator and miners' representatives an opportunity to respond to the Agency's evaluation that a pattern of violations may exist at a mine, and procedures for termination of a pattern notice.

II. Discussion of Proposed Rule
A. General Discussion

The issue most often raised by the commenters responding to the ANPRM was MSHA's enforcement practices concerning S&S violations. Because S&S violations form the basis for finding a pattern of violations, several commenters stated that a more uniform application of the criteria for determining what violations are S&S is needed in MSHA's enforcement activities. These commenters suggested that the criteria for S&S violations be defined in the rule as it was by the Review Commission in the National Gypsum case.

MSHA agrees that application of the pattern of violations provision must be in agreement with the definition of S&S violations established by the Review Commission and adopted by the Agency. However, MSHA does not believe that a definition of what constitutes an S&S violation is appropriate or necessary for this regulation. In accordance with prevailing case law, each violation must be independently evaluated by inspectors to determine whether the circumstances meet the S&S violation criteria. Although any criteria which are based, in part, on subjective elements may result in some variation in how they are applied, the Agency has been working, and will continue to work, with its inspectors toward a consistent application of principles for determining what violations are S&S.

Several commenters suggested that the compliance information used to identify mines with a potential pattern of violations only include citations and orders that have become final. This would include citations and orders that have not been timely appealed, or for which all avenues of appeal have been exhausted. Commenters also urged that the pattern provisions only apply to violations cited by MSHA after the regulations become final. Some commenters stated that they would have contested past citations and orders for S&S violations if they had known the violations could be part of an evaluation for pattern of violations.

At this stage in the rulemaking process, MSHA does not agree that the proposed pattern of violations regulations should only address S&S violations occurring after the effective date of the rule. The existing criteria for defining S&S violations are not changed by this proposal, and MSHA believes it would be appropriate to take existing S&S violations into consideration under the rule. However, the Agency does agree that any pattern notice should be based only on final citations and orders. With this approach, which is included in proposed § 104.3, mine operators would be subject to the pattern of violations enforcement provisions based on a mine's compliance history developed after a full opportunity to exercise the review procedures provided for by the Mine Act.

B. Section-by-Section Discussion

Section 104.1 Purpose and Scope

Several commenters requested that procedures for determining the existence of a pattern of violations be prefaced by a statement of the regulation's purpose. They were concerned that the provision could otherwise receive broader application than intended by Congress. In developing this proposal, MSHA has given close attention to the Mine Act's legislative history. The description of the objectives and concerns of the lawmakers who enacted the statute makes it clear that the pattern of violations enforcement provisions are directed at the few mine operators who have a history of repeated S&S violations, indicating that they habitually permit such violations to occur. In particular, Congress focused its attention on mines where citations or orders are issued for S&S violations and the violations are abated but then continue to recur without effective preventative measures being taken by mine management.

Although section 104(c) does not define "pattern of violations," the legislative history gives some general guidance on the kinds of situations to which the provision should apply. The Senate Committee stated its intent that:

A pattern may be established by violations of different standards, as well as by violations of a particular standard. Moreover, while the Committee considers that a pattern is more than an isolated violation, a pattern does not necessarily mean a prescribed number of violations of predetermined standards nor does it presuppose any element of intent or state of mind of the operator. (S. Rep. No. 181, 96th Cong., 1st Sess. 33 (1979)).

Proposed § 104.1 responds to the commenters' suggestions, in concert with this legislative background. It provides that the regulations set out the criteria and procedures to determine whether a pattern of violations exists under the Mine Act and specifies that the rule address mines where operators habitually allow S&S violations of mandatory safety and health standards to occur.

Section 104.2 Initial Screening

This section of the proposed rule describes the review process MSHA would use to initially select mines for evaluation for a pattern of violations under § 104.3. The proposal specifies that MSHA would review the compliance records of mines at least annually. Paragraph (a) requires examining each mine's history of S&S violations, withdrawal orders for failure to abate S&S violations, and withdrawal orders for conditions posing an imminent danger to miners. Violations which are designated S&S, if they continue to occur, are indicative of an unsafe or unhealthy working environment. Repeated withdrawal orders issued for failure to abate S&S violations reflect inadequate attention to correcting unsafe or unhealthy conditions. Imminent danger withdrawal orders are issued for conditions or practices which could reasonably be expected to cause death or serious physical harm before the conditions or practices can be abated.

Paragraph (b) of the proposal would require consideration of four additional factors designed to further define those mines that should be reviewed for an emerging potential pattern of violations. The proposal does not specify that a particular number or combination of these factors be found in order to identify a potential pattern of violations.

Paragraph (b)(1) would require consideration of what enforcement measures MSHA has taken to improve compliance with respect to the violations identified as a potential pattern. For example, where there are repeated S&S violations of a standard, the Agency would take into account whether the Mine Act's enforcement provisions for unwarrantable failure to comply have been used. This factor
would recognize that, in the enforcement scheme of the Mine Act, the pattern provisions are intended to be reserved for operators who are unresponsive to the other enforcement measures provided for by the statute.

Paragraph (b)(2) calls for consideration of whether there is evidence of the mine operator's lack of good faith in correcting the problem that resulted in repeated S&S violations. Perfunctory abatement of S&S violations without correction of the underlying cause indicates disregard for compliance with safety and health standards. The Agency's primary focus will be to determine if enforcement activities at the mine have been broadened beyond that expected for the operation. For example, whether the following actions occurred: meetings held between MSHA officials and the operator failed to result in improved compliance; the Agency found it necessary to increase inspector presence at the mine; or increases were requested in the special assessments for violations.

Paragraph (b)(3) would require consideration of the mine's accident, injury or illness record. In particular, the Agency will be concerned with those mines having incidence rates above the average for that type of operation, or which have been found to under report accidents, injuries or illnesses, indicating either intentional concealment of problems or a serious management problem. Where miners have been injured or killed, or occupational illnesses have developed among the work force, a mine operator is on notice that attention to the mine's safety or health programs is needed. This should be reflected in the compliance history.

Paragraph (b)(4) provides for consideration of whether mitigating circumstances exist. This factor would recognize that circumstances beyond an operator's ability to control through diligent compliance efforts can contribute to the occurrence of violations. The Mine Act's pattern provisions are directed at improving compliance at mines where repeated S&S violations result from an inadequate commitment by mine management to achieving and maintaining compliance with safety and health standards.

The initial screening process is intended to have equal application to all types and sizes of mines. It is intended to identify only mines that would then be evaluated for a potential pattern of violations through application of the criteria in § 104.3. The proposal would also retain flexibility in the initial screening process to permit MSHA to develop and improve its methods of applying the initial screening criteria. In line with these objectives, the proposal does not prescribe intervals for MSHA review, except that each mine would receive at least one review annually. Further, the rule does not specify the period of a mine's history that would be examined during the initial screening process, nor a particular number or combination of citations or orders that would result in a mine being selected for evaluation for a potential pattern of violations. Instead, each mine would be regularly looked at by MSHA for signs of a compliance problem or hazardous conditions that threaten miner safety or health.

MSHA anticipates concentrating its efforts during the initial screening process on identifying those mines with evident compliance problems. While the Agency would screen mines at least annually, mines warranting additional attention could be looked at more frequently. Initially, MSHA believes that a mine's compliance records for a period of two years would provide an informative, relevant perspective. However, interruptions in mining operations, changes in mine management, or other factors could indicate that this period should be longer or shorter.

Commenters responding to the ANPRM suggested a variety of specific screening mechanisms ranging from an automatic quarterly review of all mines with more S&S violations than an industry-wide percentile to normalization of the number of S&S violations for mine size over the previous two years. Under the proposal, these or other reasonable analytical methods could be used to evaluate mines' compliance records.

Section 104.3 Pattern Criteria

Once a mine is identified through the proposed initial screening process, MSHA would apply the provisions of this section to identify mines with a potential pattern of violations. As provided by paragraph (b), the compliance history data used for this evaluation would be the same as that used for initial screening, except that only final citations and orders would be considered. The proposal prescribes three criteria for discerning a potential pattern of violations. As with the initial screening procedures, the proposal does not quantify the violations or other factors which would identify a mine as having a pattern of violations. At this state, MSHA believes it is necessary for the Agency to retain the flexibility to individually evaluate each mine's compliance history and the particular circumstances involved when conducting the determination for a potential pattern of violations.

The proposed pattern criteria focus on a mine's history of repeated S&S violations. To facilitate identification of a potential pattern, the proposal directs attention to violations linked together in one of three ways: (1) Violations of the same standard; (2) violations of standards related to the same hazard; or (3) violations caused by unwarrantable failure to comply. Each of these three categories would be independently evaluated.

Repeated S&S violations of the same standard, or of standard related to the same hazard, may be the result of a chronic condition at a mine in which violations are abated when cited without correction of the underlying cause of the violations. Repeated S&S violations caused by unwarrantable failure to comply also suggest that an underlying safety or health management problem may exist at the mine.

Paragraph (b) provides that only final citations and orders would be considered when identifying mines with a potential pattern of violations under this section.

In response to the ANPRM, MSHA received a variety of recommendations for criteria to be used for determining whether a mine has a pattern of violations, some of which are reflected in the proposal. Several commenters stated that there should be a direct correlation between the violations identified as a pattern and reportable accidents and injuries at the mine. The proposed screening criteria do not acknowledge the relevance of accidents, injuries and illnesses to a pattern of violations regulation. MSHA is unable, however, to precisely link S&S violations to the occurrence of accidents and injuries except when they involve an accident. Individual health violations are likewise difficult to directly link with the development of occupational illnesses. In addition to being potentially unworkable, this approach would be inconsistent with the preventative purposes of the Mine Act.

Section 104.4 Issuance of Notice

As indicated in the ANPRM, MSHA believes that an important feature of an effective pattern of violations regulation is an opportunity for full and fair notice to all parties involved prior to a pattern of violations notice being issued. To serve the remedial purposes of the Mine Act, including section 104(e), the proposal also provides opportunities for
input from mine operators and the representative of miners at the mine before a pattern of violations notice would be issued. Under the proposal, the final decision of whether to issue a pattern of violations notice would be made by the administrator for Coal Mine Safety and Health or Metal and Nonmetal Mine Safety and Health, as appropriate.

Paragraph (a) of the proposal describes the notification procedures to be followed when a potential pattern of violations has been identified. The local District Manager would notify the mine operator in writing, with a copy provided to the representative of miners at the mine. Included in this notification would be the basis for identifying the mine as having a potential pattern of violations and the time within which the mine operator could respond to the notification. Recognizing that potentially dangerous conditions may exist at the mine, the proposal would limit the time for response to 20 days. A shorter period could also be set by the District Manager.

During the time for responding to a notification that a potential pattern of violations has been identified, the mine operator would be given an opportunity to review all documents upon which the pattern of violations evaluation was based, to provide additional information, and to request a conference with the District Manager. The proposal specifies that such a conference be held within 10 days of the request, again recognizing that there is evidence of potentially dangerous conditions at the mine. The miner's representative would also be notified of the conference and afforded an opportunity to participate.

During the time permitted for response to notification of potential pattern of violations, the operator could also institute a program at the mine to avoid repeated S&S violations. If this were done, the proposal authorizes the District Manager to allow additional time to determine whether the operator's program is effective. This period of evaluation could not exceed 90 days under the proposal, and the representative of the miners would be afforded an opportunity to discuss the program with the District Manager. This aspect of the proposal is intended to encourage and permit an opportunity for the operator to undertake the measures necessary to restore the mine to a safe and healthful working environment. In MSHA's view, a sound safety and health program developed and adopted by the mine operator most effectively reduces S&S violations. The District Manager's decision of whether to permit an evaluation period for an operator's program to avoid repeated S&S violations, and the length of the evaluation period, would be influenced by the quality of the operator's program. Consistent with the nature of the problem at which the Mine Act's pattern of violations provisions are directed, the operator's program would be expected to address the underlying cause of repeated S&S violations on a permanent basis.

Paragraph (b) of the proposal provides procedures for initiating a decision by the Administrator as to whether a pattern of violations exists at the mine. When the opportunities provided for by paragraph (a) of this section do not lead to a resolution of the circumstances which prompted the notice of a potential pattern of violations, the District Manager would submit a report to the Administrator. The District Manager's report, which would be required within 120 days from the notification of a potential pattern of violations at the mine, would include the evaluation made under these proposed regulations. A copy of the report would also be provided to the mine operator and representatives of the miners. Both parties would have the opportunity to comment on the report within 15 days of receipt.

Within 30 days of receipt of a report from the District Manager, paragraph (c) would require the Administrator to issue a decision as to whether a pattern of violations notice would be issued. The Administrator's decision would be provided to both the operator and miner's representative. Under paragraph (d), notification of a pattern of violations would be required to be posted at the mine.

Commenters responding to the ANPRM expressed conflicting views on the procedural steps that would be appropriate between identification of a potential pattern of violations at a mine and issuance of a notice that a pattern of violations exists. One commenter stated that Congress did not intend an operator to have any warning before the Agency issues a pattern of violations notice. According to this commenter, the citations and orders issued by MSHA to the operator for repeated S&S violations of standards provide the operator with ample warning of a pattern of violations notice. Other commenters suggested a lengthy series of conferences and appeals leading up to a pattern of violations notice, with the Secretary of Labor making the final decision.

The objective of these proposed regulations is to identify mines with a serious safety and health management problem which is indicated by repeated S&S violations of mandatory standards. In proposing these regulations, MSHA is aware that section 104(e) enforcement sanctions are severe. As discussed elsewhere in this preamble, orders of withdrawal are issued for all S&S violations occurring at a mine that has been issued a pattern of violations notice. Also, as a practical matter, reaching the level of compliance required for termination of a pattern of violations notice can be expected to be difficult at some mines. This issue is discussed further below.

With this in mind, the proposal includes, for both the mine operator and representative of the miners, procedures for notification and an opportunity to participate in the determination of whether to issue a pattern of violation notice. On the other hand, these procedures are confined to what MSHA believes are reasonable and prudently prompt time frames.

Section 104.5 Termination of Notice

This section of the proposal reflects the Mine Act's requirement that once a pattern of violations notice is issued under section 104(a)(1), the notice can only be terminated after an MSHA inspection of the entire mine finds no S&S violations of a mandatory safety or health standard. As commenters on the 1980 proposal and the recent ANPRM have observed, such a "clean inspection" of the entire mine is a difficult requirement to meet in the dynamic mining environment, particularly at large mines. As a practical matter, MSHA agrees. It is not, however, the Agency's intent that a mine under pattern orders remain so after remedial actions by the operator have restored safe and healthful conditions at the mine. Such a situation could ultimately result in having mines on a pattern sequence that have a better compliance record than mines not on a pattern sequence. MSHA requests comments on how this situation could be avoided.

To make this provision more workable, commenters suggested that the mine operator who has been issued a pattern of violations notice be permitted to request an inspection of the entire mine, or a portion of it. Partial inspections of the mine would be added together to compose an inspection of the entire mine.

The proposal includes this suggestion, with several important limitations. As specified by the Mine Act, no advance notice of an inspection would be provided. Thus, while an operator could request a mine inspection under the proposal, there could be no indication...
from MSHA of when the inspection would be conducted. In addition, the proposal provides that the scope of the inspection would be determined by MSHA. Accordingly, areas of the mine not included in an inspection request by the operator or, at the Agency's discretion, be inspected. The proposal also specifies that partial inspections covering the entire mine within 90 days would constitute an inspection of the entire mine for purposes of terminating a pattern of violations notice. The 90-day limitation would tie together a series of partial inspections so that they would be representative of the overall conditions at the mine. The 90-day limitation is consistent with the time period specified in sections 104(d) and 104(e) of the Mine Act for placing an operator on the withdrawal order sequence. The combining of a series of partial inspections to compose a complete inspection of the mine is consistent with the decision of the Federal Mine Safety and Health Review Commission regarding the 104(d) unwarrantable failure provision. Under the Mine Act, once an inspection of the entire mine is completed and no S&S violations of mandatory standards are found, the pattern of violations is terminated.

III. Executive Order 12291 and Regulatory Flexibility Act

In accordance with Executive Order 12291, MSHA has prepared an initial analysis to identify potential costs and benefits associated with proposed Part 104. This analysis has formed the basis for the initial Regulatory Flexibility Act. In this analysis, MSHA has determined that the proposed rule would not result in major cost increases nor have an incremental effect of $100 million or more on the economy. Therefore, the rule does not meet the criteria for a major rule and a Regulatory Impact Analysis is not required.

The benefits of the proposed rule are the fatalities, injuries, and illnesses that will be prevented at 15,100 mines with 243,000 employees. MSHA cannot predict whether any pattern of violation rule would prevent mine disasters. However, this pattern proposal is directed at the root of most disasters—noncompliance with mandatory safety and health standards. The Agency does believe that the rule will result in reduced fatalities, but the nature of the rule makes quantification of such benefits difficult. MSHA also estimates that a minimum of between 14 and 57 nonfatal occurrences with days lost and between 2 and 7 nonfatal occurrences without days lost can be prevented. Such estimates do not include benefits at mines that do not receive issuance notices but which would improve their health and safety program in order to avoid pattern sanctions. They also do not include any quantitative measure of the likely health benefits that will accrue to miners in the mining industry. MSHA estimates that the annual cost of complying with the proposed rule is between $30,500 and $124,300. The variation is due to the likely number of mines that would receive issuance notices. All of the costs are associated with § 104.4, issuance of notice. Any costs that the mine operator would incur to comply with other Federal standards would be borne by those standards. A cost may also occur, of course, if the pattern rule results in the closure of a mine that would not otherwise have been closed but rather would have abated the hazards as they were cited.

The Regulatory Flexibility Act requires that agencies evaluate and include, wherever possible, compliance alternatives that minimize any adverse impact on small businesses when developing proposals. The proposed rule will likely affect smaller mines to a lesser degree than large mines. Due to their size, small mines are likely to have fewer safety and health hazards per mine to correct than larger mines. Should an entire section of a smaller mine be forced to temporarily close, however, its compliance cost on a per-mine basis would be higher than a larger mine.

IV. Paperwork Reduction Act

This proposal contains no information collection requirements subject to the Paperwork Reduction Act of 1980.

List of Subjects in 30 CFR Part 104

Mine safety and health, Pattern of violations.

David C. O'Neal,
Assistant Secretary for Mine Safety and Health.

Date: May 24, 1989.

It is proposed to add a new Subchapter Q consisting of new Part 104 in Chapter I, Title 30 of the Code of Federal Regulations to read as follows:

SUBCHAPTER Q—PATTERN OF VIOLATIONS

PART 104—PATTERN OF VIOLATIONS

Sec. 104.1 Purpose and scope.
104.2 Initial screening.
104.3 Pattern criteria.
104.4 Issuance of notice.
104.5 Termination of notice.

Authority: 30 U.S.C. 814(e), 857.

§ 104.1 Purpose and scope.

This part prescribes the criteria and procedures used by MSHA to determine whether a pattern of violations exists at a mine for purposes of section 104(e) of the Federal Mine Safety and Health Act of 1977 (Act). It addresses mines where operators habitually allow the recurrence of violations of mandatory safety or health standards which significantly and substantially contribute to the cause and effect of mine safety or health hazards.

§ 104.2 Initial screening.

At least once each year, MSHA shall review the compliance records of mines. MSHA's review shall include an examination of the following:

(a) The mine's history of—
   (1) Significant and substantial violations;
   (2) Section 104(b) closure orders resulting from significant and substantial violations; and
   (3) Section 107(a) imminent danger orders.

(b) In addition, the following shall be considered:
   (1) What enforcement measures, other than section 104(e) of the Act, have been applied at the mine.
   (2) Evidence of the mine operator's lack of good faith in correcting the problem that results in repeated S&S violations.
   (3) An accident, injury, or illness at a mine that demonstrates a serious safety or health management problem at the mine.
   (4) Whether mitigating circumstances exist.

§ 104.3 Pattern criteria.

(a) The following criteria shall be used to identify mines with a potential pattern of violations:
   (1) A history of repeated significant and substantial violations of a particular standard;
   (2) A history of repeated significant and substantial violations of standards related to the same hazard; or
   (3) A history of repeated significant and substantial violations caused by unwarrantable failure to comply.

(b) Only final citations and orders shall be used to identify mines with a potential pattern of violations under this section.

§ 104.4 Issuance of notice.

(a) When a potential pattern of violations is identified, the District Manager shall notify the mine operator in writing. A copy of the notification shall be provided to the representative of miners at the mine. The notification

Authority: 30 U.S.C. 814(e), 857.
shall specify the basis for identifying the mine as having a potential pattern of violations and give the mine operator a reasonable opportunity, not to exceed 20 days from the date of notification, to—

(1) Review all documents upon which the pattern of violations evaluation is based.

(2) Provide additional information.

(3) Submit a written request for a conference with the District Manager. The District Manager shall hold any such conference within 10 days of a request. The representative of miners at the mine shall be afforded an opportunity to participate in the conference.

(4) Institute a program to avoid repeated significant and substantial violations at the mine. The District Manager may allow an additional period, not to exceed 90 days, for determining whether the program effectively reduces the occurrence of significant and substantial violations at the mine. The representative of miners shall be provided an opportunity to discuss the program with the District Manager.

(b) If the District Manager continues to believe that a potential pattern of violations exists at the mine, a report of the evaluation made under this part shall be sent to the appropriate MSHA Administrator. This report shall be submitted no more than 120 days from the notification to the operator and miners' representative under § 104.4 of this part. A copy of the report shall be provided to the mine operator and the miners' representative. Both parties will have 15 days from receipt of the report to submit written comments to the Administrator.

(c) Within 30 days of receipt of a report from a District Manager, the Administrator shall issue a decision as to whether the mine is to be issued a notice of a pattern of violations. A copy of the decision shall be provided to the mine operator and the representative of the miners.

(d) The mine operator shall post all notifications issued under this part at the mine.

§ 104.5 Termination of notice.

(a) Termination of a section 104(e)(1) pattern of violations notice shall occur when an inspection of the entire mine by MSHA finds no significant and substantial violations.

(b) The mine operator may request an inspection of the entire mine or portion of the mine. No advance notice of the inspection shall be provided, and the scope of inspection shall be determined by MSHA. Partial mine inspections covering the entire mine within 90 days shall constitute an inspection of the entire mine for the purposes of this part.

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Part V

Department of Transportation

Federal Aviation Administration

14 CFR Part 25
Electrical and Electronic Systems
Lightning Protection; Notice of Proposed Rulemaking
DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration
14 CFR Part 25
(Docket No. 25912; Notice No. 89-15)
RIN 2120-AC81
Electrical and Electronic Systems Lightning Protection
AGENCY: Federal Aviation Administration (FAA), DOT.
ACTION: Notice of Proposed Rulemaking (NPRM).
SUMMARY: This notice proposes to amend the Federal Aviation Regulations (FAR) to add a new standard for transport category airplanes which would provide lightning protection requirements for installed electrical and electronic systems. This proposal is the result of increasing concern for the vulnerability of these systems to the indirect effects of lightning. It seeks to promulgate specific lightning protection requirements for electrical and electronic systems which perform essential or critical functions.
DATE: Comments must be received on or before September 27, 1989.
ADDRESS: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket (AGC-204), Docket No. 25912, 800 Independence Avenue SW., Washington, DC 20591, or delivered in duplicate to: Room 615G, 800 Independence Avenue SW., Washington, DC 20591, or delivered in duplicate to: Room 615G, 800 Independence Avenue SW., Washington, DC 20591. Comments delivered must be marked: Docket No. 25912. Comments may be inspected in Room 615G weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. In addition, the FAA is maintaining an information docket of comments in the Assistant Chief Counsel weekdays, between 7:30 a.m. and 4:00 p.m.
SUPPLEMENTARY INFORMATION:
Comments Invited
Interested persons are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments relating to the environmental, energy, or economic impact that might result from adopting the proposals contained in this notice are invited. Substantive comments should be accompanied by cost estimates. Commenters should identify the regulatory docket or notice number and submit comments, in duplicate, to the Rules Docket address specified above. All comments received on or before the closing date for comments will be considered by the Administrator before taking action on this proposed rulemaking. The proposals contained in this notice may be changed in light of comments received. All comments will be available in the Rules Docket, both before and after the closing date for comments, for examination by interested persons. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Commenters wishing the FAA to acknowledge receipt of their comments must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 25912." The postcard will be date/time stamped and returned to the commenter.
Availability of NPRM
Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Information Center, APA-230, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-3484. Communications must identify the number of this NPRM. Persons interested in being placed on a mailing list for future rulemaking documents should also request a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedures.
Background
Concern for the vulnerability of airplane electronic systems to the effects of lightning has increased substantially over the past few years. The use of solid-state components and digital electronics in airplane system design has made such systems susceptible to transient effects of induced electrical current and voltage caused by either a direct lightning strike to the airplane or by the electric fields created by a nearby lightning flash. These induced transient currents and voltages can degrade electronic system performance by damaging components or upsetting system functions. Component damage means a permanently altered electrical characteristic which includes dielectric breakdowns and effects from heat in semiconductor junctions, resistors, and interconnection failures. Function upset refers to an impairment of system operation, either permanent or momentary (e.g., a change of digital or analog state), which includes logic changes in computer and processing systems, electronic engine and flight controls, and power generating and distribution systems.
Another factor that has contributed to this increased concern is the reduced electromagnetic shielding afforded airplane electronic systems by advanced technology airframe materials. Some of these materials have low electrical conductivity and lightning strikes often puncture them, resulting in extensive damage and allowing lightning attachment to vulnerable electronic systems or components located within the airframe. Other materials, such as graphite-reinforced composites, have some electrical conductivity. Voltages induced by lightning current that flows in airframe components made of these composite materials are much higher than those in aluminum materials because the electrical resistance of composites is higher; therefore, such composites provide much less protection to the circuits and electronic systems in the airplane.
At present, lightning protection airworthiness certification requirements are somewhat fragmented and incomplete. There are two Federal Aviation Regulations that specifically pertain to lightning protection: One for the airframe in general (§ 25.581), and the other for fuel system protection (§ 25.994). There are no regulations dealing specifically with lightning protection of electrical and electronic systems. The advent of advanced electronic systems in airplane designs submitted for FAA approval requires that additional consideration be given to protecting these systems from the effects of lightning strikes. Although § 25.581(a), in the structures subpart, requires that an airplane be protected against catastrophic effects of lightning, and § 25.1309(a) states that required systems must operate properly in all environmental conditions, it has been determined that the existing lightning protection requirements are not
adequate for these advanced electronic systems. In recent type certification programs involving advanced electronic systems, such as those used in the A320, B747-400, and MD-11 airplanes, the FAA has adopted special conditions to provide an adequate level of safety. Since trends indicate that future airplane designs will incorporate similar systems, the FAA has determined that a change in the design standards regulations is necessary.

Discussion

Full authority digital engine controls, electronic flight controls, and artificial stabilization have made avionics more critical to the safe operation of an airplane, and less able to survive even brief interruptions of function, much less actual damage. Continual reductions in the size of microcircuits, accompanied by equal reductions in the operating voltage of those circuits, cause them to be more susceptible to damage by lightning. Increased dependence on sensitive electronic equipment for the safe operation of an airplane makes adequate protection of that equipment a primary requirement. To that end, the FAA is proposing a rule that provides new lightning protection standards for electrical and electronic systems.

The proposed rule establishes two levels of lightning protection for electrical and electronic systems, depending on whether the systems perform critical or essential functions. A critical function is one whose failure would contribute to or cause a condition which would prevent the continued safe flight and landing of the airplane. An essential function is one whose failure would contribute to or cause a condition which would significantly impact the safety of the airplane or the ability of the flightcrew to cope with adverse operating conditions.

Electrical and electronic systems which perform critical functions must be protected from the effects of lightning to the extent that neither their operations nor their operational capabilities are affected. When the airplane is exposed to the direct or indirect effects of lightning, disturbance or upset of systems which perform critical functions must not be perceived by the flightcrew. That changes and flight control movement due to electromagnetic disturbances or upsets that would not be permitted. In addition, those systems possessing redundant channels, when operating in a single channel mode, must not be damaged or affected when the airplane is exposed to lightning. Mode changes due to electromagnetic disturbances will not be allowed in critical systems.

Internal monitors which indicate normal operation of critical systems must not be damaged or affected due to lightning. It should be noted that these systems may perform both critical and non-critical functions and that failures not associated with critical functions may not necessarily prevent the continued safe flight and landing of the airplane. The proposed regulation would require only those parts of the system associated with the critical function to be protected from the effects of lightning as described in this paragraph. However, it may be difficult to provide adequate "isolation" and the resultant lightning protection to "parts" of an integrated system.

Electrical and electronic systems which perform essential functions must be protected from the effects of lightning to the extent that they remain able to perform their intended functions after the airplane has been exposed to lightning. This means that a disturbance of systems that perform essential functions may be perceived by the flightcrew when the airplane is exposed to the direct or indirect effects of lightning, but such systems must be able to return to their intended functions. A momentary disruption of data flow which automatically resets and continues normal operation would be satisfactory; disruptions that require flightcrew action to return the system to normal operation (such as resetting circuit breakers, reselecting a mode of operation, or re-engaging the autopilot) also would be allowed. When required that "systems continue to perform their intended functions," we mean that the function these systems perform has not been lost after the lightning encounter, even if one or more of those systems has been affected. For example, if one of several navigation systems aboard the airplane has been damaged but the navigation function has been retained, the requirements of the regulation would be met. Note that systems may perform multiple functions and that failure of some of these functions may not necessarily compromise the safety of the airplane or the ability of the flightcrew to cope with adverse operating conditions. Those parts of the system not associated with the essential function need not be protected from the effects of lightning.

The proposal would also add an Appendix J to Part 25, setting forth an idealized representation of a severe natural lightning environment for certification purposes in the assessment of the induced effects of lightning. The amendments proposed herein would apply to all transport category airplanes for which an application for a type certificate is made after the effective date of the amendments. These amendments would also be applicable under the provisions of §21.101 to other transport category airplanes in which critical electronic control systems are installed.

Regulatory Evaluation

Benefit-Cost Analysis

The regulatory evaluation prepared for this Notice of Proposed Rulemaking analyzes the cost and benefit aspects of establishing lightning protection in transport category airplanes. This notice proposes to amend Part 25 of the Federal Aviation Regulations (FAR). The objective of the proposed rule is to ensure that all electronic systems installed in transport category airplanes built or sold in the U.S. be adequately equipped with protection against the indirect effects of lightning strikes.

This proposal is the result of increasing concern for the vulnerability of flight-critical electronic control systems to the indirect effects of lightning, and promulgates specific lightning protection requirements for systems that perform essential and critical functions. Transport category airplanes are currently being designed with advanced technology electronic systems that perform flight critical and essential functions with no mechanical backup. These systems, for the most part, sense low voltage levels and respond accordingly. As a result, they are particularly vulnerable to the strong electromagnetic interference that could be generated by a lightning strike to, or in the vicinity of, an airplane. Compounding the problem is the increasing use of composite materials in airplane structures, in which electromagnetic shielding effectiveness is usually less than that of conventional metal airplane skin. Concern for the indirect effects of lightning has led the FAA to the conclusion that regulatory requirements for lightning protection of electronic systems need to be strengthened. Presently, regulations exist for protection of the airframe (§25.581) and the fuel system (§25.594). While lighting protection of electronic systems would appear to fall within the airframe regulation, it is not specifically mandated in §25.581. This proposal would ensure that designers and installers of new electronic systems in transport category airplanes directly address the lightning protection of flight critical and essential electronic equipment.
The FAA estimates the incremental cost of compliance that would accrue from implementation of this proposal to be zero. This assessment is based on information received from industry sources which indicates that manufacturers have already taken the initiative to put in place the requirements set forth in this proposal. According to industry sources, concern for the indirect effects of lightning has been shared by U.S. and foreign manufacturers of transport category airplanes for some time. This concern, together with the existing requirements of § 25.581, has led manufacturers to incorporate a sufficient level of protection against the indirect effects of lightning in their airplanes produced over the past 10 years and in the design of those airplanes projected to come into service within the next 10 to 15 years. The most recent example is the Boeing 757 series airplane which was type certificated in the early 1980's and is equipped with adequate protection against the indirect effects of lightning strikes on its electrical and digital electronic systems. For these reasons, the FAA believes compliance with this proposal would not impose any additional cost on manufacturers of transport category airplanes.

**Benefits**

Ordinarily, the FAA would attempt to quantify the benefits of this proposal in monetary terms, based on the likelihood of accident occurrence and associated casualty losses; however, in this case such analysis is not feasible because there is no documented evidence of accidents that can be attributed to the indirect effects of lightning in transport category airplanes. This record of safety may be attributed to the employment of adequate protection against the indirect effects of lightning in the designs of transport category airplanes by manufacturers; however, maintenance of this level of safety will remain uncertain until such protection is mandated by regulation. The need to ensure this protection increases with the increasing number of new or amended type certificated airplanes with digital electronic equipment which are expected to come into service within the next 10 to 15 years.

In terms of benefit, the proposed regulation mandates a sufficient level of protection for the electronic systems of transport category airplanes. This goal can be accomplished by codifying the current industry practices. As noted earlier, U.S. and foreign manufacturers of new type certificated transport category airplanes are already in compliance with the proposed rule. As a result of these efforts, there is little chance of an accident occurring that would be caused by the indirect effects of lightning on transport category airplanes, provided that industry standards currently in effect are applied to all future transport category airplanes. If the proposed rule were not adopted and industry practices relaxed, the likelihood of aviation accidents caused by lightning would increase dramatically, although the number of accidents and when they would occur cannot be predicted. Accordingly, this rule would be cost-beneficial.

The Regulatory Evaluation that has been placed in the docket contains additional information related to the costs and benefits that are expected to accrue from implementation of this proposal.

**Regulatory Flexibility Determination**

Under the criteria of the Regulatory Flexibility Act of 1980, the FAA has determined that the proposed rule would not have a significant economic impact on a substantial number of small entities. Since the Act applies to U.S. entities, only U.S. manufacturers of transport category airplanes would be affected. In the United States, there are two manufacturers that specialize in commercial transport category airplanes, the Boeing Company and the McDonnell Douglas Corporation. In addition, there are a number of general aviation (GA) entities that manufacture other transport category airplanes such as large business jets, including Cessna Aircraft and Gates Lear Jet.

The FAA size threshold for a determination of a small entity for U.S. airplane manufacturers is 75 employees; any U.S. airplane manufacturer with more than 75 employees is considered not to be a small entity. None of the transport category airplane manufacturers is known to be a small entity. Thus, there would not be a significant economic impact on a substantial number of small entities as the result of the implementation of this proposal.

**International Trade Impact Assessment**

This proposal is not expected to have an adverse impact either on the trade opportunities of U.S. manufacturers of transport category airplanes doing business abroad or on foreign aircraft manufacturers doing business in the U.S. Since the certification rules are applicable to both foreign and domestic manufacturers selling airplanes in the U.S., there would be no competitive trade advantage to either.

**Federalism Implications**

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 significant federalism implications to warrant the preparation of a Federalism Assessment.

**CONCLUSION**

For the reasons given above, the FAA has determined that this proposed regulation is not considered to be major under Executive Order 12291, or significant under Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). In addition, the FAA certifies that this proposed rule, if promulgated, would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act, since none would be affected.

**List of Subjects in 14 CFR Part 25**

Air transportation, Aircraft, Aviation safety, Safety.

**The Proposed Amendment**

Accordingly, the Federal Aviation Administration (FAA) proposes to amend Part 25 of the Federal Aviation Regulations (FAR), 14 CFR Part 25, as follows:

**PART 25—AIRWORTHINESS STANDARDS: TRANSPORT CATEGORY AIRPLANES**

1. The authority citation for Part 25 continues to read as follows:


2. By adding a new § 25.1315 to read as follows:

   § 25.1315 System lightning protection.

   (a) Each electrical and electronic system which performs critical functions must be designed and installed to ensure that the operation and operational capabilities of these systems to perform critical functions are not affected when the airplane is exposed to lightning.

   (b) Each essential function of an electrical and electronic system must be protected to ensure that the essential...
function can be recovered in a timely manner after the airplane has been exposed to lightning.

(c) For the purposes of the above, the following definitions apply:

(1) Critical functions. Functions whose failure would contribute to or cause a condition which would prevent the continued safe flight and landing of the airplane.

(2) Essential functions. Functions whose failure would contribute to or cause a condition which would significantly impact the safety of the airplane or the ability of the flightcrew to cope with adverse operating conditions.

(d) Definition and application of the external lightning environment are found in Appendix J.

3. By adding a new Appendix J to Part 25 to read as follows:

Appendix J to Part 25—External Lightning Environment

J25.1 Idealized Waveforms

(a) The waveforms defined below are idealized representations of a severe natural lightning environment for certification purposes in the assessment of the induced effects of lightning. Waveforms A, B, C, and D are derived from cloud-to-ground lightning discharges. Waveform H represents the high rate-of-rise effects, including those from discharges. Waveform A represents the high amplitude and an action integral of 0.25 X 10^4 A^2 s. This waveform is charge transfer. This waveform is shown in Figure 1.

(b) Component D—Restrike Current. Component D has a peak amplitude of 100 kA and an action integral of 0.25 X 10^4 A^2 s. This waveform represents a restrike of 100,000 amperes peak at a rate-of-rise of 1 X 10^11 A/s at t = 0.25 us and a peak rate-of-rise of 1.4 X 10^11 A/s at t = 0.4. This waveform is defined mathematically by the following equation:

\[ i(t) = I_0 (e^{-at} - e^{-bt}) \]

where

\[ I_0 = 109,405 \text{ (A)} \]
\[ a = 11,300 \text{ (A)} \]
\[ b = 700 \text{ (A)} \]
\[ t = \text{time (s)} \]

This current waveform is shown in Figure 2.

(c) Component C—Continuing Current. Component C is a rectangular waveform delivering 200 coulombs of charge at a rate of between 200 A and 800 A in a time period of between 1 and 0.25 s. For analysis purposes, a rectangular waveform of 400 A for a period of 0.5 second should be utilized. This component transfers a charge of 200 coulombs. The primary purpose of this waveform is charge transfer. This waveform is shown in Figure 1.

(d) Component B—Intermediate Current. Component B has average amplitude of 2 kA and a charge transfer of 10 coulombs. For analysis, a double exponential current waveform should be used. This waveform is defined mathematically by the following equation:

\[ i(t) = I_0 (e^{-at} - e^{-bt}) \]

where

\[ I_0 = 11,300 \text{ (A)} \]
\[ a = 700 \text{ (A)} \]
\[ b = 2,000 \text{ (A)} \]
\[ t = \text{time (s)} \]

This current waveform is shown in Figure 1.

(e) Component A—Initial High Peak Current. Component A has a peak amplitude of 200 kA, an action integral of 1.9 X 10^12 A^2 s, and double exponential waveform. This waveform represents a first return stroke of 200,000 amperes at a rate-of-rise of 1 X 10^11 A/s at t = 0.5 us. It has a peak rate-of-rise at t = 0.4 of 1.4 X 10^11 A/s. This waveform is defined mathematically by the following equation:

\[ i(t) = I_0 (e^{-at} - e^{-bt}) \]

where

\[ I_0 = 218,680 \text{ (A)} \]
\[ a = 11.354 \text{ (A)} \]
\[ b = 647,265 \text{ (A)} \]
\[ t = \text{time (s)} \]

This current waveform is shown in Figure 1.

J25.2 Direct Strike Environment. There are five current component waveforms:

(a) Component A—Initial High Peak Current. Component A has a peak amplitude of 200 kA, an action integral of 1.9 X 10^12 A^2 s, and double exponential waveform. This waveform represents a first return stroke of 200,000 amperes at a rate-of-rise of 1 X 10^11 A/s at t = 0.5 us. It has a peak rate-of-rise at t = 0.4 of 1.4 X 10^11 A/s. This waveform is defined mathematically by the following equation:

\[ i(t) = I_0 (e^{-at} - e^{-bt}) \]

where

\[ I_0 = 218,680 \text{ (A)} \]
\[ a = 11.354 \text{ (A)} \]
\[ b = 647,265 \text{ (A)} \]
\[ t = \text{time (s)} \]

This current waveform is shown in Figure 1.

(b) Component B—Intermediate Current. Component B has average amplitude of 2 kA and a charge transfer of 10 coulombs. For analysis, a double exponential current waveform should be used. This waveform is defined mathematically by the following equation:

\[ i(t) = I_0 (e^{-at} - e^{-bt}) \]

where

\[ I_0 = 11,300 \text{ (A)} \]
\[ a = 700 \text{ (A)} \]
\[ b = 2,000 \text{ (A)} \]
\[ t = \text{time (s)} \]

This current waveform is shown in Figure 1.

(c) Component C—Continuing Current. Component C is a rectangular waveform delivering 200 coulombs of charge at a rate of between 200 A and 800 A in a time period of between 1 and 0.25 s. For analysis purposes, a rectangular waveform of 400 A for a period of 0.5 second should be utilized. This component transfers a charge of 200 coulombs. The primary purpose of this waveform is charge transfer. This waveform is shown in Figure 1.

(d) Component D—Restrike Current. Component D has a peak amplitude of 100 kA and an action integral of 0.25 X 10^4 A^2 s. This waveform represents a restrike of 100,000 amperes peak at a rate-of-rise of 1 X 10^11 A/s at t = 0.25 us and a peak rate-of-rise of 1.4 X 10^11 A/s at t = 0.4. This waveform is defined mathematically by the following equation:

\[ i(t) = I_0 (e^{-at} - e^{-bt}) \]

where

\[ I_0 = 109,405 \text{ (A)} \]
\[ a = 11,354 \text{ (s^{-1})} \]
\[ b = 2,000 \text{ (s^{-1})} \]
\[ t = \text{time (s)} \]

This current waveform is shown in Figure 2.

(e) Component H—High Rate of Rise Current. Component H has a peak current of 10 kA and a peak rate-of-rise of 2 X 10^11 A/s at t = 0.4. This waveform is defined mathematically by the following equation:

\[ i(t) = I_0 (e^{-at} - e^{-bt}) \]

where

\[ I_0 = 54,703 \text{ (A)} \]
\[ a = 106,405 \text{ (s^{-1})} \]
\[ b = 2,2708 \text{ (s^{-1})} \]
\[ t = 1,284,530 \text{ (s^{-1})} \]
\[ t = \text{time (s)} \]

This current waveform is shown in Figure 1.

J25.3 Application.

(a) Purposes of the Waveforms and Components. Current Components A, B, C, D, and H together comprise the important characteristics of a severe natural lightning flash current, although not all of the components may attach everywhere on the aircraft. Components A, B, D, and H are described by double exponential expressions to provide the important waveshape characteristics such as rise and decay times, rate-of-rise, peak amplitude, and charge transfer or action integral. Component C is a rectangular current pulse that transfers most of the charge in a lightning flash. Indirect effects need only be considered from Components A, D, and H.

(b) A typical cloud-to-ground lightning flash contains more than one restrike, a severe version of which is represented by Component D. In fact, flashes containing up to 24 strokes have been recorded. For protection against direct effects, it is adequate to consider only one return stroke or restrike (Component A or D). However, for evaluation of indirect effects, it is necessary to consider the multiple-stroke nature of an actual lightning flash, because the succession of strokes may induce corresponding pulses in data transfer circuits (for example) causing upset or cumulative damage to sensitive systems or devices. For this purpose, the following multiple stroke flash has been defined, using as a base the definitions of Components A (first return stroke) and D (restrike).

(c) The multiple stroke waveform is defined as an A current component followed by 23 randomly spaced restrikes of peak amplitude of 50,000 amperes each, all within 2 seconds, as shown in Figure 3. The restrikes have waveform parameters identical to the D current component with the exception that \[ I_0 = 54,703 \text{ amperes.} \]

(d) Component H represents a high rate-of-rise pulse whose amplitude and time duration are much less than those of a return stroke. Such pulses have been found to occur randomly throughout a lightning flash, being superimposed on, or interspersed with, the other current components. While not likely to cause physical damage to the aircraft or electronic components, the random and repetitive nature of these pulses may cause interference or upset to certain systems. The recommended waveform comprises repetitive Component H waveforms in 24 randomly spaced sets of 20 pulses each, over a 2 second period, as shown in the multiple burst waveform in Figure 4.
FIGURE 1. WAVEFORMS OF CURRENT COMPONENTS A AND B.
FIGURE 2. WAVEFORMS OF CURRENT COMPONENTS C AND D.
One current component A followed by twenty-three current component D's at half amplitude, as described in section 2.1, all occurring randomly spaced within a period of two seconds.

FIGURE 3. MULTIPLE STROKE FLASH
One burst is 20 pulses randomly spaced in 1 millisecond

Twenty-four bursts randomly spaced within 2 seconds

FIGURE 4. MULTIPLE BURST WAVEFORM
### Table 1—Summary of Idealized Waveform Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Severe stroke (Component A)</th>
<th>Intermediate current (Component B)</th>
<th>Continuing current (Component C)</th>
<th>Restrike (Component D)</th>
<th>Multiple stroke (Component D)</th>
<th>Multiple burst (Component H)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$I_0$ (A)</td>
<td>218,810</td>
<td>11,300</td>
<td>400</td>
<td>109,405</td>
<td>54,703</td>
<td>10,572</td>
</tr>
<tr>
<td>$a$ (s⁻¹)</td>
<td>11,354</td>
<td>700</td>
<td>(1)</td>
<td>22,708</td>
<td>22,708</td>
<td>187,191</td>
</tr>
<tr>
<td>$b$ (s⁻¹)</td>
<td>647,265</td>
<td>2,000</td>
<td>(1)</td>
<td>1,294,530</td>
<td>1,294,530</td>
<td>19,105,100</td>
</tr>
</tbody>
</table>

These equations produce the following characteristics:

- $i_{\text{peak}} = 200 \text{ kA}$
- $i(t) = 1.4 \times 10^{11} \text{ A}$ at $t = 0.5 \mu s$
- $\frac{d}{dt} (A/s) = 1.0 \times 10^{11}$ at $t = 0.25 \mu s$
- Action Integral ($A^2s$) = $2.0 \times 10^8$

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Not applicable.

Issued in Washington, DC, on May 22, 1989.

Thomas E. McSweeney,
Acting Director, Aircraft Certification Service.

[FR Doc. 89-12761 Filed 5-26-89; 8:45 am]

BILLING CODE 4910-13-M
Part VI

Environmental Protection Agency

40 CFR Part 304
Arbitration Procedures for Small Superfund Cost Recovery Claims; Final Rule
Arbitration Procedures for Small Superfund Cost Recovery Claims

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Pursuant to sections 107(a) and 122(h)(2) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended by the Superfund Amendments and Reauthorization Act of 1986 ("CERCLA"), and Executive Order No. 12580, 52 FR 2923 (January 29, 1987), the Environmental Protection Agency ("EPA") is promulgating today a rule which establishes and governs the procedures for EPA's arbitration of small CERCLA section 107(a) cost recovery claims. This rule implements EPA's authority under section 122(h)(2) of CERCLA, which authorizes the head of any department or agency with authority to undertake a response action under CERCLA to use arbitration as a method of settling CERCLA section 107(a) claims for recovery of response costs incurred by the United States pursuant to section 104 of CERCLA. This authority is limited to cases in which the total response costs for the facility concerned do not exceed $500,000, excluding interest, and which have not been referred to the Department of Justice for civil action.

DATES: This final rule is effective on August 28, 1989.

ADDRESSES: The public docket for this final rule is located in Room M3105, U.S. Environmental Protection Agency, Office of Enforcement and Compliance Monitoring, Waste Enforcement Division, Room M3105, Mail Code LE-1345, 401 M Street, S.W., Washington, DC 20460, and is available for viewing by appointment from 9:00 a.m. to 4:00 p.m. Monday through Friday, excluding holidays. For an appointment, please call Janice Linett at (202) 382-3077.


SUPPLEMENTARY INFORMATION: The contents of today's preamble are set forth in the following form:

I. Introduction

Section 122(h)(2) of CERCLA provides EPA, as well as any other department or agency authorized to undertake a response action under CERCLA, with authority to promulgate regulations, after consultation with the Attorney General, for the use of arbitration as a method of settling certain CERCLA section 107(a) claims for recovery of response costs incurred by the United States pursuant to section 104 of CERCLA. This authority is limited to cases in which the total response costs for the facility concerned do not exceed $500,000, excluding interest, and which have not been referred to the Department of Justice for civil action.

On August 4, 1988, EPA proposed a regulation to implement its authority under section 122(h)(2) of CERCLA (53 FR 29428). The August 4, 1988 preamble discussed the purpose of the proposed rule in Part I and provided a detailed summary of the proposed rule in Part II. EPA accepted public comment on the proposed rule for 60 days and received 4 letters totaling 12 pages of comment. Today, EPA is promulgating the final rule to implement its CERCLA section 122(h)(2) authority. This rule establishes and governs the procedures for EPA's arbitration of CERCLA section 107(a) cost recovery claims. In preparing this final rule, EPA has carefully considered all public comments on the proposed rule and is making some modifications in response to those comments. A summary of all comments received and EPA's response to each comment is provided in Part II of today's preamble.

II. Responsiveness Summary

Comments were received from 4 commenters. Commenter 1 is Texaco Inc. Commenter 2 is Ford Motor Co. Commenter 3 is The Washington Legal Foundation. Commenter 4 is The MITRE Corp. Comments that do not relate to any particular subpart of the proposed rule are identified as General.

Comments relating to specific portions of the proposed rule are organized according to the subpart, section, and paragraph of the proposed rule to which they relate. Each comment contains a summary of the comment and EPA's response.
The commenter also supports this national or precedential significance. The selection of the arbitration organization should be made prior to a PRP request for arbitration.

Response: EPA agrees that, for arbitration to be administered by the "Association," the "Association" should be selected prior to a PRP request for arbitration. EPA plans to select the "Association" by competitive procurement. Because the procurement process is a lengthy procedure, it is likely that there will be a period of time between the effective date of this final rule and the award of a contract to the "Association." During this interim period, EPA believes that a vehicle should be available for conducting arbitrations pursuant to this regulation. Thus, EPA has amended the proposed rule to permit EPA and one or more PRPs at a facility to submit one or more issues arising in an EPA cost recovery claim for resolution by arbitration, by amending section 304.12(d) to add a new subparagraph 304.12(d)(2) that provides for arbitration of issues agreed upon by the parties and will thus obviate any future disputes as to the validity of the settlement.

Response: No response needed.

Comment #7: [Commenter 2, Subpart A, § 304.12(d)] The preamble states that an organization, defined as the "Association," will be selected based upon its ability to provide technically-capable arbitrators and that such organization will be required to "make disclosures designed to ensure that it is free from any institutional biases." The proposed rule should include criteria to select such an organization, specify the technical capabilities that arbitrators should possess, and include a requirement that the selected organization make full disclosure.

Response: EPA plans to select the arbitration association by competitive procurement. A great deal of information is routinely required of organizations interested in an EPA contract (e.g., financial information, past performance on other contracts, key personnel) that will assist the Agency in identifying any possible bias. EPA regulations also specifically address organizational conflicts of interest (48 CFR 1509, 1552.209-70, 1552.209-71, and 1552.209-72). If necessary, EPA may request further organizational information and make it part of the evaluation criteria in selecting the organization. Section 304.23 of the proposed rule includes procedures for disclosure by each individual arbitrator and for disqualification of the arbitrator based on circumstances likely to affect his or her impartiality.

Comment #8: [Commenter 4, Subpart A, § 304.12(d)] The entity to serve as the "Association" should not be selected through a competitive process which includes cost as one of its criteria. Including the cost criteria will preclude organizations that have chosen not to compete on the basis of cost from consideration. Such organizations are intrinsically freer from conflict of interest and bias and are better suited to serve as the "Association" than those which belong to the profit-making or cost-competitive sector. A not-for-profit status coupled with a refusal to compete are indicative of a company's determination to provide independent and objective analysis and to work in the public interest rather than as the agent of a client. This posture is essential in any third-party neutral and is particularly important in Superfund settlements. Selection on the basis of cost may create the impression that the entity serves at the pleasure of EPA rather than occupying a neutral position, because an entity selected due to financial considerations is more subject to influence on the basis of those considerations than one that is not. Selection on the basis of qualifications and suitability, without cost, would achieve fairness without endangering the success of the process. This is not to say that not-for-profit, non-cost- competing companies are not subject to cost controls; they undergo rigorous continual federal government audits which result in governmental approval of cost sensitive parameters for each upcoming year. Some also voluntarily adhere to the Cost Accounting Standards incorporated by reference in the Federal Acquisition Regulations. By procuring the services of one of these companies on the basis of qualifications, the government procures services, the costs of which have been previously determined by the government to be appropriate and competitive.

Response: As noted in EPA's Response to Comments 6 and 7 above, EPA plans to select the "Association" by competitive procurement. Competitive procurement is the primary method by which Federal agencies award contracts. EPA has not determined that profit-making organizations are inherently biased, subject to influence, or otherwise incapable of performing the functions of the "Association," or that there is some other compelling reason to restrict the basis for the selection of the "Association" in the manner requested by the commenter. Accordingly, EPA declines to adopt the commenter's suggestion.

Comment #9: [Commenter 1, Subpart B, § 304.20(b)] As written, if, during the course of the arbitration, projected response costs exceed $500,000, the arbitration will become nonbinding or terminate. Instead, the arbitrator should retain jurisdiction, and the arbitration should proceed as a binding arbitration so long as the original estimate of $500,000 was made in good faith and was supportable when the request for arbitration was submitted.

Response: EPA's authority to use arbitration is contained in section 122(h)(2) of CERCLA. That section authorizes use of arbitration as a method of settling cost recovery claims of the United States "where the total response costs for the facility concerned do not exceed $500,000 (excluding interest)." If response costs increase to an amount that exceeds this statutory ceiling prior to the rendering of a final arbitral decision, EPA lacks authority to resolve the claim by binding arbitration and, therefore, declines to make the change requested. As noted in Part II.B.
of the preamble to the proposed rule. EPA does not anticipate that the procedure for converting the proceeding to a non-binding arbitration will be often invoked, because the Agency does not intend to use arbitration under this rule unless and until it can establish, with reasonable accuracy and certainty, the total amount of response costs incurred and to be incurred at the site.

Comment #10: (Commenter 2, Subpart B, § 304.20(c)) The second sentence of this paragraph states, “Any issues arising in EPA’s claim that are not submitted for resolution shall be deemed to be not in dispute and shall not be raised in any action seeking enforcement of the decision for the purpose of overturning or otherwise challenging the final decision, except as provided in section 304.40(c) of this part.” This sentence and the last sentence of § 304.40(c)(3) should be deleted. (The last sentence of § 304.40(c)(3) restates the prohibition and includes an exception that allows a party to raise new issues if necessary to show that the decision was achieved through fraud, misconduct, partiality, excess of jurisdiction or authority, or violation of public policy.) These provisions should be deleted because the language can be interpreted to mean that any issue not raised during the arbitration, including unforseeable issues or issues that are not yet ripe, cannot be disputed in the future in any forum. For example, a PRP group may wish to implement a proposed remedy, but may dispute EPA’s claim for response costs. In such a case, arbitration of EPA’s costs may be useful. Since the above language could be interpreted to mean that PRPs may not challenge issues that arise during implementation of the remedy, they may be reluctant to submit costs issues to arbitration or feel compelled to raise all imaginable remedy issues, thereby increasing the complexity and cost of the arbitration. CERCLA cases typically involve several phases and all issues may not be ripe for resolution at the same time.

Response: First, it is highly unlikely that arbitration under this rule could be used in the hypothetical situation posed by the commenter, because it can only be used if the total past and future response costs of the United States do not exceed $500,000. The United States’ response costs at a site at which remedial action will be undertaken will most likely exceed the statutory ceiling. Second, the purpose of the language to which the commenter refers is to ensure that the arbitral proceeding results in a final and binding decision on the EPA cost recovery claim submitted for arbitration by precluding the parties from subsequently raising issues not presented to the arbitrator as a defense to payment of the arbitrator’s award. The achievement of a final and binding decision is one of the primary advantages of arbitration, which benefits EPA and the participating PRPs alike. Third, § 304.20(c) deals only with issues in the arbitration proceeding and enforcement thereof, and does not purport to limit the issues parties may raise in other proceedings. Finally, the decision will not produce the result the commenter fears because, under § 304.40(d) of the proposed rule, the final decision is not admissible as evidence of any issue of fact or law in any proceeding, except as needed for the United States to enforce the decision and obtain payment and except as needed for a participating PRP to defend against a contribution action concerning the EPA cost recovery claim submitted for arbitration. For these reasons, EPA declines to make the change requested.

Comment #11: (Commenter 2, Subpart B, §§ 304.20(d)(1)(ii) and (d)(4)(i)(ii)) The proposed rule, in § 304.20(d)(4)(i), identifies ability to pay as one of the factors that an arbitrator may use to allocate costs among participating PRPs if the joint request for arbitration does not specify the factors. Ability to pay should be deleted as one of the factors because: (1) it is dissimilar to the other factors which relate to the relative hazard to the public, e.g., mobility, toxicity, volume; (2) it may sanction the fundamentally unjust proposition that liability should be assessed based on ability to pay; (3) it may result in “deep pocket” PRPs shunning the arbitration process; and (4) it may be used as a tool by the arbitrator to allocate liability under § 304.20(d)(3), which allows the arbitrator to allocate liability even if not requested by the parties.

Response: As the commenter points out, § 304.20(d)(4)(i), without waiving the general applicability of the joint and several liability standard, offers the parties the option of specifying in the joint request for arbitration, the factors to be applied by the arbitrator in performing the allocation. Thus, the parties may agree on a case-by-case basis that ability to pay will not be considered by the arbitrator as one of the factors. If the parties do not so provide their own factors, this section specifies that the arbitrator shall base the allocation on such factors as the arbitrator considers relevant, in his or her sole discretion, such as volume, toxicity, and mobility of the hazardous substances, ability to pay, and inequities and aggravating factors. EPA believes that ability to pay is an appropriate factor because, among other reasons, it is among the factors Congress has authorized the President to consider when evaluating CERCLA settlements. In addition to permitting the parties to specify their own allocation factors, the rule also addresses, through § 304.20(d)(4)(ii), the commenter’s specific concern that PRPs will avoid using arbitration if certain PRPs at the site are non-viable. That section permits the parties to specify in the joint request that the arbitrator may allocate less than all response costs awarded to EPA. As noted in Part II.B of the preamble to the proposed rule, one of the reasons this provision was included is to encourage PRPs to use arbitration even if certain PRPs at the site are non-viable.

Finally, the commenter’s concern that an arbitrator will consider ability to pay when allocating liability for payment under the second sentence of § 304.20(d)(4)(ii) is unfounded. That provision directs the arbitrator to allocate liability based upon the portion of the harm attributable to each participating PRP, if the arbitrator finds that the actual or threatened harm at the facility is divisible. The provision applies only if the arbitrator finds that harm at the facility is divisible and specifically directs the arbitrator to allocate liability for payment of EPA’s award based upon the portion of the harm attributable to each participating PRP. It does not provide the arbitrator with the discretion to apply any other factors. For these reasons, EPA declines to make the change requested.

Comment #12: (Commenter 3, Subpart B, §§ 304.20(d)(4)(ii)) The commenter argues that the second sentence of § 304.20(d)(4)(ii) infringes on the right to an adequate opportunity to raise all arguable defenses and purports to limit the issues parties may present to the arbitrator. The commenter’s concern is unfounded. The achievement of a final and binding decision will not produce the result the commenter fears because, under § 304.40(d) of the proposed rule, the final decision is not admissible as evidence of any issue of fact or law in any proceeding, except as needed for the United States to enforce the decision and obtain payment and except as needed for a participating PRP to defend against a contribution action concerning the EPA cost recovery claim submitted for arbitration. For these reasons, EPA declines to make the change requested.

Response: EPA agrees that the provision that sets forth a standard of review and procedure that is more generous than that provided for under the statute and case law. It is EPA’s conclusion that, under section 107
of CERCLA and established case law, EPA is entitled to recover “all costs” incurred by EPA in connection with all aspects of a response action upheld as not arbitrary and capricious. For the limited purpose of encouraging PRP participation in arbitrations under this rule, the Agency has adopted the approach contained in § 304.20(b)(4)(ii).

Response: Under section 113(f) of CERCLA, judicial review of any issue concerning the adequacy of any response action taken or ordered by the President is limited to the administrative record upon which the President has based the selection of the response action. See, e.g., U.S. v. Seymour, 679 F. Supp. 659 (S.D. Ind. 1987); U.S. v. Rohm & Haas, 660 F. Supp. 672 (D. N.J. 1987). As noted in Part I.B. of the preamble to the proposed rule, EPA maintains that, consistent with section 113(f), the arbitrator’s view of any issue concerning EPA’s response action shall be based upon the documents which formed the basis for the selection of the response action, i.e., the administrative record. These documents will include any written public comments received by EPA concerning the selection of the response action and any EPA responses thereto. For this reason, EPA declines to make the change requested. EPA has, however, deleted the phrase “compiled by EPA” from this section, because, in addition to EPA, a State or political subdivision of a State, or an Indian Tribe, or another Federal agency may compile the administrative record when it has been designated as the “lead agency” for the site within the meaning of the National Contingency Plan, 40 CFR Part 300. A conforming change has been made to §§ 304.30(b)(3), 304.30(c)(3), and 304.32(j)(6).

Comment #14: (Commenter 3, Subpart B, § 304.20(e)(2)(iii) and (e)(3)(iii)) Under the proposed rule, once EPA’s response action is upheld (in part or in full), the arbitrator is required to review EPA’s costs on an arbitrary and capricious standard and to award EPA all costs incurred (for the portions of the response action upheld) unless the participating PRPs can show the costs were: (1) Not actually incurred or to be incurred; or (2) not actually incurred or to be incurred in connection with the response action; or (3) clearly excessive, taking into account the circumstances of the response action and relative to acceptable government procurement and contracting practices in light of the circumstances of the response action. Under U.S. v. NEPACCO, the United States is entitled to recover all costs associated with any response action upheld as not arbitrary and capricious. As such, the “clearly excessive” standard is more generous than the standard applied in judicial cost recovery proceedings. However, it has several limitations that weigh in favor of its use: (1) It encourages PRPs to use arbitration rather than take their chances in court, in which forum the issue of excessive costs is not necessarily relevant; (2) it places the burden of proof upon the PRP and thus requires additional work on the part of the Agency; (3) it contains sufficient qualifications that PRPs will rarely be able to prove the costs were excessive. Thus, although the standard is more generous than that which would be applied in the judicial arena, the benefits clearly outweigh any detriment.

Response: Again, as set forth in the Response to Comment #12, EPA agrees that the standard of review provided in § 304.20(e)(2)(iii) and (e)(3)(iii) is more generous than PRPs are entitled to in judicial cost recovery actions. It is EPA’s view that, under the language of section 107 of CERCLA, judicial review of EPA’s costs is limited to whether the costs incurred were not inconsistent with the NCP. Under this standard, matters to be reviewed are confined to: Whether the implemented cleanup was consistent with the response action selected by EPA; whether the response action was performed; and whether the claimed costs were actually incurred. Unless the selection of the response action is determined to be inconsistent with the NCP, based on a standard of review of arbitrary and capricious or otherwise not in accordance with law, EPA is entitled to recover all its actual costs of implementation of the response action. This circumscribed review of costs is intended to support the principal objectives of CERCLA: (1) To place the ultimate financial burden of hazardous waste cleanup on those parties responsible for the problem; and (2) to assure prompt replenishment of the Superfund so that monies can be redeployed to response work at the thousands of other hazardous waste sites in the country that remain unaddressed. EPA has developed a more flexible standard of review for the limited purpose of encouraging use of the arbitration regulation for small cost recovery cases. Permitting PRPs to challenge actual costs to the extent they are clearly excessive, an issue which is not relevant in litigation, may make arbitration more attractive to PRPs than litigation.

Comment #15: (Commenter 1, Subpart B, § 304.21(b)(2)) Waiver of the right to notice and service by a party who fails to furnish information relating to the service (i.e., a party’s name, address, and telephone number, and, if the party is represented by an attorney, the attorney’s name, address, and telephone number) should be limited only to the period of time during which the party fails to provide such information.

Response: EPA agrees with this comment and has amended this subparagraph accordingly.

Comment #18: (Commenter 1, Subpart B, § 304.24(b)) The last sentence of this paragraph should not allow EPA greater rights to withdraw from the arbitration than provided to other parties.

Response: Under § 304.24(b), any party may move to withdraw from the arbitral proceeding within thirty days after receipt of notice of appointment of the arbitrator. After this thirty-day period, only EPA may withdraw from the proceeding in accordance with § 304.20(b)(3) or § 304.33(e). Sections 304.20(b)(3) and 304.33(e) address EPA’s right to withdraw if public comments received on the proposed arbitral decision disclose to EPA facts or considerations which indicate the proposed decision is inappropriate, improper or inadequate. Section 122(i)(j) of CERCLA requires that EPA provide a thirty-day public comment period on all settlements reached through arbitration pursuant to section 122(h)(2). Section 122(i)(3) of CERCLA requires EPA to consider any comments filed in determining whether to finalize the settlement and authorizes EPA to withdraw from the settlement if the comments disclose facts or considerations which indicate the proposed settlement is inappropriate, improper or inadequate. EPA’s right to withdraw based upon public comments is authorized by section 122(i)(3) of CERCLA, and, for this reason, EPA declines to make the requested change. As noted in Part I.C. of the preamble to the proposed rule, EPA anticipates that withdrawal from the proceeding as a result of public comment will be an infrequent occurrence, because small cost recovery decisions of this kind are not likely to generate a large amount of public comment.

Comment #17: (Commenter 1, Subpart C, § 304.32(i)(6)) This subparagraph unfairly gives only EPA the right to supplement the documents compiled by EPA which formed the basis for the selection of the response action.
Response: As noted in EPA's Response to Comment #13 above, EPA maintains that any review of any issue concerning the adequacy of any response action taken or ordered by EPA should, consistent with section 113(j) of CERCLA, be based upon the documents which formed the basis for the selection of the response action. Section 113(j)(1) of CERCLA permits supplemental materials to be considered by a court in accordance with applicable principles of administrative law. EPA has, therefore, amended § 304.32(j)(6) to authorize the arbitrator to permit any party to supplement the documents which formed the basis for the selection of the response action if any party demonstrates that supplementation is appropriate based upon applicable principles of administrative law. The language to which the commenter objects has been deleted.

Comment #19: [Commenter 1, Subpart D, § 304.40(c)(2)(iv)] Among the grounds providing for challenging a final arbitral decision is that it violates "public policy." This term is so broad that arbitral decisions will be subject to challenge for virtually any reason so long as the appeal is couched in terms of "public policy."

Response: Section 304.40(c)(2) provides four grounds for challenging the final arbitral decision, the last of which is that the decision violates public policy. As noted in Part II.D of the preamble to the proposed rule, these four grounds are based upon generally accepted common law grounds for overturning an arbitrator's decision, as reflected in case law. See, Local Union No. 295, Newspaper Agency Corp., 483 F. Supp. 511 (D. Utah 1980). The Agency does not agree that allowing challenges based upon violation of public policy will permit challenges for virtually any reason. Whether an arbitrator's decision violates public policy is an issue for reason. Whether an arbitrator's decision will permit challenges for virtually any reason so long as the appeal is couched in terms of "public policy."

Section 304.12: Two clarifying changes have been made to this section. Paragraph (d) of this section, which defines the "Association," has been amended to add the words "to conduct arbitrations pursuant to this part" to the end of the definition. Paragraph (g) of this section, which defines "interested person," has been amended to add the words "to the proceeding" after the word "party."

Section 304.20: Two changes have been made to this section. First, for clarification, the words "actual or threatened" have been inserted before the word "may" to appear in the second sentence of paragraph (d)(3) of this section. Second, the words "compiled by EPA" have been deleted from the last sentence of paragraph (e)(1) of this section because the administrative record may be compiled by a Federal agency other than EPA, or by a State or political subdivision of a State, or by an Indian Tribe when such non-EPA entity is designated as "lead agency" within the meaning of the NCP. The identical change has been made to §§ 304.30(b)(3), 304.30(c)(3), and 304.32(j)(6). This change is explained in Comment #13, Part II, of this preamble.

Section 304.21: Four changes have been made to this section. First, the words "may be" in the first clause of paragraph (a) of this section have been changed to "is" for clarification. Second, the last sentence of paragraph (b)(2) of this section has been amended to clarify that a party who fails to furnish the information necessary for notice and service under this part is deemed to have waived his or her right to notice and service only until such time as that party furnishes the missing information. (See Comment #5, Part II, of this preamble for explanation.) Third, paragraph (b)(ix)(x) of this section has been deleted. This preamble clarified that EPA will select the "Association" through competitive procurement. Since EPA cannot guarantee that a contractor, references in the proposed rule implying advances by EPA of filing fees, administrative fees and expenses, and the arbitrator's fee have been deleted. (See § 304.41(a) and (d) and the discussion of changes to these two paragraphs below.) Fourth, a new paragraph (e) has been added to this section. This paragraph explains that, prior to EPA's selection of the Association, EPA and one or more PRPs at a facility may agree to submit one or more issues arising in an EPA cost recovery claim for resolution by arbitration. Any such agreement must be contained in a joint request for arbitration which meets all requirements of paragraph (b) of this section. New paragraph (e) also provides that any arbitration agreed upon in this manner shall be governed by this final rule, except for those provisions which pertain specifically to the duties of the Association, which duties shall be performed in a manner agreed upon by the parties. It also explains that in any arbitration initiated pursuant to new paragraph (e), the selection and appointment of the arbitrator shall be governed by new § 304.22(e), and payment of all costs of the arbitration shall be governed by new § 304.41(e), both of which are described below. The third and fourth changes to this section are explained in Comment #6, Part II, of this preamble.

Section 304.22: Two changes have been made to this section. First, the word "accepted" in the fifth sentence of paragraph (b) has been changed to "invited" for clarification. Second, a new paragraph (e) has been added to this section. This new paragraph (e) explains that if EPA and one or more PRPs at a facility agree to arbitrate an EPA cost recovery claim prior to the selection of the Association as provided in § 304.21(e), they shall reach mutual agreement upon the selection and appointment of an arbitrator on a case-by-case basis, and the Administrator shall obtain the consent of the arbitrator using appropriate procurement procedures. New paragraph (e) further provides that any person appointed as an arbitrator in this manner shall make disclosures to the parties pursuant to § 304.23 of this part, shall arbitrate the claim pursuant to the jurisdiction and authority granted to the arbitrator under § 304.20 of this part, and shall otherwise conduct the arbitration pursuant to the procedures established by this rule. This second change is explained in Comment #6, Part II, of this preamble.

Section 304.31: Paragraph (e) of this section has been amended to require a party who intends to be represented by counsel to provide the telephone number of counsel in addition to the name and address. The identical change has been made to § 304.32(e). This change is needed to make the information required by §§ 304.31(e) and 304.32(e) consistent with that required by § 304.21(b)(2) (Referral of Claims).

Section 304.32: Paragraph (j)(b) of this section has been amended. The first
sentence has been changed to allow the arbitrator to permit any party to supplement the documents which formed the basis for the selection of the response action (with additional documents, affidavits, or oral testimony) if any party demonstrates that supplementation is appropriate based upon applicable principles of administrative law. The second sentence of this paragraph has been deleted. This change is explained in Comment #17, Part II, of this preamble.

Section 304.32 Paragraph (d) of this section has been amended to require service of the proposed decision to be made by certified mail, return receipt requested, or by personal service to ensure that the decision is received by the parties.

Section 304.42: Two changes have been made to this section. First, the last sentence of paragraph (c) of this section has been amended to clarify that the final decision is a settlement under section 122(h) of CERCLA, which may be directly enforced pursuant to section 122(h)(3) of CERCLA. As amended, the first and second sentences of paragraph (c) have been modified to provide that "If any award made in the final decision is not paid within the time required by § 304.33(f) of this part, the final decision may be enforced as a settlement under section 122(h) of CERCLA, 42 U.S.C. 9622(h), by the Attorney General on behalf of EPA in an appropriate Federal district court pursuant to section 122(h)(3) of CERCLA, 42 U.S.C. 9622(h)(3)." The remainder of this paragraph is unchanged. Second, the first clause of paragraph (d) of this section, "[except as otherwise provided in this section," has been amended for clarification to indicate the more precise cross-reference to paragraph (c) of this section.

Section 304.41: Three changes have been made to this section. First, the last two sentences of paragraph (a) of this section have been deleted. As noted in the discussion of § 304.21 above, EPA cannot advance fees to a contractor. Accordingly, the requirement that all parties advance the filing fee has been deleted from paragraph (a). PRPs may, of course, provide such an advance. Second, paragraph (d) of this section has been similarly revised to delete references to advance deposits from all parties for the arbitrator’s fee and the administrative fee, and to provide that the "Association" make appropriate arrangements for payment of these fees by the parties. Third, a new paragraph (c) has been added to this section. It provides that in any arbitration conducted prior to the selection of the Association (see § 304.21(e)), all fees and expenses of the arbitral proceeding, including the arbitrator’s fee, shall be divided equally among all parties, except that expenses of witnesses shall be borne by the party producing such witnesses, expenses of an interpreter shall be borne by the party requesting such interpreter, and expenses of the stenographic record and all transcripts thereof shall be prorated equally among all parties ordering copies.

Section 304.42: Paragraph (c) of this section has been amended to require the parties to serve all papers associated with the proceeding by personal service or by certified mail, return receipt requested, or by first class mail, and to require the arbitrator and the “Association” to serve all papers associated with the proceeding by personal service or by certified mail, return receipt requested. This change is to ensure that all papers from the arbitrator and the “Association” are received by the parties.

IV. Summary of Supporting Analyses

A. Executive Order No. 12291

Regulations must be classified as major or non-major to satisfy the rulemaking protocol established by Executive Order No. 12291. According to Executive Order No. 12291, major rules are regulations that are likely to result in:

1. An annual effect on the economy of $100 million or more; or
2. A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographic regions; or
3. Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

EPA has determined that this regulation is a non-major rule under Executive Order No. 12291 because it will not result in any of the impacts identified above. This regulation provides an entirely voluntary procedure by which PRPs at a facility may reach agreement with EPA to have their liability for a CERCLA section 107(a) cost recovery claim resolved by arbitration. Arbitration is an alternative dispute resolution technique that should provide a quicker and less expensive method of resolution than traditional litigation or negotiation. Therefore, EPA has not prepared a Regulatory Flexibility Analysis.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires that a Regulatory Flexibility Analysis be performed for all rules that are likely to have "significant economic impact on a substantial number of small entities." EPA certifies that this regulation will not have a significant economic impact on a substantial number of small entities because the rule provides a wholly voluntary procedure by which PRPs at a facility may reach agreement with EPA to have their liability for a CERCLA section 107(a) cost recovery claim resolved by arbitration. Arbitration is an alternative dispute resolution technique that should provide a quicker and less expensive method of resolution than traditional litigation or negotiation. Therefore, EPA has not prepared a Regulatory Flexibility Analysis.

C. Paperwork Reduction Act

This regulation is not subject to the provisions of the Paperwork Reduction Act. Any collection of information in this regulation is required in the course of an enforcement action against a specific party or parties and, therefore, is exempt from coverage under the Act.

List of Subjects in 40 CFR Part 304

Administrative practice and procedure. Claims, Intergovernmental relations. Hazardous substances, Hazardous wastes, Natural resources, Superfund.

Date: May 22, 1980.

William K. Reilly,
Administrator.

For the reasons set forth in the preamble, Part 304, Title 40 of the Code of Federal Regulations is added as set forth below:

PART 304—ARBITRATION PROCEDURES FOR SMALL SUPERFUND COST RECOVERY CLAIMS

Subpart A—General

Sec.
304.10 Purpose.
304.11 Scope and applicability.
304.12 Definitions.

Subpart B—Jurisdiction of Arbitrator, Referral of Claims, and Appointment of Arbitrator

304.20 Jurisdiction of Arbitrator.
304.21 Referral of claims.
304.22 Appointment of Arbitrator.
Sec. 304.23 Disclosure and challenge procedures.
304.24 Intervention and withdrawal.
304.25 Ex parte communication.

Subpart C—Hearings Before the Arbitrator

304.30 Filing of pleadings.
304.31 Pre-hearing conference.
304.32 Arbitral hearing.
304.33 Arbitral decision and public comment.

Subpart D—Other Provisions

304.40 Effect and Enforcement of final decision.
304.41 Administrative fees, expenses, and Arbitrator's fee.
304.42 Miscellaneous provisions.

Authority: 42 U.S.C. 9607(a) and 9622(h)(2).
Executive Order No. 12580, 52 FR 29223 (January 29, 1987).

Subpart A—General

§ 304.10 Purpose.


§ 304.11 Scope and applicability.

The procedures established by this regulation govern the arbitration of EPA claims for recovery, under section 107(a) of CERCLA, 42 U.S.C. 9607(a), of response costs incurred at or in connection with a facility by the United States pursuant to section 104 of CERCLA, 42 U.S.C. 9604. The procedures are applicable when:

(a) The total past and projected response costs for the facility concerned do not exceed $500,000, excluding interest.
(b) The Administrator and one or more PRPs have submitted a joint request for arbitration pursuant to § 304.21 of this part.

§ 304.12 Definitions.

Terms not defined in this section have the meaning given by section 101 of CERCLA, 42 U.S.C. 9601, or the National Oil and Hazardous Substances Pollution Contingency Plan, 40 CFR Part 300. All time deadlines in this part are specified in calendar days and shall be computed in the manner described in Rule 6(a) of the Federal Rules of Civil Procedure. Except where otherwise specified, the following terms are defined for purposes of this part as follows:

(b) "Administrator" means the EPA Administrator or his designee.
(C) "Arbitrator" means the person appointed in accordance with § 304.22 of this part and governed by the provisions of this part.
(d) "Association" means the organization offering arbitration services selected by EPA to conduct arbitrations pursuant to this part.
(e) "Claim" means the amount sought by EPA as recovery of response costs incurred and to be incurred by the United States at a facility, which does not exceed $500,000, excluding interest.
(f) "Ex parte communication" means any communication, written or oral, relating to the merits of the arbitral proceeding, between the Administrator and any interested person, which was not originally filed or stated in the administrative record of the proceeding. Such communication is not "ex parte communication" if all parties to the proceeding have received prior written notice of the proposed communication and have been given the opportunity to be present and to participate therein.
(g) "Interested person" means the Administrator, any EPA employee, any party to the proceeding, any potentially responsible party associated with the facility concerned, any person who filed written comments in the proceeding, any participant or intervenor in the proceeding, all officers, directors, employees, consultants, and agents of any party, and any attorney of record for any of the foregoing persons.
(h) "National Contingency Plan" or "NCP" means the National Oil and Hazardous Substances Pollution Contingency Plan, developed under section 311(c)(2) of the Federal Water Pollution Control Act, 33 U.S.C. 1251, et seq., as amended, revised periodically pursuant to section 105 of CERCLA, 42 U.S.C. 9605, and published at 40 CFR Part 300.
(i) "National Panel of Environmental Arbitrators" or "Panel" means a panel of environmental arbitrators selected and maintained by the Association to arbitrate cost recovery claims under this part.
(j) "Participating PRP" is any potentially responsible party who has agreed, pursuant to § 304.21 of this part, to submit one or more issues arising in an EPA claim for resolution pursuant to the procedures established by this part.
(k) "Party" means EPA and any person who has agreed, pursuant to § 304.21 of this part, to submit one or more issues arising in an EPA claim for resolution pursuant to the procedures established by this part, and any person who has been granted leave to intervene pursuant to § 304.24(a) of this part.
(l) "Persons" means an individual, firm, corporation, association, partnership, trust, commercial venture, commercial entity, United States Government, State, municipality, commission, political subdivision of a State, or any interstate body.
(m) "Potentially responsible party" or "PRP" means any person who may be liable pursuant to section 107(a) of CERCLA, 42 U.S.C. 9607(a), for response costs incurred and to be incurred by the United States not inconsistent with NCP.
(n) "Response action" means remedial action, as those terms are defined by section 101 of CERCLA, 42 U.S.C. 9001, including enforcement activities related thereto.
(o) "Response costs" means all costs of removal or remedial action incurred and to be incurred by the United States at a facility pursuant to section 104 of CERCLA, 42 U.S.C. 9604, including, but not limited to, all costs of investigation and information gathering, planning and implementing a response action, administration, enforcement, litigation, interest and indirect costs.

Subpart B—Jurisdiction of Arbitrator, Referral of Claims, and Appointment of Arbitrator

§ 304.20 Jurisdiction of Arbitrator.

(a) In accordance with the procedures established by this part, the Arbitrator is authorized to arbitrate one or more issues arising in an EPA claim when:

(1) The total past and projected response costs for the facility concerned do not exceed $500,000, excluding interest; and
(2) The Administrator and one or more PRPs have submitted a joint request for arbitration pursuant to § 304.21 of this part.

(b)(1) If the total past and projected response costs for the facility concerned increase to a dollar amount in excess of $500,000, excluding interest, prior to the rendering of the final decision pursuant to § 304.33 of this part, the parties may mutually agree to continue the proceeding as non-binding arbitration pursuant to the procedures established by this part, except that §§ 304.33(e) and 304.40 of this part shall not apply.
(2) If all of the parties agree to continue the proceeding as non-binding arbitration, the proposed decision
rendered by the Arbitrator pursuant to § 304.33 of this part shall not be binding upon the parties, unless all of the parties agree to adopt the proposed decision as an administrative settlement pursuant to section 107(h) of CERCLA, 42 U.S.C. 9622(h)(1). Any administrative settlement agreed upon in this manner shall be subject to the prior written approval of the Attorney General (or his designee) pursuant to section 122(h)(1) of CERCLA, 42 U.S.C. 9622(i).

(3) If the parties do not agree to continue the proceeding as non-binding arbitration, or if the administrative settlement agreed upon is not approved by the Attorney General (or his designee), or if EPA withdraws or withholds consent from the administrative settlement as a result of public comment, EPA shall withdraw from the proceeding and the Association shall assess or refund, as appropriate, any administrative fees, expenses, or Arbitrator’s fees.

(c) The Arbitrator’s authority, as defined by paragraphs (d) and (e) of this section, to determine issues arising in EPA’s claim is limited only to the issues submitted for resolution by the parties in the joint request for arbitration pursuant to § 304.21 of this part. Any issues arising in EPA’s claim that are not submitted for resolution shall be deemed to be not in dispute and shall not be raised in any action seeking enforcement of the decision for the purpose of overturning or otherwise challenging the final decision, except as provided in § 304.40(c) of this part.

(d)(1) If the issue of liability of any participating PRP has been submitted for resolution, the Arbitrator shall determine whether the participating PRP is liable pursuant to section 107(a) of CERCLA, 42 U.S.C. 9607(a), subject only to the defenses specifically enumerated in section 107(b) of CERCLA, 42 U.S.C. 9607(b).

(2) If the issue of the dollar amount of response costs recoverable by EPA has been submitted for resolution, the Arbitrator shall determine, pursuant to paragraph (e) of this section, the dollar amount of response costs recoverable by EPA pursuant to section 107(a) of CERCLA, 42 U.S.C. 9607(a), and shall award the total amount of such costs to EPA.

(3) Unless the Arbitrator finds that the actual or threatened harm at the facility is divisible, any participating PRP whom the Arbitrator determines to be liable shall be jointly and severally liable for the total amount of response costs awarded to EPA. If the Arbitrator finds that the actual or threatened harm is divisible, the Arbitrator shall allocate liability for payment of EPA’s award among the participating PRPs based on the portion of the actual or threatened harm attributable to each participating PRP.

(4) Notwithstanding the indivisibility of the actual or threatened harm, and without waiving the general applicability of the joint and several liability standard, as an alternative to paragraph (d)(3) of this section, the parties may request the Arbitrator to allocate responsibility for payment of response costs awarded to EPA among the participating PRPs whom the Arbitrator determines to be liable. Any such request shall be made in the joint request for arbitration pursuant to § 304.21 of this part. If such a request is made, the provisions of paragraphs (d)(4)(i), (d)(4)(ii), and (d)(4)(iii) of this section shall apply.

(i) The joint request for arbitration may specify the factors to be applied by the arbitrator when allocating among the participating PRPs responsibility for payment of the response costs awarded to EPA. If the joint request does not specify such factors, the Arbitrator shall base the allocation on such factors as the arbitrator considers relevant, in his or her sole discretion, such as volume, toxicity, and mobility of the hazardous substances contributed to the facility by each participating PRP, ability to pay, and inequities and aggravating factors.

(ii) The joint request for arbitration may specify that the Arbitrator may allocate among the participating PRPs less than all response costs awarded to EPA. If this is not specified, the Arbitrator shall allocate among the participating PRPs 100% of the response costs awarded to EPA.

(iii) The burden of establishing the appropriate allocation of responsibility for payment of the response costs awarded to EPA shall rest entirely with the participating PRPs.

(5) The parties may request that the Arbitrator perform an allocation even if the issue of the liability of the participating PRPs is not submitted for resolution in the joint request for arbitration. Such a request for allocation shall be made in the joint request for arbitration pursuant to § 304.21 of this part. If such a request is made, the provisions of paragraphs (d)(4)(i), (d)(4)(ii), and (d)(4)(iii) of this section shall apply.

(e)(1) If any issue concerning the adequacy of EPA’s response action has been submitted for resolution or arises during the Arbitrator’s determination of the dollar amount of response costs recoverable by EPA, the Arbitrator shall uphold EPA’s selection of the response action, unless any participating PRP can establish that the selection was inconsistent with the NCP. The Arbitrator’s review of the adequacy of any response action taken by EPA shall be based upon the documents which formed the basis for the selection of the response action.

(2) If the Arbitrator upholds EPA’s selection of the response action in full, the Arbitrator shall award EPA all response costs incurred and to be incurred in connection with the response action, unless any participating PRP can establish that all or part of such costs were:

(i) Not actually incurred or to be incurred; or

(ii) Not actually incurred or to be incurred in connection with the response action; or

(iii) Clearly excessive, taking into account the circumstances of the response action and relative to acceptable government procurement and contracting practices in light of the circumstances of the response action.

(3) If the Arbitrator upholds EPA’s selection of the response action only in part, the Arbitrator shall award EPA only those response costs incurred and to be incurred in connection with the portions of the response action that were upheld, unless any participating PRP can establish that all or part of such response costs were:

(i) Not actually incurred or to be incurred; or

(ii) Not actually incurred or to be incurred in connection with the portions of the response action that were upheld; or

(iii) Clearly excessive, taking into account the circumstances of the response action and relative to acceptable government procurement and contracting practices in light of the circumstances of the response action.

(4) The standard of review to be applied by the Arbitrator under paragraphs (e)(1), (e)(2), and (e)(3) of this section is arbitrary and capricious or otherwise not in accordance with law.

(5) In reviewing any procedural errors alleged by any party, the Arbitrator may disallow response costs only if the errors were so serious and related to matters of such central relevance that the response action would have been significantly changed had such errors not been made.

§ 304.21 Referral of claims.

(a) If EPA believes that a claim is an appropriate candidate for arbitration, EPA will notify all identified PRPs for the facility concerned and provide such
PRPs with an opportunity to discuss referral of one or more issues arising in the claim for resolution pursuant to the procedures established by this part. Alternatively, one or more PRPs at a facility may propose to EPA use of arbitration, after receipt of a demand by EPA for payment of a claim, but prior to commencement of civil litigation of the claim. Where practicable, before an agreement to refer a claim for arbitration is made final under this alternative, either the PRPs or EPA shall notify the other PRPs at the facility of the potential use of arbitration.

(b)(1) The Administrator and one or more PRPs associated with a facility may submit to the Association a joint request for arbitration of one or more issues arising in an EPA claim concerning the facility. The joint request shall be signed by all of the parties and shall include:

(i) A brief description of the facility, the EPA response action taken at the facility, the EPA claim, and the parties;

(ii) A statement of the issues arising in the claim that are being submitted by the parties for resolution by arbitration;

(iii) A statement that the parties consent to resolution of the issues jointly submitted pursuant to the procedures established by this part by an Arbitrator appointed pursuant to § 304.22 of this part;

(iv) A statement that the parties agree to be bound by the final decision on all issues jointly submitted by the parties for resolution and to pay any award made in the final decision, subject to the right to challenge the final decision solely on the grounds and in the manner prescribed by § 304.40(c) of this part;

(v) A statement that the parties agree that the award made in the final decision may be enforced pursuant to § 304.40(c) of this part;

(vi) A statement that the parties agree that the final decision shall be binding only with respect to the response costs at issue in the claim submitted for arbitration;

(vii) A statement that the parties agree that the statute of limitations governing the EPA claim submitted for arbitration shall be extended for a time period equal to the number of days from the date the joint request for arbitration is submitted to the Association to the date of resolution of any enforcement action relating to the final decision; and

(viii) A statement that each signatory to the joint request is authorized to enter into the arbitration and to bind legally the party represented by him or her to the terms of the joint request.

(2) The joint request shall also include the name, address and telephone number of each party, and, if a party is represented by an attorney, the attorney's name, address and telephone number. A party changing any of this information must promptly communicate the change in writing to the Association and all other parties. A party who fails to furnish such information or any changes thereto is deemed to have waived notice and service under this part until such time as the party furnishes the missing information.

(c) Any party may move to modify the joint request for arbitration to include one or more additional issues arising in the referred claim. To be effective, any such modification must be signed by the Arbitrator and all other parties. The joint request for arbitration may also be modified to add one or more additional parties, if such intervention is permitted by § 304.24(a) of this part. To be effective, any such modification must be signed by the Arbitrator, the intervening party or parties, and all other parties.

(d) The statute of limitations governing the EPA claim submitted for arbitration shall be extended for a time period equal to the number of days from the date the joint request for arbitration is submitted to the Association to the date of resolution of any enforcement action relating to the final decision.

(e) Prior to the selection of the Association, the Administrator and one or more PRPs associated with a facility may agree to submit one or more issues arising in an EPA claim for resolution by arbitration. Any such agreement shall be contained in a joint request for arbitration which meets all requirements of paragraph (b) of this section. In any such arbitration, the arbitrator shall be selected pursuant to § 304.22(e) of this part, and payment of all costs associated with the arbitration shall be made pursuant to § 304.41(e) of this Part. Arbitrations agreed upon pursuant to this paragraph shall be governed by the procedures established by this part, except for those procedures which pertain specifically to the duties of the Association. All duties of the Association shall be performed in a manner agreed upon by all of the parties.

§ 304.22 Appointment of Arbitrator.

(a) The Association shall establish and maintain a National Panel of Environmental Arbitrators.

(b) Within ten days of the filing of the joint request for arbitration, the Association shall identify and submit simultaneously to all parties an identical list of ten persons chosen from the National Panel of Environmental Arbitrators, whom the Association believes will not be subject to disqualification because of circumstances likely to affect impartiality pursuant to § 304.23 of this part. Each party shall have ten days from the date of receipt of the list to identify any persons objected to, to rank the remaining persons in the order of preference, and to return the list to the Association. If a party does not return the list within the time specified, all persons on the list are deemed acceptable to that party. From among the persons whom the parties have indicated as acceptable, and, in accordance with the designated order of mutual preference, if any, the Association shall invite an Arbitrator to serve. If the parties fail to mutually agree upon any of the persons named, or if the invited Arbitrator is unable to serve, or if for any other reason the appointment cannot be made from the submitted lists, the Association shall make the appointment from among the other members of the Panel. In no event shall appointment of the Arbitrator by the Association take longer than thirty days from the filing of the joint request for arbitration.

(c) Within seven days of the appointment of the Arbitrator, the Association shall mail to each of the parties notice of the identity of the Arbitrator and the date of the appointment, together with a copy of these rules. The Arbitrator shall, within five days of his or her appointment, file a signed acceptance of the case with the Association. The Association shall, within seven days of receipt of the Arbitrator's acceptance, mail notice of such acceptance to the parties.

(d) If any appointed Arbitrator should resign, die, withdraw, be disqualified or otherwise be unable to perform the duties of the office, the Association may, on satisfactory proof, declare the office vacant. Vacancies shall be filled in accordance with the applicable provisions of this section, and the matter shall be resumed.

(e) If the Administrator and one or more PRPs associated with a facility enter into a joint request for arbitration prior to the selection of the Association (see § 304.21(e) of this part), the Administrator and the participating PRPs shall reach mutual agreement upon the selection and appointment of an Arbitrator on a case-by-case basis, and the Administrator shall obtain the services of that person using appropriate procurement procedures. Any person appointed as an Arbitrator pursuant to this paragraph shall make disclosures to the parties pursuant to § 304.25 of this part, shall resolve the issues submitted for resolution pursuant to the
jurisdiction and authority granted to the Arbitrator in § 304.20 of this part, and shall otherwise conduct the arbitral proceeding pursuant to the procedures established by this part.

§ 304.23 Disclosure and challenge procedures.
(a) A person appointed as an Arbitrator under § 304.22 of this part shall, within five days of receipt of his or her notice of appointment, disclose to the Association any circumstances likely to affect impartiality, including any bias or any financial or personal interest in the result of the arbitration, or any past or present relationship with the parties or their counsel, or any past or present relationship with any PRP to which the claim may relate.
(b) Upon receipt of such information from an appointed Arbitrator or other source, the Association shall, within two days of receipt, communicate such information to the parties. Such communication may be made orally or in writing, but if made orally, shall be confirmed in writing.
(c) If any party wishes to request disqualification of an Arbitrator, such party shall notify the Association and the other parties of such request and the basis therefor within seven days of receipt of the information on which such request is based.
(d) The Association shall make a determination on any request for disqualification of an Arbitrator within seven days after the Association receives any such request, and shall notify the parties in writing of such determination. This determination shall be within the sole discretion of the Association, and its decision shall be final.

§ 304.24 Intervention and withdrawal.
(a) (1) No later than thirty days prior to the pre-hearing conference (see § 304.31 of this part), any PRP associated with the facility which is the subject of the referred claim may move to intervene in the arbitral proceeding for the purpose of having one or more issues relating to his or her responsibility for payment of the referred claim resolved.
(2) If the Arbitrator has not yet been appointed, a motion to intervene shall be submitted to the Association and a copy shall be served upon all parties. If the Arbitrator has not yet been appointed, a motion to intervene shall be submitted to the Association and a copy shall be served upon all parties.
(3) Any such motion to intervene may be granted only upon the written approval of the Arbitrator and all of the parties in the form of a modification to the joint request for arbitration pursuant to § 304.21(c) of this part. By signing such a modification, the intervening party consents to be bound by the terms of the joint request for arbitration submitted pursuant to § 304.21(b) of this part and any modifications previously made thereto pursuant to § 304.21(c) of this part, and consents to be bound by such revisions to the time limits for the filing of pleadings as the Arbitrator may make to prevent delaying the pre-hearing conference.
(b) Any party may move to withdraw from the arbitral proceeding within thirty days after receipt of the notice of appointment of the Arbitrator (see § 304.22 of this part). The Arbitrator may approve such withdrawal, without prejudice to the moving party, and shall assess such administrative fees and expenses (see § 304.41 of this part) against the withdrawing party as the Arbitrator deems appropriate. No party may withdraw from the arbitral proceedings after this thirty-day period, except that EPA may withdraw from the proceeding in accordance with § 304.20(b)(9) or § 304.33(e) of this part.

§ 304.25 Ex parte communication.
(a) No interested person shall make or knowingly cause to be made to the Arbitrator an ex parte communication.
(b) The Arbitrator shall not make or knowingly cause to be made to any interested person an ex parte communication.
(c) The Association may remove the Arbitrator in any proceeding in which it is demonstrated to the Association's satisfaction that the Arbitrator has engaged in prohibited ex parte communication to the prejudice of any party. If the Arbitrator is removed, the procedures in § 304.22(d) of this part shall apply.
(d) Whenever an ex parte communication in violation of this section is received by or made known to the Arbitrator, the Arbitrator shall immediately notify in writing all parties to the proceeding of the circumstances and substance of the communication and may require the party who made the communication or caused the communication to be made, or the party whose representative made the communication or caused the communication to be made, to show cause why that party's arguments or claim should not be denied, disregarded, or otherwise adversely affected on account of such violation.
(e) The prohibitions of this section apply upon appointment of the Arbitrator and terminate on the date of the final decision.

Subpart C—Hearings Before the Arbitrator
§ 304.30 Filing of pleadings.
(a) Discovery shall be in accordance with this section and § 304.31 of this part.
(b) Within thirty days after receipt of the notice of appointment of the Arbitrator (see § 304.22 of this part), EPA shall submit to the Arbitrator two copies of a written statement and shall serve a copy of the written statement upon all other parties. The written statement shall in all cases include the information requested in paragraphs (b)(1), (b)(6), and (b)(7) of this section, shall include the information requested in paragraph (b)(2) of this section if the issue of liability of any participating PRP has been submitted for resolution, shall include the information requested in paragraph (b)(3) of this section if any issue concerning the adequacy of EPA's response action has been submitted for resolution or may arise during the Arbitrator's determination of the dollar amount of response costs recoverable by EPA, shall include the information requested in paragraph (b)(4) of this section if the issue of the dollar amount of response costs recoverable by EPA has been submitted for resolution, and shall include the information requested in paragraph (b)(5) of this section if any issue concerning allocation of liability for payment of EPA's award has been submitted for resolution.

(1) A statement of facts, including a description of the facility, the EPA response action taken at the facility, the response costs incurred and to be incurred by the United States in connection with the response action taken at the facility, and the parties;
(2) A description of the evidence in support of the following four elements of liability of the participating PRP(s) whose liability pursuant to section 107(a) of CERCLA, 42 U.S.C. 9607(a), is at issue, and any supporting documentation therefor:
(i) The site at which EPA's response action was taken is a "facility" as defined by section 101(9) of CERCLA, 42 U.S.C. 9001(9);
(ii) There was a "release or threat of release" within the meaning of sections 101(22) and 104(a) of CERCLA, 42 U.S.C. 9001(22) and 9004(a), of a "hazardous substance" as defined by section 101(14) of CERCLA, 42 U.S.C. 9001(14), at the facility at which EPA's response action was taken;
(iii) The release or threat of release caused the United States to incur "response costs" as defined in § 304.12(o) of this part; and
(iv) The participating PRP is in one of the categories of liable parties in section 107(a) of CERCLA, 42 U.S.C. 9607(a).

(c) The pre-hearing conference shall include the information requested in paragraphs (c)(1), (c)(6), and (c)(7) of this section if any issue concerning the adequacy of EPA's response action has been submitted for resolution or may arise during the Arbitrator's determination of the dollar amount of response costs recoverable by EPA, shall include the information requested in paragraph (c)(4) of this section if the issue of the dollar amount of response costs recoverable by EPA has been submitted for resolution, and shall include the information requested in paragraph (c)(5) of this section if any issue concerning the allocation of responsibility for payment of EPA's award has been submitted for resolution:

(1) Any objections to the statement of facts in EPA's written statement; and, if so, a counterstatement of facts;
(2) Any objections to EPA's position on the liability of the answering participating PRP pursuant to section 107(a) of CERCLA, 42 U.S.C. 9607(a), a description of the evidence in support of the defenses to liability of the answering participating PRP which are specifically enumerated in section 107(b) of CERCLA, 42 U.S.C. 9607(b) (i.e., that the release or threat of release of a hazardous substance at the facility was caused solely by an act of God, an act of war, an act or omission of an unrelated third party, or any combination thereof), and any supporting documentation thereof;
(3) Any objections to the response action taken by EPA at the facility based upon any documents which formed the basis for the selection of the response action:
(4) Any objections to EPA's summary and supporting documentation for all response costs incurred and to be incurred by the United States in connection with the response action taken by EPA at the facility, and any supporting documentation for the summary shall be made available to any participating PRP pursuant to the procedures described in Rule 1006 of the Federal Rules of Evidence;
(5) To the extent such information is available, the names and addresses of all identified PRPs for the facility, the volume and nature of the substances contributed to the facility by each identified PRP, and a ranking by volume of the substances contributed to the facility;
(6) A recommended location for the pre-hearing conference and the arbitral hearing and
(7) Any other statement or documentation that EPA deems necessary to support its claim.
(c) The pre-hearing conference shall include the information requested in paragraphs (c)(1), (c)(6), and (c)(7) of this section, shall include the information requested in paragraph (c)(2) of this section if the issue of the liability of the answering participating PRP has been submitted for resolution, shall include the information requested in paragraph (c)(3) of this section if any issue concerning the adequacy of EPA's response action has been submitted for resolution or may arise during the Arbitrator's determination of the dollar amount of response costs recoverable by EPA, shall include the information requested in paragraph (c)(4) of this section if the issue of the dollar amount of response costs recoverable by EPA has been submitted for resolution, and shall include the information requested in paragraph (c)(5) of this section if any issue concerning the allocation of responsibility for payment of EPA's award has been submitted for resolution:

(1) Any objections to the statement of facts in EPA's written statement, and, if so, a counterstatement of facts;
(2) Any objections to EPA's position on the liability of the answering participating PRP pursuant to section 107(a) of CERCLA, 42 U.S.C. 9607(a), a description of the evidence in support of the defenses to liability of the answering participating PRP which are specifically enumerated in section 107(b) of CERCLA, 42 U.S.C. 9607(b) (i.e., that the release or threat of release of a hazardous substance at the facility was caused solely by an act of God, an act of war, an act or omission of an unrelated third party, or any combination thereof), and any supporting documentation thereof;
(3) Any objections to the response action taken by EPA at the facility based upon any documents which formed the basis for the selection of the response action:
(4) Any objections to EPA's summary and supporting documentation for all response costs incurred and to be incurred by the United States in connection with the response action taken by EPA at the facility;
(5) Any documentation which the participating PRP deems relevant to the allocation of responsibility for payment of EPA's award.
(6) A recommended location for the pre-hearing conference and the arbitral hearing and
(7) Any other statement or documentation that the participating PRP deems necessary to support its claim.
(1) The Arbitrator and the parties shall exchange witness lists (with a brief summary of the testimony of each witness) and any exhibits or documents that the parties have not submitted in their pleadings pursuant to § 304.30 of this part, within 110 days after the appointment of the Arbitrator (see § 304.22 of this part).
(b) The Arbitrator shall select the location, date, and time for the pre-hearing conference, giving due consideration to any recommendations by the parties.
(c) The pre-hearing conference shall be held within one hundred twenty days after the appointment of the Arbitrator (see § 304.22 of this part).
(d) The Arbitrator shall mail to each party notice of the pre-hearing conference not later than twenty days in advance of such conference, unless the parties by mutual agreement waive such notice.
(e) Any party may be represented by counsel at the pre-hearing conference. A party who intends to be so represented shall notify the other parties and the Arbitrator of the name, address and telephone number of counsel at least three days prior to the date set for the pre-hearing conference. When an attorney has initiated the arbitration by signing the joint request for arbitration on behalf of a party, or when an attorney has filed a pleading on behalf of a party, such notice is deemed to have been given.
(f) The pre-hearing conference may proceed in the absence of any party who, after due notice, fails to appear.
(g) (1) At the pre-hearing conference, the Arbitrator and the parties shall exchange evidence and documentation, a stipulation of uncontested facts, a statement of disputed issues, and any other documents, including written direct testimony, that will assist in prompt resolution of the dispute and avoid unnecessary proof.
(2) The Arbitrator and the parties shall consider the settlement of all or part of the claim. The Arbitrator may encourage further settlement discussions among the parties. Any settlement reached may be set forth in a proposed decision in accordance with § 304.33 of this part. If such a settlement is not set forth in a proposed decision, the settlement shall be treated as an administrative settlement pursuant to section 122(h)(1) of CERCLA, 42 U.S.C. 9622(h)(1), and shall be subject to public comment pursuant to section 122(i) of CERCLA, 42 U.S.C. 9622(i).

§ 304.31 Pre-hearing conference.
(a) The Arbitrator and the parties shall exchange witness lists (with a brief summary of the testimony of each witness) and any exhibits or documents that the parties have not submitted in their pleadings pursuant to § 304.30 of this part, within 110 days after the appointment of the Arbitrator (see § 304.22 of this part).
(b) The Arbitrator shall select the location, date, and time for the pre-hearing conference, giving due consideration to any recommendations by the parties.
(c) The pre-hearing conference shall be held within one hundred twenty days after the appointment of the Arbitrator (see § 304.22 of this part).
(d) The Arbitrator shall mail to each party notice of the pre-hearing conference not later than twenty days in advance of such conference, unless the parties by mutual agreement waive such notice.
(e) Any party may be represented by counsel at the pre-hearing conference. A party who intends to be so represented shall notify the other parties and the Arbitrator of the name, address and telephone number of counsel at least three days prior to the date set for the pre-hearing conference. When an attorney has initiated the arbitration by signing the joint request for arbitration on behalf of a party, or when an attorney has filed a pleading on behalf of a party, such notice is deemed to have been given.
(f) The pre-hearing conference may proceed in the absence of any party who, after due notice, fails to appear.
(g) (1) At the pre-hearing conference, the Arbitrator and the parties shall exchange evidence and documentation, a stipulation of uncontested facts, a statement of disputed issues, and any other documents, including written direct testimony, that will assist in prompt resolution of the dispute and avoid unnecessary proof.
(2) The Arbitrator and the parties shall consider the settlement of all or part of the claim. The Arbitrator may encourage further settlement discussions among the parties. Any settlement reached may be set forth in a proposed decision in accordance with § 304.33 of this part. If such a settlement is not set forth in a proposed decision, the settlement shall be treated as an administrative settlement pursuant to section 122(h)(1) of CERCLA, 42 U.S.C. 9622(h)(1), and shall be subject to public comment pursuant to section 122(i) of CERCLA, 42 U.S.C. 9622(i).

§ 304.32 Arbitral hearing.
(a) The Arbitrator may, in his sole discretion, schedule a hearing with the parties on one or more of the disputed issues identified in the statement of disputed issues pursuant to § 304.31(g)(1) of this part.
(b) The Arbitrator shall select the location, date, and time for the arbitral hearing, giving due consideration to any recommendations by the parties.
(c) The hearing shall commence within forty-five days after the pre-hearing conference (see § 304.31 of this part). The Arbitrator may, upon a showing by the parties that settlement is likely, extend the date for the hearing for up to thirty additional days, if further
settlement discussions have been held pursuant to §304.31(a)(2) of this part. The Arbitrator shall mail to each party notice of the hearing not later than twenty days in advance of the hearing, unless the parties by mutual agreement waive such notice. Such notice shall include a statement of the disputed issues to be addressed at the hearing. The Arbitrator need not mail a second notice to the parties if the date for the hearing is extended pursuant to paragraph (c) of this section.

(e) Any party may be represented by counsel at the hearing. A party who intends to be so represented shall notify the other parties and the Arbitrator of the name, address and telephone number of counsel at least three days prior to the date set for the hearing. When an attorney has initiated the arbitration by signing the joint request on behalf of a party, or when an attorney has filed a pleading on behalf of a party, or when notice has been given pursuant to §304.31(e) of this part, such notice is deemed to have been given.

(f) The Arbitrator shall make the necessary arrangements for the making of a true and accurate record of the arbitral hearing. The Arbitrator shall make the necessary arrangements for the services of an interpreter upon the request of one or more of the parties.

(h) The Arbitrator may take adjournments upon the request of any party or upon the Arbitrator's own initiative and shall take such adjournment when all of the parties agree thereto.

(i) The Arbitrator shall administer oaths to all witnesses before they testify at the arbitral hearing. A hearing shall be opened by the recording of the location, date, and time of the hearing, the presence of the Arbitrator and the parties, and counsel if any, and by the Arbitrator's acknowledgment for the record of all pleadings and all other documents that have been filed by the parties.

(k) The Arbitrator may, at any time, require oral statements clarifying the issues to be addressed at the hearing. The Arbitrator may require the parties to present witnesses for questioning by the Arbitrator and for direct and cross-examination by the parties on any of the disputed issues, except for any disputed issues concerning the selection or adequacy of the response action, which shall be governed by paragraph (j)(8) of this section.

(l) The Arbitrator shall define the scope of oral testimony. A party may present oral direct testimony only upon a showing of good cause why such testimony could not have been submitted in written form, or upon consent of all of the parties.

(2) The proposed decision shall also supplement the documents which formed the basis for the selection of the response action (with additional documents, affidavits, or oral testimony). If any party demonstrates that supplementation is appropriate based upon applicable principles of administrative law.

(3) Except as provided in paragraph (j)(6) of this section, exhibits and other documentary evidence not included in a party's pleadings, not exchanged prior to the pre-hearing conference pursuant to §304.31(a)(3) of this part, or not exchanged at the pre-hearing conference pursuant to §304.31(a)(1) of this part, may be presented at the hearing only upon a showing of good cause by the moving party or upon consent of all of the parties.

(4) Except as provided in paragraph (j)(6) of this section, witnesses not identified in a party's witness list may be presented at the hearing only upon a showing of good cause by the moving party or upon consent of all of the parties.

(5) The Arbitrator shall be the judge of the relevancen and materiality of the evidence offered during the proceeding and of the propriety of legal privileges. Conformity to legal rules of evidence shall not be required.

(6) The Arbitrator may make such orders as may be necessary for in camera consideration of evidence for reasons of business confidentiality as defined by 40 CFR 2201(e) and as consistent with section 122(i) of CERCLA, 42 U.S.C. 9622(e)(7).

(1) The hearing may proceed in the absence of any party who, after due notice, fails to appear or fails to obtain an adjournment. If a party, after due notice, fails to appear or fails to obtain an adjournment, such party will be deemed to have waived the right to be present at the hearing.

(2) After all disputed issues have been heard by the Arbitrator, the Arbitrator may permit the parties to make closing statements, after which the Arbitrator shall declare the hearing closed.

(c) The Arbitrator may permit the parties to submit proposed findings of fact, rulings, or orders within ten days after receipt of the hearing transcript or such longer time upon a finding of good cause.

(p) The parties may provide, by written agreement, for the waiver of the hearing.
proposed decision shall be published promptly by EPA in the Federal Register. Such notice shall include the name and location of the facility concerned, the names of the parties to the proceeding, and a brief summary of the proposed decision, and shall provide persons who are not parties to the proceeding a thirty-day period in which to file written comments relating to the proposed decision. Any filed comments shall be made available to the participating PRPs and to the public. The participating PRPs shall have ten days from the close of the public comment period in which to submit to EPA in writing their views on the merits of any comments filed. EPA shall consider any comments filed, and shall, within thirty days after the close of the ten-day period during which the participating PRPs may submit their views on any comments filed, provide written notice to the Arbitrator and the participating PRPs. The written notice shall be made available to the public and shall include:

(i) A summary of any comments filed;
(ii) Responses to any comments filed;
(iii) A discussion of whether any comments filed disclose to EPA facts or considerations which indicate the proposed decision is inappropriate, improper or inadequate; and
(iv) EPA's determination as to whether modification of the proposed decision or withdrawal from the arbitral proceeding is necessary based upon such comments.

(2) If EPA's written notice does not state that modification or withdrawal is necessary based upon public comments, then the proposed decision shall become final thirty days after the date of issuance of EPA's written notice. If EPA's written notice states that modification or withdrawal is necessary, the parties shall have thirty days from the date of issuance of EPA's written notice to modify the proposed decision so that it is no longer inappropriate, improper or inadequate and to set forth the proposed decision, as modified, in an agreed settlement. If an agreed settlement is reached, such agreed settlement shall be the final decision. If the parties do not modify the proposed decision in an agreed settlement within thirty days, the proposed decision shall be null and void and of no legal effect, EPA shall withdraw from the proceeding, and the Arbitrator shall assess such administrative fees and expenses (see § 304.41 of this part) against the parties as the Arbitrator deems appropriate.

(f) Payment of EPA's award, if any, and any fees or expenses due pursuant to the final decision, shall be made within thirty days after the date of the final decision.

(g) The Arbitrator shall, upon written request of any party, furnish to such party certified facsimiles of all papers in the Arbitrator's possession that may be required in judicial proceedings relating to the arbitration pursuant to § 304.40 of this part.

Subpart D—Other Provisions

§ 304.40 Effect and enforcement of final decision.

(a) Pursuant to section 122(h)(4) of CERCLA, 42 U.S.C. 9622(h)(4), any participating PRP who has resolved his or her liability for an EPA claim through a final decision reached pursuant to the procedures established by this part shall not be liable for claims for contributions regarding matters addressed by the final decision.

(b) The final decision shall be binding and conclusive upon the parties as to issues that were jointly submitted by the parties for resolution and addressed in the decision.

(c) (1) If any award made in the final decision is not paid within the time required by § 304.43(f) of this part, the final decision may be enforced as a judgment under section 122(h) of CERCLA, 42 U.S.C. 9622(h), by the Attorney General on behalf of EPA in any appropriate Federal district court pursuant to section 122(h)(3) of CERCLA, 42 U.S.C. 9622(h)(3). Pursuant to section 122(h)(3) of CERCLA, the terms of the final decision shall not be subject to review in any such action.

(2) In any such enforcement action initiated by the United States, the final decision may be challenged by any party if:

(i) It was achieved through fraud, misconduct, or partiality on the part of the Arbitrator;

(ii) It was achieved through fraud or misconduct by one of the parties affecting the result;

(iii) The Arbitrator exceeded his or her jurisdiction under § 304.20 of this part or failed to decide the claim within the bounds of his or her authority under this part; or

(iv) It violates public policy.

(3) Except as necessary to show such fraud, misconduct, partiality, excess of jurisdiction or authority, or violation of public policy, in any such enforcement action, a party may not raise, for the purpose of overturning or otherwise challenging the final decision, issues arising in the claim that were not submitted for resolution by arbitration.

(d) Except as provided in paragraph (c) of this section, and except as necessary for a participating PRP to defend against an action seeking contribution for matters addressed by the final decision, no final decision shall be admissible as evidence of any issue of fact or law in any proceeding brought under any provision of CERCLA or any other provision of law.

(e) Neither the initiation of an arbitral proceeding nor the rendering of a final decision on an EPA claim shall preclude or otherwise affect the ability of the United States, including EPA, to:

(1) Seek injunctive relief against any participating PRP for further response action at the facility concerned pursuant to CERCLA or any other applicable statute, regulation or legal theory; or

(2) Take further response action at the facility concerned pursuant to CERCLA or any other applicable statute, regulation or legal theory; or

(3) Seek reimbursement from any participating PRP for any costs not the subject of the arbitral proceeding pursuant to CERCLA or any other applicable statute, regulation or legal theory; or

(4) Seek any relief for any violation of criminal law from any participating PRP; or

(5) Seek damages for injury to, destruction of, or loss of natural resources from any participating PRP; or

(6) Seek any relief, civil or criminal, from any person not a party to the arbitral proceeding under CERCLA or any other applicable statute, regulation or legal theory.

§ 304.41 Administrative fees, expenses, and Arbitrator's fee.

(a) The Association shall prescribe an Administrative Fee Schedule and a Refund Schedule, which shall be subject to the approval of EPA. The schedule in effect at the time of filing or the time of refund shall be applicable.

(b) Expenses of witnesses shall be borne by the party producing such witnesses. The expense of the stenographic record and all transcripts thereof shall be prorated equally among all parties ordering copies, unless otherwise agreed by the parties, or unless the Arbitrator assesses such expenses or any part thereof against any specified party in the decision. The expense of an interpreter shall be borne by the party requesting the interpreter.

(c) The Association shall establish the per diem fee for the Arbitrator, subject to the approval of EPA, prior to the commencement of any activities by the Arbitrator. Arrangements for compensation of the Arbitrator shall be made by the Association.

(d) The Association shall make appropriate arrangements to pay the...
Arbitrator's fee and the administrative fee, and shall render an accounting to the parties in accordance with the Arbitrator's award, within thirty days after the date of the final decision.

(e) In any arbitration conducted prior to the selection of the Association (see § 304.21(e) of this part), all fees and expenses of the arbitral proceeding, including the Arbitrator's fee, shall be divided equally among all parties, except that expenses of witnesses shall be borne by the party producing such witnesses, expenses of an interpreter shall be borne by the party requesting such interpreter, and the expense of the stenographic record and all transcripts thereof shall be prorated equally among all parties ordering copies.

§ 304.42 Miscellaneous provisions.

(a) Any party who proceeds with the arbitration knowing that any provision or requirement of this part has not been complied with, and who fails to object thereto either orally or in writing in a timely manner, shall be deemed to have waived the right to object.

(b) The original of any joint request for arbitration, modification to any joint request for arbitration, pleading, letter, or other document filed in the proceeding (except for exhibits and other documentary evidence) shall be signed by the filing party or by his or her attorney.

(c) All papers associated with the proceeding that are served by a party to an opposing party shall be served by personal service, or by United States first class mail, or by United States certified mail, return receipt requested, addressed to the party's attorney, or if the party is not represented by an attorney or the attorney cannot be located, to the last known address of the party. All papers associated with the proceeding that are served by the Arbitrator or by the Association shall be served by personal service or by United States certified mail, return receipt requested, addressed to the party's attorney, or if the party is not represented by an attorney or the party cannot be located, to the last known address of the party.

(d) If any provision of this part, or the application of any provision of this part to any person or circumstance, is held invalid, the application of such provision to other persons or circumstances and the remainder of this part shall not be affected thereby.

[FR Doc. 89-12792 Filed 5-26-89; 8:45 am]
BILLING CODE 6560-50-M
Tuesday
May 30, 1989

Part VII

Department of Education

Notices Inviting Applications For New Awards Under the Secretary’s Fund For Innovation In Education
DEPARTMENT OF EDUCATION  

[CFDA No.: 84.215A]

Notice Inviting Applications for Awards Under the Secretary's Fund for Innovation in Education (FIE): Comprehensive School Health Education Program for Fiscal Year 1989

Purpose of Program: To encourage the provision of comprehensive school health education for elementary and secondary students through assistance to State educational agencies (SEAs), local educational agencies (LEAs), institutions of higher education (IHEs), private schools, and other public and private agencies, organizations and institutions.

Deadline for Transmittal of Applications: July 14, 1989.


Estimated Range of Awards: From $100,000 to $300,000.

Estimated Number of Awards: 15.

Project Period: 12 to 36 months.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR Part 74 (Administration of Grants to Institutions of Higher Education, Hospitals, and Nonprofit Organizations), Part 75 (Direct Grant Programs), Part 77 (Definitions that Apply to Department of Education Regulations), Part 79 (Intergovernmental Review of Department of Education Programs and Activities), Part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments), Part 81 (General Education Provisions Act—Enforcement), Part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)), and Part 98 (Student Rights in Research, Experimental Programs, and Testing).

Invitational Priorities: The Secretary is particularly interested in projects to identify and systematically assess promising approaches in comprehensive school health education, by examining practice in an entire State or the Nation; projects to demonstrate and evaluate model programs in a manner that will permit generalization of the results and findings; and projects to disseminate, Statewide or nationally, information on effective school health education programs.

The Secretary is interested in supporting projects that will:

• Demonstrate promising approaches to providing comprehensive health education services, especially for schools that enroll large numbers of disadvantaged students, and disseminate information to others who may wish to replicate such approaches;

• Develop collaborative efforts, including consortia of SEAs and LEAs, institutions of higher education, health and medical professionals and community and social service organizations, to identify, assess, and disseminate information on effective comprehensive school health education programs for elementary and secondary students;

• Provide preservice and inservice training for elementary and secondary teachers and administrators necessary to provide comprehensive school health education programs; and

• Involve parents in the planning and implementation of comprehensive school health education programs for elementary and secondary students.

Under 34 CFR 75.105(c)(1), however, an application that addresses one or more of these invitational priorities does not receive competitive or absolute preference over other applications. Therefore, under this competition, the Secretary will consider applications for activities other than those described in the invitational priorities that provide comprehensive school health education for elementary and secondary students.

Selection Criteria: Under EDGAR, 34 CFR 75.210(c), the Secretary is authorized to distribute an additional 15 points among the criteria to bring the total to a maximum of 100 points. For the purpose of this competition, the Secretary will distribute the additional points as follows:

Plan of operation. (§ 75.210(b)(3)) Five (5) additional points will be included for a possible total of 20 points for this criterion; and,

Evaluation plan. (§ 75.210(b)(6)) Ten (10) additional points will be included for a possible total of 15 points for this criterion.

Supplementary Information: While the Secretary has chosen to use the EDGAR selection criteria and invitational priorities for this competition, he may establish specific regulations and/or absolute priorities for future grant competitions.

For Applications or Information Contact: Fund for the Improvement and Reform of Schools and Teaching, 555 New Jersey Avenue NW., Room 522, Washington, DC 20206-5524.


Bruno V. Manno,
Acting Assistant Secretary, Office of Educational Research and Improvement.

[FR Doc. 89-12859 Filed 5-25-89; 8:45 am]

BILLING CODE 4000-01-M

[CFDA No. 84.215A]

Notice Inviting Applications for New Awards Under the Secretary's Fund for Innovation in Education (FIE): Computer-Based Instruction Program for Fiscal Year 1989

Purpose of Program: To provide assistance to State educational agencies (SEAs), local educational agencies (LEAs), institutions of higher education (IHEs), private schools, and other public and private agencies, organizations or institutions for projects that strengthen and expand computer-based education in public and private elementary and secondary schools.

Deadline For Transmittal of Applications: July 14, 1989.


Estimated Range of Awards: $100,000 to $300,000.

Estimated Number of Awards: 25.

Project Period: 12 to 36 months.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR Part 74 (Administration of Grants to Institutions of Higher Education, Hospitals, and Nonprofit Organizations), Part 75 (Direct Grant Programs), Part 77 (Definitions that Apply to Department of Education Regulations), Part 79 (Intergovernmental Review of Department of Education Programs and Activities), Part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments), Part 81 (General Education Provisions Act—Enforcement), Part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)), and Part 98 (Student Rights in Research, Experimental Programs, and Testing).

Invitational Priorities: The Secretary is particularly interested in projects to identify and systematically assess promising approaches in computer-based instruction by examining practice across an entire State or the Nation; projects to demonstrate and evaluate model programs in a manner that will permit generalization of results and
Notice Inviting Applications for New Awards Under the Secretary’s Fund for Innovation in Education (FIE): Innovation in Education Program for Fiscal Year 1989

Purpose of Program: To provide assistance to State educational agencies (SEAs), local educational agencies (LEAs), institutions of higher education (IHEs), private schools, and other public and private agencies, organizations and institutions for projects that show promise of identifying and disseminating innovative educational approaches at the preschool, elementary, and secondary levels.

Estimated Range of Awards: $200,000-$600,000.
Estimated Number of Awards: 16.
Project Period: 12 to 36 Months.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR Part 74 (Administration of Grants), Part 75 (Direct Grant Organizations), Part 77 (Definitions that Apply to Department of Education Regulations), Part 79 (Intergovernmental Review of Department of Education Programs and Activities), Part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments), Part 81 (General Education Provisions Act—Enforcement), Part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)), and Part 98 (Student Rights in Research, Experimental Programs, and Testing).

Selection Criteria: Under EDGAR, 34 CFR 75.210(c), the Secretary is authorized to distribute an additional 15 points among the criteria to bring the total to a maximum of 100 points. For the purpose of this competition, the Secretary will distribute the additional points as follows:

- Plan of operation. (§ 75.210(b)(3)) Five (5) additional points will be included for a possible total of 20 points for this criterion; and
- Evaluation plan. (§ 75.210(b)(6)) Ten (10) additional points will be included for a possible total of 15 points for this criterion.

Supplementary Information: While the Secretary has chosen to use the EDGAR selection criteria and invitational priorities for this competition, he may establish specific regulations and/or absolute priorities for future grant competitions.

For Applications or Information Contact: Fund for the Improvement and Reform of Schools and Teaching, U.S. Department of Education, 555 New Jersey Avenue NW., Room 522, Washington, DC 20208-5524.
Bruno V. Manno,
Acting Assistant Secretary, Office of Educational Research and Improvement.
[FR Doc. 89-12951 Filed 5-28-89; 8:45 am]
BILLING CODE 4000-01-M

[CFDA No. 84.215A]
Projects to synthesize and disseminate information about effective educational reforms. Applicants should describe the reform area to be addressed, the procedures and criteria by which effective programs will be identified, the potential significance of the programs to improvement in other schools, districts, or States, the populations expected to benefit, and the means of dissemination to be employed. Under 34 CFR 75.106(c)(1), however, an application that addresses one or more of these invitational priorities will not receive an absolute or competitive preference over other applications. Therefore, under this competition, the Secretary will consider applications for activities other than those described in the invitational priorities that show promise of identifying and disseminating innovative educational approaches at the preschool, elementary, or secondary level.

Selection Criteria: Under EDGAR, 34 CFR 75.210(c), the Secretary is authorized to distribute an additional 15 points among the criteria to bring the total to a maximum of 100 points. For the purpose of this competition, the Secretary will distribute the additional points as follows:

Plan of operation. (§ 75.210(b)(3)) Five (5) additional points will be included for a possible total of 20 points for this criterion; and

Evaluation plan. (§ 75.210(b)(6)) Ten (10) additional points will be added for a possible total of 15 points for this criterion.

Supplementary Information: Although the Secretary has chosen to use the EDGAR selection criteria and invitational priorities for this competition, he may establish specific regulations and/or absolute priorities for future grant competitions.

For Applications or Information Contact: Fund for the Improvement and Reform of Schools and Teaching, U.S. Department of Education, 555 New Jersey Avenue NW., Room 522, Washington, DC 20208–5524.


Bruno V. Manno,
Acting Assistant Secretary, Office of Educational Research and Improvement.

[FR Doc. 89–12952 Filed 5–26–89; 8:45 am]

BILLING CODE 4000–01–M
### Reader Aids

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