

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[ID-04-002; FRL -7842-3]

Approval and Promulgation of Air Quality Implementation Plans; Idaho; Revised Format for Materials Being Incorporated by Reference**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule; notice of administrative change.

SUMMARY: EPA is revising the format of 40 CFR part 52 for materials submitted by the State of Idaho that are incorporated by reference (IBR) into its State Implementation Plan (SIP). The regulations affected by this format change have all been previously submitted by Idaho and approved by EPA.

EFFECTIVE DATE: This action is effective January 25, 2005.

ADDRESSES: SIP materials which are incorporated by reference into 40 CFR part 52 are available for inspection at the following locations: US Environmental Protection Agency, Region 10, Office of Air, Waste, and Toxics (OAWT-107), 1200 Sixth Avenue, Seattle, Washington 98101; U.S. Environmental Protection Agency Docket Center, EPA West, 1301 Constitution Avenue, NW., Room B102, Washington, DC 20004; and the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FOR FURTHER INFORMATION CONTACT: Donna Deneen at the above Region 10 address or at (206) 553-6706.

SUPPLEMENTARY INFORMATION: Throughout this document, wherever "we" or "our" is used it means the EPA.

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I. Change of Incorporation by Reference (IBR) Format

This format revision will affect the "identification of plan" section of 40 CFR part 52, as well as the format of the SIP materials that will be available for public inspection at NARA; Air and Radiation Docket and Information Center; and the EPA Region 10 Office. The sections of 40 CFR part 52, pertaining to provisions promulgated by EPA or state-submitted materials not subject to IBR review, remain unchanged.

A. Description of a SIP

Each state has a SIP containing the control measures and strategies used to attain and maintain the national ambient air quality standards (NAAQS). The SIP is extensive, containing such elements as air pollution control regulations, emission inventories, monitoring network, attainment demonstrations, and enforcement mechanisms.

B. How EPA Enforces the SIP

Each SIP revision submitted by a state must undergo reasonable notice and public hearing at the state level, and SIPs submitted to EPA to attain or maintain the NAAQS must include enforceable emission limitations and other control measures, schedules and timetables for compliance.

EPA evaluates submitted SIPs to determine if they meet the Clean Air Act's requirements. If a SIP meets the Clean Air Act's requirements, EPA will approve the SIP. EPA's notice of approval is published in the **Federal Register** and the approval is then codified in the Code of Federal Regulations (CFR) at 40 CFR part 52. Once EPA approves a SIP, it is enforceable by EPA and citizens in federal district court.

The full text of the state regulation approved by EPA is not reproduced in its entirety in 40 CFR part 52, but is incorporated by reference ("IBR"). This means that EPA has approved a given state regulation with a specific effective date. The public is referred to the location of the full text version should they want to know which measures are contained in a given SIP (see "I.F. Where You Can Find a Copy of the SIP

Compilation"). The information provided allows EPA and the public to monitor the extent to which a state implements the SIP to attain and maintain the NAAQS and to take enforcement action if necessary.

C. How the State and EPA Update the SIP

The SIP is a living document which the state can revise as necessary to address the unique air pollution problems in the state. Therefore, EPA from time to time must take action on SIP revisions containing new and/or revised regulations as being part of the SIP. On May 22, 1997 (62 FR 27968), EPA revised the procedures for incorporating by reference Federally-approved SIPs.

EPA began the process of developing: (1) A revised SIP document for each state that would be incorporated by reference under the provisions of 1 CFR part 51; (2) a revised mechanism for announcing EPA approval of revisions to an applicable SIP and updating both the IBR document and the CFR; and (3) a revised format of the "identification of plan" sections for each applicable subpart to reflect these revised IBR procedures.

The description of the revised SIP document, IBR procedures, and "identification of plan" format are discussed in further detail in the May 22, 1997, **Federal Register** document.

D. How EPA Compiles the SIP

The Federally-approved regulations and source-specific permits (entirely or portions thereof) submitted by each state agency have been organized by EPA into a SIP compilation. The SIP Compilation contains the updated regulations and source-specific requirements approved by EPA through previous rulemaking actions in the **Federal Register**. The compilations are in hard copy and will be updated, primarily on an annual basis.

E. How EPA Organizes the SIP Compilation

Each compilation contains two parts. Part 1 contains the state regulations and Part 2 contains the source-specific requirements that have been approved as part of the SIP. Each part has a table of contents identifying each regulation or each source-specific requirement. The effective date in the tables indicates the date of the most recent revision to a particular regulation. The table of contents in the compilation corresponds to the table of contents published in 40 CFR part 52 for each state. The EPA Regional Offices have the primary

responsibility for ensuring accuracy and updating the compilations.

F. Where You Can Find a Copy of the SIP Compilation

EPA Region 10 developed and will maintain the annually updated hard copy of the compilation for Idaho. The hard copy of the annually updated compilation will also be maintained at the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, Room B-108 (Mail Code 6102T), 1301 Constitution Ave., NW., Washington, DC 20460; and NARA. For information on the availability of this material at NARA, call 202-741-6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies of Idaho regulations approved by EPA are also available on the following web page: www.epa.gov/r10earth/sips.htm.

G. The Format of the New Identification of Plan Section

In order to better serve the public, EPA revised the organization of the "identification of plan" section and included additional information to clarify the enforceable elements of the SIP.

The revised identification of plan section contains five subsections:

- (a) Purpose and scope;
- (b) Incorporation by reference;
- (c) EPA-approved regulations;
- (d) EPA-approved source-specific requirements; and
- (e) EPA-approved nonregulatory provisions such as transportation control measures, statutory provisions, control strategies, monitoring networks, etc.

H. When a SIP Revision Becomes Federally Enforceable

All revisions to the applicable SIP become Federally enforceable as of the effective date of the revisions to paragraphs (c), (d) or (e) of the applicable identification of plan found in each subpart of 40 CFR part 52.

I. The Historical Record of SIP Revision Approvals

To facilitate enforcement of previously approved SIP provisions and to provide a smooth transition to the new SIP processing system, we are retaining the original identification of plan section (see 40 CFR 52.677). This section previously appeared in 40 CFR 52.670. After an initial two-year period, EPA will review its experience with the new system and its ability to enforce previously approved SIP measures, and will decide whether or not to retain the

identification of plan appendices for some further period.

II. What EPA Is Doing in This Action

Today's action constitutes a "housekeeping" exercise to ensure that all previous revisions to the state SIP-approved regulations and source-specific requirements are accurately reflected in 40 CFR part 52. When EPA receives a formal SIP revision request, the Agency must publish the proposed revision in the **Federal Register** and provide for public comment before approval.

Note that the revisions in today's rule include State source-specific requirements that may no longer be appropriate for inclusion in the Idaho SIP. These permits, some of which were issued by the State as early as 1979, are listed in section (d) because EPA previously approved them as state source-specific requirements and they continue to be a part of the Federally-approved SIP until the Idaho Department of Environmental Quality submits a SIP revision meeting Clean Air Act requirements requesting that such permits be removed from the SIP and EPA approves the SIP revision. EPA does not have the authority to remove these permits in the absence of a demonstration that their removal would not interfere with attainment or maintenance of the NAAQS, violate any prevention of significant deterioration increment or result in visibility impairment. Idaho Department of Environmental Quality may request removal by submitting such a demonstration to EPA as a SIP revision. EPA will take action on Idaho's request after providing for public comment.

III. Good Cause Exemption

EPA has determined that today's rule falls under the "good cause" exemption in section 553(b)(3)(B) of the Administrative Procedures Act (APA) which, upon finding "good cause," authorizes agencies to dispense with public participation and section 553(d)(3) which allows an agency to make a rule effective immediately (thereby avoiding the 30-day delayed effective date otherwise provided for in the APA). Today's rule simply codifies provisions which are already in effect as a matter of law in Federal and approved State programs.

Under section 553 of the APA, an agency may find good cause where procedures are "impractical, unnecessary, or contrary to the public interest." Public comment is "unnecessary" and "contrary to the public interest" since the codification only reflects existing law. Immediate

notice in the CFR benefits the public by updating citations.

IV. Statutory and Executive Order Review

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and is therefore not subject to review by the Office of Management and Budget. This rule is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866. Because the agency has made a "good cause" finding that this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute as indicated in the Supplementary Information section above, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. This rule also does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant. This rule does not involve technical standards; thus the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. The rule also does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as

required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996). EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1998) by examining the takings implications of the rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the executive order. This rule does not impose an information collection burden under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). EPA's compliance with these statutes and Executive Orders for the underlying rules are discussed in previous actions taken on the State's rules.

B. Submission to Congress and the Comptroller General

The Congressional Review Act (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. Today's action simply codifies provisions which are already in effect as a matter of law in Federal and approved State programs. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefore, and established an effective date of January 25, 2005. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. These corrections to the identification of plan for Idaho is not a "major rule" as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

EPA has also determined that the provisions of section 307(b)(1) of the Clean Air Act pertaining to petitions for judicial review are not applicable to this action. Prior EPA rulemaking actions for each individual component of the Idaho SIP compilation had previously afforded interested parties the opportunity to file a petition for judicial review in the United States Court of Appeals for the appropriate circuit within 60 days of such rulemaking action. Thus, EPA sees no need in this action to reopen the 60-day period for filing such petitions for judicial review for these "identification of plan" reorganization actions for Idaho.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: November 15, 2004.

Ronald A. Kreizenbeck,

Acting Regional Administrator, Region 10.

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

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401 *et seq.*

Subpart N—Idaho

■ 2. Section 52.670 is redesignated as § 52.677 and the heading and paragraph (a) are revised to read as follows:

§ 52.677 Original identification of plan section.

(a) This section identifies the original "Idaho Air Quality Implementation Plan" and all revisions submitted by Idaho that were federally approved prior to November 12, 2004.

* * * * *

■ 3. A new § 52.670 is added to read as follows:

§ 52.670 Identification of plan.

(a) Purpose and scope. This section sets forth the applicable State implementation plan for Idaho under section 110 of the Clean Air Act, 42 U.S.C. 7401, and 40 CFR part 51 to meet national ambient air quality standards.

(b) Incorporation by reference.

(1) Material listed in paragraphs (c) and (d) of this section with an EPA approval date prior to November 12, 2004, was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Material is incorporated as it exists on the date of the approval, and notice of any change in the material will be published in the **Federal Register**. Entries in paragraphs (c) and (d) of this section with EPA approval dates after November 12, 2004, will be incorporated by reference in the next update to the SIP compilation.

(2) EPA Region 10 certifies that the rules/regulations provided by EPA in the SIP compilation at the addresses in paragraph (b)(3) of this section are an exact duplicate of the officially promulgated State rules/regulations which have been approved as part of the State Implementation Plan as of November 12, 2004.

(3) Copies of the materials incorporated by reference may be inspected at the Region 10 EPA Office at 1200 Sixth Avenue, Seattle, WA 98101; the EPA, Air and Radiation Docket and Information Center, Air Docket, 1301 Constitution Avenue, NW., Washington, DC 20004; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(c) EPA approved regulations.

EPA—APPROVED IDAHO REGULATIONS

[Idaho Administrative Procedures Act (IDAPA) Chapter 58, Rules for the Control of Air Pollution in Idaho, Previously Codified at IDAPA Chapter 39 (Appendix A.3)]

State citation	Title/subject	State effective date	EPA approval date	Explanations
58.01.01—Rules for the Control of Air Pollution in Idaho				
001	Title and Scope	5/1/94	01/16/03, 68 FR 2217.	
004	Catchlines	5/1/94	01/16/03, 68 FR 2217.	
005	Definitions	5/1/94	01/16/03, 68 FR 2217.	

EPA—APPROVED IDAHO REGULATIONS—Continued

[Idaho Administrative Procedures Act (IDAPA) Chapter 58, Rules for the Control of Air Pollution in Idaho, Previously Codified at IDAPA Chapter 39 (Appendix A.3)]

State citation	Title/subject	State effective date	EPA approval date	Explanations
006	General Definitions	4/5/00 3/20/97 5/1/95 5/1/94	01/16/03, 68 FR 2217.	(Except subsection 107.03).
007	Definitions for the Purposes of Sections 200 Through 225 and 400 Through 461.	4/5/00 6/30/95 5/1/95 5/1/94	01/16/03, 68 FR 2217.	
106	Abbreviations	5/1/94	01/16/03, 68 FR 2217.	
107	Incorporations by Reference	7/1/97 5/1/94	01/16/03, 68 FR 2217	
121	Compliance Requirements by Department.	5/1/94	01/16/03, 68 FR 2217.	
122	Information Orders by the Department.	4/5/00 5/1/94	01/16/03, 68 FR 2217.	
123	Certification of Documents	5/1/94	01/16/03, 68 FR 2217.	
124	Truth, Accuracy Completeness of Documents.	5/1/94	01/16/03, 68 FR 2217.	
125	False Statements	3/23/98	01/16/03, 68 FR 2217.	
126	Tampering	3/23/98	01/16/03, 68 FR 2217.	
127	Format of Responses	5/1/94	01/16/03, 68 FR 2217.	
130	Startup, Shutdown, Scheduled Maintenance, Safety Measures, Upset and Breakdown.	4/5/00	01/16/03, 68 FR 2217.	
131	Excess Emissions	4/5/00	01/16/03, 68 FR 2217.	
132	Correction of Condition	4/5/00	01/16/03, 68 FR 2217.	
133	Startup, Shutdown and Scheduled Maintenance Requirements.	4/5/00 3/20/97	01/16/03, 68 FR 2217.	
134	Upset, Breakdown, and Safety Requirements.	4/5/00 3/20/97	01/16/03, 68 FR 2217.	
135	Excess Emission Reports	4/5/00 3/20/97	01/16/03, 68 FR 2217.	
136	Excess Emission Records	4/5/00 3/23/98 3/20/97	01/16/03, 68 FR 2217.	
155	Circumvention	4/5/00	01/16/03, 68 FR 2217.	
156	Total Compliance	5/1/94	01/16/03, 68 FR 2217.	
157	Test Methods and Procedures	4/5/00	01/16/03, 68 FR 2217.	
160	Provisions Governing Specific Activities and Conditions.	4/5/00	01/16/03, 68 FR 2217.	
162	Modifying Physical Conditions	5/1/94	01/16/03, 68 FR 2217.	
163	Source Density	5/1/94	01/16/03, 68 FR 2217.	
164	Polychlorinated Biphenyls (PCBs) ..	5/1/94	01/16/03, 68 FR 2217.	
200	Procedures and Requirements for Permits to Construct.	4/5/00	01/16/03, 68 FR 2217.	
201	Permit to Construct Required	3/30/01	01/16/03, 68 FR 2217.	(Except subsection 203.03).
202	Application Procedures	4/5/00 5/1/94	01/16/03, 68 FR 2217.	
203	Permit Requirements for New and Modified Stationary Sources.	5/1/94	01/16/03, 68 FR 2217	
204	Permit Requirements for New Major Facilities or Major Modifications in Nonattainment Areas.	3/30/01 4/5/00 5/1/94	4/17/2001, 66 FR 19722.	
205	Permit Requirements for New Major Facilities or Major Modifications in Attainment or Unclassifiable Areas.	4/5/00 5/1/94	01/16/03, 68 FR 2217.	
206	Optional Offsets for Permits to Construct.	6/30/95	01/16/03, 68 FR 2217.	
207	Requirements for Emission Reduction Credit.	5/1/94	01/16/03, 68 FR 2217.	
208	Demonstration of Net Air Quality Benefit.	4/5/00 5/1/94	01/16/03, 68 FR 2217.	
209	Procedures for Issuing Permits	4/5/00 3/19/99 3/23/98 5/1/94	01/16/03, 68 FR 2217.	
211	Conditions for Permits to Construct	5/1/94	01/16/03, 68 FR 2217.	
212	Obligation to Comply	5/1/94	01/16/03, 68 FR 2217.	

EPA—APPROVED IDAHO REGULATIONS—Continued

[Idaho Administrative Procedures Act (IDAPA) Chapter 58, Rules for the Control of Air Pollution in Idaho, Previously Codified at IDAPA Chapter 39 (Appendix A.3)]

State citation	Title/subject	State effective date	EPA approval date	Explanations
213	Pre-permit Construction	4/5/00	01/16/03, 68 FR 2217.	(Except subsection 222.03).
220	General Exemption Criteria for Permit to Construct Exemptions.	3/23/98 4/5/00	01/16/03, 68 FR 2217.	
221	Category I Exemption	4/5/00	01/16/03, 68 FR 2217.	
222	Category II Exemption	4/5/00	01/16/03, 68 FR 2217.	
400	Procedures and Requirements for Tier II Operating Permits.	7/1/97 5/1/94	01/16/03, 68 FR 2217.	(Except subsections 401.01.a and 401.04).
401	Tier II Operating Permit	4/5/00	01/16/03, 68 FR 2217.	
402	Application Procedures	3/19/99 5/1/94	01/16/03, 68 FR 2217.	
403	Permit Requirements for Tier II Sources.	4/5/00	01/16/03, 68 FR 2217.	
404	Procedure for Issuing Permits	5/1/94	01/16/03, 68 FR 2217.	
405	Conditions for Tier II Operating Permits.	4/5/00	01/16/03, 68 FR 2217.	
406	Obligation to Comply	5/1/94	01/16/03, 68 FR 2217.	
460	Requirements for Emission Reduction Credit.	4/5/00	01/16/03, 68 FR 2217.	
461	Requirements for Banking Emission Reduction Credits (ERC's).	5/1/94	01/16/03, 68 FR 2217.	
470	Permit Application Fees for Tier II Permits.	3/7/95	01/16/03, 68 FR 2217.	
500	Registration Procedures and Requirements for Portable Equipment.	5/1/94	01/16/03, 68 FR 2217.	
510	Stack Heights and Dispersion Techniques.	5/1/94	01/16/03, 68 FR 2217.	
511	Applicability	4/5/00	01/16/03, 68 FR 2217.	
512	Definitions	4/5/00	01/16/03, 68 FR 2217.	
513	Requirements	5/1/94	01/16/03, 68 FR 2217.	
514	Opportunity for Public Hearing	4/5/00	01/16/03, 68 FR 2217.	
515	Approval of Field Studies and Fluid Models.	5/1/94	01/16/03, 68 FR 2217.	
516	No Restriction on Actual Stack Height.	5/1/94	01/16/03, 68 FR 2217.	
550	Air Pollution Emergency Rule	5/1/94	01/16/03, 68 FR 2217.	
551	Episode Criteria	5/1/94	01/16/03, 68 FR 2217.	
552	Stages	3/15/02	01/16/03, 68 FR 2217.	
553	Effect of Stages	5/1/94	01/16/03, 68 FR 2217.	
556	Criteria for Defining Levels Within Stages.	3/15/02	01/16/03, 68 FR 2217.	
557	Public Notification	4/5/00	01/16/03, 68 FR 2217.	
558	Information to Be Given	5/1/94	01/16/03, 68 FR 2217.	
559	Manner and Frequency of Notification.	3/15/02	01/16/03, 68 FR 2217.	
560	Notification to Sources	5/1/94	01/16/03, 68 FR 2217.	
561	General Rules	4/5/00	01/16/03, 68 FR 2217.	
562	Specific Emergency Episode Abatement Plans for Point Sources.	5/1/94	01/16/03, 68 FR 2217.	
563	Transportation Conformity	4/5/00	01/16/03, 68 FR 2217.	
564	Incorporation by Reference	5/1/94	01/16/03, 68 FR 2217.	
565	Abbreviations	3/30/01	04/12/01, 66 FR 18873.	
566	Definitions for the Purpose of Sections 563 Through 574 and 582.	3/30/01	04/12/01, 66 FR 18873.	
567	Agencies Affected by Consultation ..	3/30/01	04/12/01, 66 FR 18873.	
568	ICC Member Roles in Consultation	3/30/01	04/12/01, 66 FR 18873.	
569	ICC Member Responsibilities in Consultation.	3/30/01	04/12/01, 66 FR 18873.	

EPA—APPROVED IDAHO REGULATIONS—Continued

[Idaho Administrative Procedures Act (IDAPA) Chapter 58, Rules for the Control of Air Pollution in Idaho, Previously Codified at IDAPA Chapter 39 (Appendix A.3)]

State citation	Title/subject	State effective date	EPA approval date	Explanations
570	General Consultation Process	3/30/01	04/12/01, 66 FR 18873.	(Except subsection 577.06).
571	Consultation Procedures	3/30/01	04/12/01, 66 FR 18873.	
572	Final Conformity Determinations by USDOT.	3/30/01	04/12/01, 66 FR 18873.	
573	Resolving Conflicts	3/30/01	04/12/01, 66 FR 18873.	
574	Public Consultation Procedures	3/30/01	04/12/01, 66 FR 18873.	
575	Air Quality Standards and Area Classification.	4/5/00	01/16/03, 68 FR 2217.	
576	General Provisions for Ambient Air Quality Standards.	5/1/94	01/16/03, 68 FR 2217.	
577	Ambient Air Quality Standards for Specific Air Pollutants.	5/1/94	01/16/03, 68 FR 2217.	
578	Designation of Attainment, Unclassifiable, and Nonattainment Areas.	5/1/94	01/16/03, 68 FR 2217.	
579	Baselines for Prevention of Significant Deterioration.	4/5/00	01/16/03, 68 FR 2217.	
580	Classification of Prevention of Significant Deterioration Areas.	5/1/94	01/16/03, 68 FR 2217.	
581	Prevention of Significant Deterioration (PSD) Increments.	4/5/00	01/16/03, 68 FR 2217.	
582	Interim Conformity Provisions for Northern Ada County Former Nonattainment Area for PM-10.	7/1/97	01/16/03, 68 FR 2217.	
600	Rules for Control of Open Burning ..	5/1/94	04/12/01, 66 FR 18873.	
601	Fire Permits, Hazardous Materials and Liability.	3/30/01	01/16/01.	
602	Nonpreemption of Other Jurisdictions.	5/1/94	01/16/03.	
603	General Restrictions	5/1/94	1/16/03, 68 FR 2217.	
604	Alternatives to Open Burning	5/1/94	01/16/03, 68 FR 2217.	
606	Categories of Allowable Burning	5/1/94	01/16/03, 68 FR 2217.	
607	Recreational and Warming Fires	5/1/94	01/16/03, 68 FR 2217.	
608	Weed Control Fires	5/1/94	01/16/03, 68 FR 2217.	
609	Training Fires	5/1/94	01/16/03, 68 FR 2217.	
610	Industrial Flares	5/1/94	01/16/03, 68 FR 2217.	
611	Residential Solid Waste Disposal Fires.	5/1/94	01/16/03, 68 FR 2217.	
612	Landfill Disposal Site Fires	3/19/99	01/16/03, 68 FR 2217.	
613	Orchard Fires	4/5/00	01/16/03, 68 FR 2217.	
614	Prescribed Burning	5/1/94	01/16/03, 68 FR 2217.	
615	Dangerous Material Fires	5/1/94	01/16/03, 68 FR 2217.	
616	Infectious Waste Burning	5/1/94	01/16/03, 68 FR 2217.	
625	Visible Emissions	4/5/00	01/16/03, 68 FR 2217.	
626	General Restrictions on Visible Emissions from Wigwam Burners.	5/1/94	01/16/03, 68 FR 2217.	
650	Rules for Control of Fugitive Dust ..	4/5/00	01/16/03, 68 FR 2217.	
651	General Rules	5/1/94	01/16/03, 68 FR 2217.	
675	Fuel Burning Equipment—Particulate Matter.	4/5/00	01/16/03, 68 FR 2217.	
676	Standards for New Sources	5/1/94	01/16/03, 68 FR 2217.	
677	Standards for Minor and Existing Sources.	5/1/94	01/16/03, 68 FR 2217.	
678	Combinations of Fuels	5/1/94	01/16/03, 68 FR 2217.	
679	Averaging Period	4/5/00	01/16/03, 68 FR 2217.	
680	Altitude Correction	5/1/94	01/16/03, 68 FR 2217.	
681	Test Methods and Procedures	5/1/94	01/16/03, 68 FR 2217.	
700	Particulate Matter—Process Weight Limitations.	4/5/00	01/16/03, 68 FR 2217.	
701	Particulate Matter—New Equipment Process Weight Limitations.	4/5/00	01/16/03, 68 FR 2217.	
702	Particulate Matter—Existing Equipment Process Weight Limitations.	4/5/00	01/16/03, 68 FR 2217.	
703	Particulate Matter—Other Processes.	5/1/94	01/16/03, 68 FR 2217.	
		4/5/00	01/16/03, 68 FR 2217.	

EPA—APPROVED IDAHO REGULATIONS—Continued

[Idaho Administrative Procedures Act (IDAPA) Chapter 58, Rules for the Control of Air Pollution in Idaho, Previously Codified at IDAPA Chapter 39 (Appendix A.3)]

State citation	Title/subject	State effective date	EPA approval date	Explanations
725	Rules for Sulfur Content of Fuels	4/5/00	01/16/03, 68 FR 2217.	(Except subsection 824.01).
726	Definitions as Used in Sections 727 Through 729.	5/1/94	01/16/03, 68 FR 2217.	
727	Residual Fuel Oils	5/1/94	01/16/03, 68 FR 2217.	
728	Distillate Fuel Oil	5/1/94	01/16/03, 68 FR 2217.	
729	Coal	5/1/94	01/16/03, 68 FR 2217.	
785	Rules for Control of Incinerators	5/1/94	01/16/03, 68 FR 2217.	
786	Emission Limits	4/5/00	01/16/03, 68 FR 2217.	
787	Exceptions	3/23/98	01/16/03, 68 FR 2217.	
805	Rules for Control of Hot-mix Asphalt Plants.	5/1/94	01/16/03, 68 FR 2217.	
806	Emission Limits	5/1/94	01/16/03, 68 FR 2217.	
807	Multiple Stacks	5/1/94	01/16/03, 68 FR 2217.	
808	Fugitive Dust Control	5/1/94	01/16/03, 68 FR 2217.	
815	Rules for Control of Kraft Pulping Mills.	5/1/94	01/16/03, 68 FR 2217.	
816	Statement of Policy	5/1/94	01/16/03, 68 FR 2217.	
817	General Rules	5/1/94	01/16/03, 68 FR 2217.	
821	Recovery Furnace Particulate Standards.	5/1/94	01/16/03, 68 FR 2217.	
822	Lime Kiln Standards	5/1/94	01/16/03, 68 FR 2217.	
823	Smelt Tank Standards	5/1/94	01/16/03, 68 FR 2217.	
824	Monitoring and Reporting	4/5/00	01/16/03, 68 FR 2217.	
825	Special Studies	5/1/94	01/16/03, 68 FR 2217.	
826	Exceptions	5/1/94	01/16/03, 68 FR 2217.	
845	Rules for Control of Sulfur Oxide Emissions from Sulfuric Acid Plants.	5/1/94	01/16/03, 68 FR 2217.	
846	Emission Limits	4/5/00	01/16/03, 68 FR 2217.	
847	Monitoring and Testing	4/5/00	01/16/03, 68 FR 2217.	
848	Compliance Schedule	5/1/94	01/16/03, 68 FR 2217.	

City and County Ordinances

City of Sandpoint Ordinance No. 939.	Material Specifications for Street Sanding Material.	02/22/94 (City adoption date).	06/26/02, 67 FR 43006	Sandpoint PM10 Nonattainment Area Plan.
City of Sandpoint Ordinance No. 965.	Solid Fuel Heating Appliance Ordinance.	02/21/95 (City adoption date).	06/26/02, 67 FR 43006	Sandpoint PM10 Nonattainment Area Plan.
Ada County Ordinance.	The 1999 Motor Vehicle Emissions Control Ordinance.	06/15/99 (County approval date).	10/28/2002, 67 FR 65713.	Northern Ada County CO Maintenance Plan.
City of Boise Ordinance.	The 1999 Motor Vehicle Emissions Control Ordinance.	07/20/99 (City approval date).	10/28/2002, 67 FR 65713.	Northern Ada County CO Maintenance Plan.
City of Eagle Ordinance.	The 1999 Motor Vehicle Emissions Control Ordinance.	04/27/99 (City approval date).	10/28/2002, 67 FR 65713.	Northern Ada County CO Maintenance Plan.
City of Garden City Ordinance.	The 1991 Vehicle Emission Control Ordinance.	08/13/96 (Most recently amended).	10/28/2002, 67 FR 65713.	Northern Ada County CO Maintenance Plan.
City of Meridian Ordinance.	The 1999 Motor Vehicle Emissions Control Ordinance.	06/01/99 (City approval date).	10/28/2002, 67 FR 65713.	Northern Ada County CO Maintenance Plan.
Boise City Ordinance 4432.	Parking Permits	08/13/79 (City approval date).	06/06/85, 50 FR 23810	Transportation Control Plan for carbon monoxide, Ada County.
City of Garden City Ordinance 514,533, and 624.	Solid Fuel Heating Appliance Ordinance of the City of Garden City, Idaho.	05/14/87, 01/10/89, 09/13/94 (City approval dates).	05/30/96, 61 FR 27019	Northern Ada County PM10 Nonattainment Area Plan.
Meridian Ordinance 667.	Meridian Clean Air Ordinance	08/16/94 (City approval date).	05/30/96, 61 FR 27019	Northern Ada County PM10 Nonattainment Area Plan.
City of Eagle Ordinance 245.	City of Eagle Clean Air Ordinance ..	04/26/94 (City approval date).	05/30/96, 61 FR 27019	Northern Ada County PM10 Nonattainment Area Plan.
Ada County Ordinance 254.	Ada County Clean Air Ordinance	11/03/92 (County adoption date).	05/30/96, 61 FR 27019	Northern Ada County PM10 Nonattainment Area Plan.
Table: Ordinance-1 ..	Explanation of enforcement procedures, responsibilities and sources of funding for the Northern Ada County Wood Burning Control Ordinances.	12/30/94 (date of table).	05/30/96, 61 FR 27019	Northern Ada County PM10 Nonattainment Area Plan.

(d) EPA-approved State Source-specific requirements.

EPA-APPROVED IDAHO SOURCE-SPECIFIC REQUIREMENTS ¹

Name of source	Permit number	State effective date	EPA approval date	Explanation
LP Wood Polymers, Inc., Meridian, Idaho	001-00115	07/12/02	10/27/03, 68 FR 61106	The following conditions: 1.1, 1.3, 3.1, and the Appendix. (Boise/Ada County Maintenance Plan).
Consolidated Concrete Company, Boise, Idaho.	001-00046	12/03/01	10/27/03, 68 FR 61106	The following conditions: 1.1, 1.3, 2.3, 3.1, 3.2, and the Appendix. (Boise/Ada County Maintenance Plan).
Crookham Company, Caldwell, Idaho	027-00020	01/18/02	10/27/03, 68 FR 61106	The following conditions: 1.1, 1.3, 2.1, 2.3, 3.1, 3.1.1, 3.1.2, 3.2, and the Appendix. (Boise/Ada County Maintenance Plan).
Double D Service Center, Meridian, Idaho.	001-00168	02/04/02	10/27/03, 68 FR 61106	The following conditions: 1.1, 1.3, 3.1, 3.2.1, 3.2.2, 3.2.3, and the Appendix. (Boise/Ada County Maintenance Plan).
Plum Creek Northwest Lumber, Inc., Meridian, Idaho.	001-00091	07/12/02	10/27/03, 68 FR 61106	The following conditions: 1.1, 1.3, 2.1.2, 3.1, and the Appendix. (Boise/Ada County Maintenance Plan).
C. Wright Construction, Inc., Meridian, Idaho.	T2-000033	07/08/03	10/27/03, 68 FR 61106	The following conditions: 2 (heading only), 2.5, (2.12, Table 2.2 as it applies to PM ₁₀), 2.14, 3 (heading only), 3.3, Table 3.2, 3.4, 3.5, 3.6, 3.7, 3.8, 3.10, 4 (heading only), 4.2, 4.3, 4.4, 4.7, 5, and Table 5.1.(Boise/Ada County Maintenance Plan).
Nelson Construction Co., Boise, Idaho	T2-020029	07/21/03	10/27/03, 68 FR 61106	The following conditions: 2 (heading only), 2.12, 2.14, 3 (heading only), 3.3, 3.4, 3.6, 3.7, 3.9, 3.10, 3.11, 3.12, 4 (heading only), 4.3, 4.4, 4.5, 4.6, 5, and Table 5.1. (Boise/Ada County Maintenance Plan).
Mike's Sand and Gravel, Nampa, Idaho ..	001-00184	07/12/02	10/27/03, 68 FR 61106	The following conditions: 1.1, 1.3, 2.2.1, 3.1, and the Appendix. (Boise/Ada County Maintenance Plan).
Idaho Concrete Co., Eagle, Idaho	T2-020031	07/08/03	10/27/03, 68 FR 61106	The following conditions: 2 (heading only), 2.5, 2.13, 3 (heading only), 3.3, 3.4, 3.6, 3.7, 3.8, 4 (heading only), and Table 4.1.(Boise/Ada County Maintenance Plan).
Idaho Concrete Co., Eagle, Idaho	T2-020032	07/08/03	10/27/03, 68 FR 61106	The following conditions: 2 (heading only), 2.5, 2.13, 3 (heading only), 3.3, 3.4, 3.6, 3.7, 3.8, 4 (heading only), and Table 4.1.(Boise/Ada County Maintenance Plan).
Idaho Concrete Co. Eagle, Idaho	T2-020033	07/08/03	10/27/03, 68 FR 61106	The following conditions: 2 (heading only), 2.5, 2.13, 3 (heading only), 3.3, 3.4, 3.6, 3.7, 3.8, 4 (heading only), and Table 4.1. (Boise/Ada County Maintenance Plan).

EPA-APPROVED IDAHO SOURCE-SPECIFIC REQUIREMENTS ¹—Continued

Name of source	Permit number	State effective date	EPA approval date	Explanation
The Amalgamated Sugar Company LLC, Nampa, Idaho.	027-00010	09/30/02	10/27/03, 68 FR 61106 and 11/01/04, 69 FR 63324.	The following conditions: 2 (heading only), (2.7, Table 2.2 as it applies to PM ₁₀), 2.10, 2.10.1, 2.10.2, 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.11.5, 2.12, 2.12.1, 2.12.2, 2.12.3, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.14, 2.14.1, 2.14.2, 2.16, 3 (heading only), (3.3, Table 3.2 as it applies to PM ₁₀), 3.5, 3.7, 3.8, 3.8.1, 3.8.2, 3.8.3, 3.8.4, 3.8.5, 3.8.6, 3.8.7, 3.8.8, 3.9, 4 (heading only), (4.3, Table 4.1 as it applies to PM ₁₀), 4.5, 4.6, 4.7, 5 (heading only), (5.3, Table 5.3 as it applies to PM ₁₀), 5.5, 5.9, 5.9.1, 5.9.2, 5.9.3, 5.9.4, 5.9.5, 5.9.6, 5.9.7, 5.9.8, 5.9.9, 5.10, 5.11, 6 (heading only), 6.3, Table 6.1, 6.5, 6.6, 6.7, 6.7.1, 6.7.2, 6.8, 7 (heading only), 7.3, Table 7.1 as it applies to PM ₁₀ , 7.5, 7.7, 7.7.1, 7.7.2, 7.8, 8 (heading only), 8.3, Table 8.1, 8.5, 8.7, 8.7.1, 8.7.2, 8.8, 9 (heading only), 9.3, Table 9.1, 9.5, 9.7, 9.7.1, 9.7.2, 9.8, 10 (heading only), 10.3, Table 10.1, 10.6, 10.8, 10.8.1, 10.8.2, 10.9, 11 (heading only), 11.3, Table 11.2, 11.6, 11.8, 11.8.1, 11.8.2, 11.9, 12 (heading only), 12.3, Table 12.1, 12.5, 12.7, 12.7.1, 12.7.2, 12.8, 13 (heading only), 13.1 (except as it applies to condition 13.3, 13.3.1, 13.3.2, 13.5, 13.5.1, 13.5.2, 13.5.3, 13.6, 13.6.1, 13.6.2 and 13.9), Table 13.1 (except conditions 13.3, 13.5 and 13.6), (13.2, Table 13.2 as it applies to PM ₁₀), 13.2.1, 13.4, 13.4.1, 13.4.2, 13.4.3, 13.7, 13.7.1, 13.7.2, 13.8, 13.8.1, 13.8.2, 13.8.3, 13.10, and 13.11. (Boise/Ada County PM ₁₀ Maintenance Plan).
Lake Pre-Mix, Sandpoint, Idaho	777-00182	05/17/96	06/26/02, 67 FR 43006	The following conditions for the cement silo vent: 1.1, 2.1.1, 2.1.2, 3.1.1, and 3.1.2. (Sandpoint nonattainment area plan).
Interstate Concrete and Asphalt, Sandpoint, Idaho.	017-00048	08/02/99	06/26/02, 67 FR 43006	The following conditions: for the asphalt plant, 2.2, 3.1.1, 4.1, 4.1.1, 4.1.2, 4.2.1 (as it applies to the hourly PM ₁₀ emission limit in Appendix A), 4.2.2, 4.2.2.1, 4.2.2.2, and 4.2.2.3; for the concrete batch plant, 2.1, 3.1.1, 4.1, 4.1.1, and 4.1.2; Appendix A (as it applies to PM ₁₀ emission rates after 7/1/96) and Appendix B (as it applies after 7/1/96). (Sandpoint nonattainment area plan).
Louisiana Pacific Corporation, Sandpoint, Idaho.	017-00003	10/31/01	06/26/02, 67 FR 43006	The following conditions: for the Kipper and Sons Hog Fuel Boiler, 2.3 (as it applies to PM ₁₀), 2.5, 2.7, 2.13, 2.14, 2.17, 2.19; Natural Gas Boilers, 3.2 (as it applies to PM ₁₀); Pneumatic Conveyance, 4.2, 4.4, 4.7; Drying Kilns, 5.2, 5.4, 5.5; Fugitive Emission Sources, 6.5, 6.7, 6.13; and the Appendix (as it applies to PM ₁₀). (Sandpoint nonattainment area plan).
Whiteman Lumber Company, Cataldo, ID	13-1420-062	7/16/79 (date issued).	07/28/82, 47 FR 32530	Silver Valley TSP Nonattainment Area Plan.

EPA-APPROVED IDAHO SOURCE-SPECIFIC REQUIREMENTS ¹—Continued

Name of source	Permit number	State effective date	EPA approval date	Explanation
Potlatch Corporation, Pulp and Paper Unit, Lewiston, ID.	13-1140-0001-00	07/05/79 (date issued).	07/28/82, 47 FR 32530	Lewiston TSP Nonattainment Area Plan.
Potlatch Corporation, Clearwater Unit, Lewiston, ID.	13-1140-0003	07/05/79 (date issued).	07/28/82, 47 FR 32530	Lewiston TSP Nonattainment Area Plan.
Coast Trading Company, Inc., Lewiston, ID.	13-1140-0011	06/29/79 (date issued).	07/28/82, 47 FR 32530	Lewiston TSP Nonattainment Area Plan.
Lewis-Clark Terminal Association, Lewiston, ID.	13-1140-0010	06/29/79 (date issued).	07/28/82, 47 FR 32530	Lewiston TSP Nonattainment Area Plan.
Poe Asphalt, Lewiston, ID	0880-0008	03/01/76 (effective date).	07/28/82, 47 FR 32530	Lewiston TSP Nonattainment Area Plan.
FMC Corporation, Pocatello, ID ²	13-1260-0005	02/26/80 (date issued).	07/28/82, 47 FR 32530	Pocatello TSP Nonattainment Area Plan.
J.R. Simplot, Pocatello, ID	13-1260-0006-00	03/04/80 (date issued).	07/28/82, 47 FR 32530	Pocatello TSP Nonattainment Area Plan.
Idaho Portland Cement Company, Inkom, ID.	13-0080-0004-00	07/18/79 (date issued).	07/28/82, 47 FR 32530	Pocatello TSP Nonattainment Area Plan.
J.R. Simplot Company, Conda, ID	13-0420-0021-00	07/18/79 (date issued).	07/28/82, 47 FR 32530	Soda Springs TSP Nonattainment Area Plan.
Beker Industries, Conda, ID	13-0420-0003-00	07/18/79 (date issued).	07/28/82, 47 FR 32530	Soda Springs TSP Nonattainment Area Plan.
Monsanto, Soda Springs, ID	13-0420-0001-00	07/18/79 (date issued).	07/28/82, 47 FR 32530	Soda Springs TSP Nonattainment Area Plan.
Kerr McGee, Soda Springs, ID	13-0420-0002-00	07/18/79 (date issued).	07/28/82, 47 FR 32530	Soda Springs TSP Nonattainment Area Plan.

¹ EPA does not have the authority to remove these source-specific requirements in the absence of a demonstration that their removal would not interfere with attainment or maintenance of the NAAQS, violate any prevention of significant deterioration increment or result in visibility impairment. Idaho Department of Environmental Quality may request removal by submitting such a demonstration to EPA as a SIP revision.

² Only a small portion of this facility is located on State lands. The vast majority of the facility is located in Indian Country. It is EPA's position that unless EPA has explicitly approved a program as applying in Indian country, State or local regulations or permits are not effective within the boundaries of that Indian country land for purposes of complying with the CAA. 68 FR 2217, 2220 (January 16, 2003).

(e) EPA Approved Nonregulatory provisions and Quasi-Regulatory Measures.

EPA-APPROVED IDAHO NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Comments
Chapter I—Introduction	State-wide	01/15/80	07/28/82, 47 FR 32530.	
Chapter II—Administration	State-wide	01/15/80	07/28/82, 47 FR 32530.	
Chapter III—Emission Inventory	State-wide	01/15/80, 02/14/80 ..	07/28/82, 47 FR 32530.	
Chapter IV—Air Quality Monitoring.	State-wide	01/15/80	07/28/82, 47 FR 32530.	
Chapter V—Source Surveillance	State-wide	01/15/80	07/28/82, 47 FR 32530.	
Chapter VI—Emergency Episode Plan.	State-wide	01/15/80	07/28/82, 47 FR 32530.	

EPA-APPROVED IDAHO NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES—Continued

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Comments
Chapter VIII—Nonattainment Area Plans				
Chapter VIII-a	Silver Valley TSP Nonattainment Area Plan.	01/15/80	07/28/82, 47 FR 32530.	
Chapter VIII-b	Lewiston TSP Nonattainment Area Plan.	01/15/80, 12/04/80, and 02/05/81.	07/28/82, 47 FR 32530.	
Chapter VIII-c	Transportation Control Plan for carbon monoxide, Ada County.	05/24/84, 01/03/85, 03/25/85, and 06/29/94.	7/28/82, 47 FR 32530, 06/06/85, 50 FR 23810, and 12/1/94, 59 FR 61546.	
Chapter VIII-d	Pocatello TSP Nonattainment Area Plan.	03/07/80 and 02/05/81.	07/28/82, 47 FR 32530.	
Chapter VIII-e	Soda Springs TSP Nonattainment Area Plan.	01/15/80	07/28/82, 47 FR 32530.	
Chapter VIII-f	Pinehurst PM-10 Nonattainment Area Plan.	04/14/92	08/25/94, 59 FR 43745.	
Chapter VIII-g	Northern Ada County PM10 Nonattainment Area Plan.	11/14/91, 12/30/94, and 7/13/95.	05/30/96, 61 FR 27019.	
Chapter VIII-h	Sandpoint PM10 Nonattainment Area Plan.	08/16/96	06/26/02, 67 FR 43006.	
Chapter VIII-i	Northern Ada County CO Limited Maintenance Plan.	01/17/02	10/28/02, 67 FR 65713.	
Chapter VIII-j	Ada County/Boise Idaho PM-10 Maintenance Plan.	09/27/02, 07/10/03, and 07/21/03.	10/27/03, 68 FR 61106.	
Chapter IX—Reserved.				
Chapter X—Plan for Maintenance of National Ambient Air Quality Standards for Lead.	State-wide	02/03/84	06/04/84 (EPA effective date).	
Small Business Assistance Program.	State-wide	01/03/94	09/19/94, 59 FR 47801.	
Appendix A—Legal Authority and Other Administrative Matters.	State-wide	01/15/80	07/28/82, 47 FR 32530.	
Appendix A.2—Idaho Environmental Protection and Health Act, Idaho Code Section 39-101 et seq.	State-wide	03/15/01	01/16/03, 68 FR 2217.	
Four sections of Appendix A.3—Rules and Regulations for Control of Air Pollution in Idaho—that were approved but not incorporated by reference in section (c).	State-wide	05/17/94	01/16/03, 68 FR 2217.	IDAPA 58.01.01000 (legal authority), 58.01.01002 (written interpretations), 58.01.01003 (administrative appeals), and 58.01.01128 (confidential business information).

■ 4. Remove and reserve § 52.679.

§ 52.679 [Remove and reserve]

[FR Doc. 05–619 Filed 1–24–05; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 70

RIN 0920–AA11

Establishment of Vaccination Clinics; User Fees for Investigational New Drug (IND) Influenza Vaccine Services and Vaccines

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Interim final rule and request for comments.

SUMMARY: We are amending 42 CFR part 70 to establish vaccination clinics and a user fee in connection with the administration of vaccination services and vaccine. On December 7, 2004, HHS Secretary Tommy G. Thompson announced the purchase of 1.2 million doses of GlaxoSmithKline (GSK) influenza vaccine, Fluarix, for distribution to areas most in need as determined by State public health authorities. The Fluarix vaccine has been approved in seventy-eight foreign countries, and FDA has recently reviewed extensive manufacturing and summary clinical information and conducted an inspection of the GSK manufacturing facility in Germany to determine that this vaccine, although not licensed in the United States, is suitable for use under an Investigational New Drug application (IND). The Food and Drug Administration (FDA) reviewed GSK's IND application as well as the clinical protocol and manufacturing data. CDC and CDC's Institutional Review Board approved the GSK flu vaccine response protocol including the informed consent document.

To ensure that the vaccine is properly administered to individuals identified to be most at risk and facilitate compliance with IND requirements, CDC is establishing vaccination clinics. CDC is proceeding without delay because of the unprecedented nature of this season's influenza vaccine shortage caused by contamination problems with Chiron Corporation's production facility in the United Kingdom, which effectively cut in half the expected United States supply of inactivated influenza vaccine. A user fee is being established in order to recoup the costs

associated with administering the vaccine and for the vaccine itself. All individuals, other than those who are enrolled in Medicare Part B, will be required to pay the user fee.

DATES: This interim final rule is effective upon publication.

Written comments must be submitted on or before February 24, 2005. A final rule will be published after consideration of the comments.

ADDRESSES: Questions or comments concerning this interim final rule may be submitted to: Sheila Humphrey, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop D–38, Atlanta, GA 30333; telephone 404–498–4025. Comments may be emailed to: sph5@cdc.gov.

FOR FURTHER INFORMATION CONTACT: For information concerning program operations contact: Lisa Rotz, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop C–18, Atlanta, GA 30333; telephone 404–639–0153.

SUPPLEMENTARY INFORMATION:

I. Background

Section 361 of the Public Health Service Act (42 U.S.C. 264) authorizes the Secretary of HHS to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or from one state or possession into any other state or possession. Influenza is a communicable disease caused by influenza viruses that spreads from person to person primarily through respiratory droplets of coughs and sneezes. Adults may be able to infect others 1 day before getting symptoms and up to 7 days after onset of illness. In light of the nature of the disease and the high mobility of the population, it is inevitable that influenza viruses will spread from individuals in one state to individuals of another state. The best way to prevent the transmission of influenza is for individuals to receive the influenza vaccine. Under the authority of section 361, the Secretary may establish vaccination clinics because vaccination with the influenza vaccine is the best way to prevent the transmission of influenza from one state into another.

Title V of the Independent Offices Appropriation Act of 1952 (31 U.S.C. 9701) (“IOAA”) provides general authority to Federal agencies to establish user fees through regulations. The IOAA sets parameters for any fee charged under its authority. Each charge shall be:

- (1) Fair; and
- (2) Based on—
 - (A) The costs to the Government;
 - (B) The value of the service or thing to the recipient;
 - (C) Public-policy or interest served; and
 - (D) Other relevant facts.

OMB Circular A–25 (“the Circular”) establishes general policy for implementing user fees, including criteria for determining amounts and exceptions, and guidelines for implementation. According to the Circular, its provisions must be applied to any fees collected pursuant to the IOAA authority.

The Circular states that “[a] user charge * * * will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.” The Circular gives three examples of when the special benefit is considered to accrue, including when a Government service: (a) Enables the beneficiary to obtain more immediate or substantial gains or values (which may or may not be measurable in monetary terms) than those that accrue to the general public (e.g., receiving a patent, insurance, or guarantee provision, or a license to carry on a specific activity or business or various kinds of public land use); or (b) provides business stability or contributes to public confidence in the business activity of the beneficiary (e.g., insuring deposits in commercial banks); or (c) is performed at the request of or for the convenience of the recipient, and is beyond the services regularly received by other members of the same industry or group or by the general public (e.g., receiving a passport, visa, airman's certificate, or a Customs inspection after regular duty hours).

The Circular sets forth guidelines for determining the amount of user charges to assess. When the Government is acting in its sovereign capacity, user charges should be sufficient to cover the full cost to the Federal Government of providing the service, resource, or good.

The Circular sets forth criteria for determining full cost. “Full cost includes all direct and indirect costs to any part of the Federal Government of providing a good, resource, or service.” Examples of these types of costs include, but are not limited to, direct and indirect personnel costs, including salaries and fringe benefits; physical overhead, consulting, and other indirect costs, including material and supply costs, utilities, insurance, travel, and rents; management and supervisory costs; and the costs of enforcement, collection, research, establishment of standards, and regulation. Full costs are