

## Subpart J—Distribution

### § 212.90 What actions must I take to control the distribution of PET drug products?

(a) *Written distribution procedures.* You must establish, maintain, and follow written procedures for the control of distribution of PET drug products shipped from the PET production facility to ensure that the method of shipping chosen will not adversely affect the identity, purity, or quality of the PET drug product.

(b) *Distribution records.* You must maintain distribution records for each PET drug product that include or refer to the following:

(1) The name, address, and telephone number of the receiving facility that received each batch of a PET drug product;

(2) The name and quantity of the PET drug product shipped;

(3) The lot number, control number, or batch number for the PET drug product shipped; and

(4) The date and time you shipped the PET drug product.

## Subpart K—Complaint Handling

### § 212.100 What do I do if I receive a complaint about a PET drug product produced at my facility?

(a) *Written complaint procedures.* You must develop and follow written procedures for the receipt and handling of all complaints concerning a PET drug product.

(b) *Complaint review.* The procedures must include review by a designated person of any complaint involving the possible failure of a PET drug product to meet any of its specifications and an investigation to determine the cause of the failure.

(c) *Complaint records.* A written record of each complaint must be maintained in a file designated for PET drug product complaints. The record must include the name and strength of the PET drug product, the batch number, the name of the complainant, the date the complaint was received, the nature of the complaint, and the response to the complaint. It must also include the findings of any investigation and followup.

(d) *Returned products.* A PET drug product that is returned because of a complaint may not be reprocessed and must be destroyed in accordance with applicable Federal and State law.

## Subpart L—Records

### § 212.110 How must I maintain records of my production of PET drug products?

(a) *Record availability.* Records must be maintained at the PET production

facility or another location that is reasonably accessible to responsible officials of the production facility and to employees of FDA designated to perform inspections.

(b) *Record quality.* All records, including those not stored at the inspected establishment, must be legible, stored to prevent deterioration or loss, and readily available for review and copying by FDA employees.

(c) *Record retention period.* You must maintain all records and documentation referenced in other parts of this regulation for a period of at least 1 year from the date of final release, including conditional final release, of a PET drug product.

Dated: September 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-18510 Filed 9-15-05; 8:45 am]

BILLING CODE 4160-01-S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[R05-OAR-2005-WI-0003; FRL-7970-7]

### Approval and Promulgation of Implementation Plans; Wisconsin; General and Registration Permit Programs

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve revisions to the Wisconsin State Implementation Plan (SIP) submitted by the State of Wisconsin on July 28, 2005. These revisions include General and Registration permit programs that provide for the issuance of general and registration permits as part of the State's construction permit and operation permit programs. In addition, these permit programs may include the regulation of hazardous air pollutants (HAPs) which may be regulated under section 112 of the Clean Air Act (the Act). Thus, EPA is also proposing approval of Wisconsin's general and registration permit program under section 112(l) of the Act.

These SIP revisions also contain changes to definitions related to Wisconsin's air permit program, as well as a minor technical change to provide correct references to the recently updated chapter NR 445, which was inadvertently omitted in the processing of that rule package. Additionally, these revisions clarify an existing construction permit exemption and

operation permit exemption for certain grain storage and drying operations. This clarification is necessary to ensure that column dryers and rack dryers are included in the exemption criteria.

**DATES:** Written comments must be received on or before October 20, 2005.

**ADDRESSES:** Submit comments, identified by Regional Material in EDocket (RME) ID No. R05-OAR-2005-WI-0003, by one of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

Agency Web site: <http://docket.epa.gov/rmepub/>. RME, EPA's electronic public docket and comments system, is EPA's preferred method for receiving comments. Once in the system, select "quick search," then key in the appropriate RME Docket identification number. Follow the on-line instructions for submitting comments.

E-mail: [blakley.pamela@epa.gov](mailto:blakley.pamela@epa.gov).

Fax: (312) 886-5824.

Mail: You may send written comments to: Pamela Blakley, Chief, Air Permit Section, (AR-18)), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Hand Delivery or Courier: Deliver your comments to: Pamela Blakley, Chief, Air Permit Section, (AR-18)), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, 18th floor, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to RME ID No. R05-OAR-2005-WI-0003. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://docket.epa.gov/rmepub/>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through RME, [www.regulations.gov](http://www.regulations.gov), or e-mail. The EPA RME website and the federal [www.regulations.gov](http://www.regulations.gov) Web site are "anonymous access" systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through RME or

regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the RME index at <http://docket.epa.gov/rmepub/>. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in hard copy at Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. We recommend that you telephone Susan Siepkowski, Environmental Engineer, at (312) 353-2654 before visiting the Region 5 office. This Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** Susan Siepkowski, Environmental Engineer, Air Permit Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353-2654, [siepkowski.susan@epa.gov](mailto:siepkowski.susan@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA. This supplementary information section is arranged as follows:

- I. Does This Action Apply to Me?
- II. What Has Wisconsin Submitted?
  - A. General Permit Rule
  - B. Registration Permit Rule
  - C. Clarification to Grain Elevator Exemption
  - D. Changes to Definitions, References, and Numbering
- III. Do These Rules Comply With Federal Requirements?
  - A. Evaluation of the General Permit Rule
  - B. Evaluation of the Registration Permit Rule

- C. Evaluation of the Clarification to Grain Elevator Exemption
- D. Evaluation of the Changes to Definitions, References, and Numbering
- IV. What Action Is EPA Taking Today?
- V. Statutory and Executive Order Reviews

#### **I. Does This Action Apply to Me?**

This rule provides certain owners and operators in Wisconsin with alternatives to traditional construction and operation air permits. Wisconsin has created new permitting programs to provide registration and general air permits as an alternative to individual source permits. The rule sets certain standards for developing the permits and criteria under which sources would qualify for coverage under the permits. Specific terms and conditions will be established during the development of each permit, which will then be standard for all sources that are covered under the permit. Sources may apply for coverage under these permits by submitting an application to the Wisconsin Department of Natural Resources (WDNR), who will determine whether the source is eligible for the permit.

Under the registration permit rule, registration construction and registration operation permits will be developed for sources with low actual or potential emissions of air pollutants. The rule provides that a registration construction permit will be issued to a facility for the construction, reconstruction, replacement, relocation or modification of stationary sources whose actual emissions do not exceed 25% of any major source threshold. The rule also provides that a registration operation permit must be issued to facilities whose actual emissions do not exceed 25% of major source thresholds.

The second revision to the Wisconsin SIP permitting program is the general permit rule. This rule establishes that general construction and general operation permits will be developed for categories of sources with the same or similar emissions, operations, control systems, and regulatory requirements. Categories of sources that are or could be eligible for general permits include nonmetallic mineral processing plants, asphalt plants, small natural gas fired generators, small heating units, printing presses and hospital sterilization equipment. If an eligible owner or operator elects to comply with the rule, a generic permit that requires operation in compliance with the applicable sections of the Wisconsin rules will be issued to the source.

#### **II. What Has Wisconsin Submitted?**

On July 28, 2005, Wisconsin submitted the following revisions to its

SIP: To repeal NR 406.04(1)(c) and 407.03(1)(c); to renumber NR 406.02(1) to (4); to amend NR 406.04(1)(ce), (cm) and (m)(intro.), 406.11(1)(intro.) and (c), 407.03(1)(ce) and (cm), 407.05(7), 407.15(intro.) and (3), 410.03(1)(a)(5), and 484.05(1); to repeal and recreate NR 407.02(3) and 407.10; and to create NR 400.02(73m) and (131m), 406.02(1) and (2), 406.04(2m), 406.11(3), 406.16, 406.17, 406.18, 407.02(3m), 407.105, 407.107, 407.14 Note, 407.14(4)(c) and 410.03(1)(a)(6) and (7). These rules, as discussed in more detail below, establish general and registration permit programs, clarify an exemption for grain elevators under the State's construction and operation permit programs, define terms related to the State's permitting programs, and correct a reference in Wisconsin's regulations.

The WDNR held a second public comment period on this rule because it made significant changes to the proposed rule to address comments received during the first comment period. The first comment period ran during October and November 2004, and the second through February and March 2005. WDNR held public hearings during both comment periods. As a result of the public comments, WDNR made more specific the criteria for developing the permits and the criteria under which sources would be eligible for coverage.

In April 2005, WDNR proposed this rule revision to the Wisconsin Natural Resources Board for adoption, and the Board approved the rule on April 27, 2005. WDNR submitted its request that EPA approve the rules as a SIP revision to EPA on July 28, 2005, and EPA determined on August 11, 2005 that the submittal was complete.

#### **A. General Permit Rule**

On February 5, 2004, Wisconsin enacted Act 118, which gave WDNR the authority to develop a general construction permit program. The State has existing authority to issue general operation permits under its operation permit program. Act 118 required WDNR to establish the general permit program to provide industry and the WDNR with a streamlined approach for permitting sources that have similar operations and air emissions levels. The general construction and operation permit provisions are codified at NR 406.16 and NR 407.10 of the Wisconsin Administrative Code, respectively. A definition for “general permit” is codified at NR 400.02(73m) of the Wisconsin Administrative Code.

Under the general permit program, WDNR must develop construction and operation permits for categories of

sources with the same or similar emissions, operations, control systems and regulatory requirements, as described at NR 407.16(1) and NR 407.10(1) of the Wisconsin Administrative Code. Categories of sources that are, or could be, eligible for general permits include: Nonmetallic mineral processing plants, asphalt plants, small natural gas fired generators, small heating units, printing presses, and hospital sterilization equipment. The procedure for establishing general construction or operation permits includes the preparation of an air quality analysis and preliminary determination, and the distribution of a notice of the opportunity for public and EPA comment and of the opportunity to request a public hearing. Once WDNR has established a general permit, individual sources may apply for coverage.

Pursuant to NR 406.16(2) and NR 407.10(2), sources that are not eligible for coverage under general permits include: Municipal solid waste combustion sources; projects that require a Prevention of Significant Deterioration (PSD) or New Source Review (NSR) permit or emission units that may cause or exacerbate, a violation of an ambient air quality standard or air increment. Further, NR 406.11(1)(g) and NR 407.15(8) provide the methodologies that WDNR will use to determine for general construction and general operation permits, respectively, whether a source covered under a general permit has emissions that may cause or exacerbate a violation of an ambient air quality standard or air increment.

The process for determining coverage under a general construction or operation permit is described under NR 406.16(3) and NR 407.10(3), respectively. This process requires the source to submit an application to the WDNR, who will then determine whether the source is eligible for coverage.

NR 406.16(4) of the Wisconsin Administrative Code requires that the general construction permit be incorporated into the facility operation permit. NR 407.10(4) of the Wisconsin Administrative Code creates an exemption from the requirement to obtain a construction permit for sources covered under a general operation permit as long as, among other things, the modification does not result in a violation of the terms and conditions of the general operation permit. NR 406.04(2m) creates a similar exemption for sources that are covered under either a registration or general operation permit.

NR 406.16(5) and NR 407.10(5) describe the process by which sources covered under a general construction or operation permit may apply for and request a different type of permit. In addition, NR 407.10(6) provides that sources covered under a general operation permit which are later determined not to qualify would be subject to legal action.

The rule also creates NR 406.18 and NR 407.107, both of which describe the procedures for a party to petition WDNR to develop a general permit for other categories of stationary sources, and describe the factors that WDNR will use in setting its priorities for general permit development.

In addition to criteria pollutants, Wisconsin's general permit program applies to HAPs. Certain HAPs are, or will be, regulated under sections 111 and 112 of the Act. Thus, EPA is also approving Wisconsin's general permit program under section 112(l) of the Act for the purpose of creating federally enforceable limitations on the potential to emit HAPs regulated under section 112.

#### *B. Registration Permit Rule*

Wisconsin Act 118 also provided WDNR with the authority to develop a registration permit program for construction and operation permits. The registration permit program is designed to provide industry and the WDNR with a streamlined approach for permitting sources with low actual or potential emissions. The registration permit program is also a mechanism to permit small sources that may otherwise be subject to the Federally Enforceable State Operating Permit (FESOP) program and require an individual source permit. This program thereby reduces the permitting burden on both sources and the WDNR. Registration construction permit provisions are codified at NR 406.17, and the registration operation permit provisions are codified at NR 407.105. A definition was created for "registration permit" at NR 400.02(131m).

NR 406.17(1) and NR 407.105(1) allow the WDNR to issue registration permits to sources which meet specific criteria. The process for issuing these permits includes the preparation of an air quality analysis and preliminary determination, and the distribution of a notice of the opportunity for public and EPA comment and of the opportunity to request a public hearing. Once WDNR has issued the registration permit, individual sources may apply for coverage. The registration permit will essentially cap, or limit, the facility, or unit emissions to a specified level.

NR 406.17(2) establishes the criteria for issuance of a registration construction permit. It provides that a registration construction permit shall be issued to a facility for the construction, reconstruction, replacement, relocation or modification of stationary sources whose actual emissions do not exceed 25% of any major source threshold. NR 407.105(2) establishes the criteria for issuance of a registration operation permit. A source is eligible for coverage under a registration operation permit if its actual emissions do not exceed 25% of any major source threshold. This section also establishes physical design and air dispersion modeling criteria.

Sources that are not eligible for coverage under a registration permit are described at NR 406.17(3) and NR 407.105(3), and include: Municipal solid waste combustion sources; projects that require a PSD or NSR major source permit (NR 406.16); emission units subject to section 111 or 112 of the Act other than those deemed by WDNR not to preclude eligibility for the registration operation permit; or emission units that may cause or exacerbate, a violation of an ambient air quality standard or air increment. NR 406.11(1) and NR 407.15(8) authorize WDNR, among other things, to withdraw a source from coverage of the general or registration permits, and provide the methodologies that WDNR must use to determine if a source covered under a registration permit has emissions that may cause or exacerbate a violation of an ambient air quality standard or air increment.

NR 406.17(4) and NR 407.105(4) describe the process for determining coverage under a registration construction or operation permit, respectively. This process requires the source to submit an application to the WDNR, who will then determine whether the source is eligible for coverage.

NR 406.17(5) requires that the terms of a registration construction permit be incorporated into the facility's registration operation permit. NR 407.105(5) exempts sources with a registration operation permit from obtaining a construction permit for construction activities that will not violate the terms or conditions of the registration operation permit. NR 406.04(2m) also creates this exemption for sources that are covered under a registration or general operation permit.

NR 406.17(6) and NR 407.105(6) describe the process by which a source with a registration construction or operation permit can apply for a different type of permit. NR 407.105(7) describes the criteria WDNR will use for

determining whether a facility under the registration operation permit is in compliance with all applicable requirements.

The rule also creates provisions NR 406.18 and NR 407.107, which describe the procedures for a person to petition WDNR to develop a general or registration construction or operation permit for a category of stationary sources, and describes the factors that WDNR will consider in determining whether to grant or deny the petition.

Wisconsin's registration permit program not only applies to criteria pollutants, but also to hazardous air pollutants (HAPs). Certain HAPs are, or will be, regulated under sections 111 and 112 of the Act. Thus, EPA is also approving under section 112(l) of the Act Wisconsin's registration permit program for the purposes of creating federally enforceable limitations on the potential to emit HAPs regulated under section 112 of the Act.

#### *C. Clarification to Grain Elevator Exemption*

This rule amends provisions of Wisconsin's construction and operation permit programs, NR 406.04(1) and NR 407.03(1), respectively, relating to an existing exemption for certain grain storage and processing facilities from needing to obtain a construction or operation permit. This clarification is necessary to ensure that facilities with column dryers and rack dryers that remain below the major source threshold for air permit programs are included in the exemption. This exemption does not apply to sources subject to New Source Performance Standards (NSPS), Standards of Performance for Grain Elevators, (40 CFR part 60, subpart DD) or subject to part 70 (40 CFR part 70).

#### *D. Changes to Definitions, References, and Numbering*

Several other changes are being made to Wisconsin's construction and operation permit program rules, NR 406 and NR 407. Several sections are renumbered because of the addition of new provisions and definitions. Additional changes are being made to NR 410, Wisconsin's air permit fee rules. NR 410.03(1)(a)(5), related to the fees for a construction permit revision, is amended to exempt the fee if the requested revision is to make the source eligible for a registration operation permit. NR 410.03(1)(a)(6) and (7) provide that sources subject to Part 70 pay fees for coverage under a general or registration construction permit.

### **III. Do These Rules Comply With Federal Requirements?**

EPA reviewed Wisconsin's July 28, 2005, SIP revision submittal to determine completeness, in accordance with the completeness criteria set out at 40 CFR part 51, appendix V (1991), as amended by 57 FR 42216 (August 26, 1991). We found the submittal to be complete, and sent a letter dated August 11, 2005, to the WDNR Bureau of Air Management Director indicating the completeness of the submittal.

The next step in the review process was EPA's analysis of the State's submittal. EPA evaluated Wisconsin's general and registration permit programs with respect to the SIP approval criteria established in EPA's June 28, 1989, rulemaking "Requirements for the Preparation, Adoption, and Submittal of Implementation Plans," (EPA's 1989 rulemaking); Approval and Promulgation of Implementation Plans, 54 FR 27274. In addition, EPA has evaluated portions of Wisconsin's rule with respect to relevant EPA guidance documents, as discussed in more detail below.

The EPA's 1989 rulemaking criteria are as follows:

1. The state operating permit program (*i.e.*, the regulations or other administrative framework describing how such permits are issued) is submitted and approved by EPA into the SIP.

2. The SIP imposes a legal obligation that operating permit holders adhere to the terms and limitations of such permits (or subsequent revisions of the permit made in accordance with the approved operating permit program.)

3. The State operating permit program requires that all emissions, limitations, controls and other requirements imposed by such permits will be at least as stringent as any other applicable limitation or requirement contained in the SIP or enforceable under the SIP, and that the program may not issue permits that waive, or make less stringent, any limitation or requirement contained in or issued pursuant to the SIP, or that are otherwise 'federally enforceable' (*e.g.*, standards established under sections 111 and 112 of the Act).

4. The limitations, controls, and requirements in the operating permits are permanent, quantifiable and otherwise enforceable as a practical matter.

5. The permits are issued subject to public participation.

#### *A. Evaluation of the General Permit Rule*

The general permit rule establishes the fundamental framework for the general permits to be issued by setting certain criteria for developing the permits, and criteria under which sources would qualify for coverage under the permits. WDNR will establish specific terms and conditions during the development of each general permit, which then will be standard for all sources that are covered under the permit.

In the past, Wisconsin has issued general operation permits for certain source categories, such as rock crushers. WDNR now is establishing standard general construction permits with this rule, and revising its general operation permit program. EPA has the authority to enforce these types of permits if the permit program establishing them is approved into the SIP. EPA acknowledged in our July 10, 1995 memorandum, "White Paper for Streamlined Development of Part 70 Permit Applications," as well as in various other policy and guidance documents related to permitting, the development of general permits as a mechanism for streamlining.

For example, EPA's April 14, 1998, memorandum "Potential to Emit (PTE) Guidance for Specific Source Categories" discusses approaches that permitting authorities can use to establish enforceable emission limits, such as general permits. Generally appropriate for less complex sources, states create a standard set of terms and conditions for many similar sources at the same time. Sources wishing to be subject to the general permit must provide a notification to the permitting agency, and must comply with the standard terms and conditions. This EPA memorandum also states that "[i]n making any change to a minor NSR program, the State or local agency needs to address air quality impact considerations in addition to those discussed here." Additionally, Section 110 of the Act specifies that permit programs must ensure that the National Ambient Air Quality Standards (NAAQS) are protected.

Wisconsin's submittal satisfies this requirement. Rules NR 406.16(2)(c) and NR 407.10(2)(b), for general construction and general operation permits, respectively, state that a source is ineligible for coverage under a general permit if the emissions unit or units cause or exacerbate, or may cause or exacerbate, a violation of any ambient air quality standard or ambient air

increment, as determined by the WDNR through an air quality assessment.

Another guidance document, EPA's January 25, 1995 memorandum "Guidance an Enforceability Requirements for Limiting Potential to Emit through SIP and section 112 Rules and General Permits" (sic) (EPA's 1995 guidance) discusses general permit rule requirements. This guidance states that "[a]lthough this concept [of general permits] is generally thought of as an element of Title V permit programs there in no reason that a state or local agency could not submit a general permit program as a SIP submittal aimed at creating synthetic minor sources." This guidance document further states that, although general permit programs can be separate from Title V permit programs, the issuance of general permits under the general permit program should comply with Title V procedures. Therefore, EPA will evaluate Wisconsin's general permit program with these procedures. That is, all general permits must meet certain legal and practical federal requirements. The guidance states "[w]ith respect to legal sufficiency, the operating permit regulations provide that once the general permit has been issued, after opportunity for public participation and, EPA and affected State review, the permitting authority may grant or deny a sources request to be covered by a general permit without further public participation or EPA or affected State review." *Id.* at 4. Wisconsin's general construction permit rule provides for public participation at NR 406.16(1)(c), which states that WDNR shall use the applicable procedures in Wisconsin Statutes s. 285.61 and s. 285.63 to issue a general construction permit. The general operation permit rule at NR 407.10(1)(c) states that WDNR shall use the applicable procedures in Statutes s. 285.62 to issue the general operation permit. Both of these statutes require that the WDNR distribute a notice of the availability of the proposed general permit and of the WDNR's analysis and preliminary determination, a notice of the opportunity for public comment and a notice of the opportunity to request a public hearing.

The general permit rule also provides that the WDNR may grant or deny a source's request to be covered by a general permit. NR 406.16(1)(c) and NR 407.10(1)(c), for general construction and operation permits, respectively, require the WDNR to prepare an air quality analysis and a preliminary determination on the approvability of the proposed general permit. Both NR 406.16(3)(c) and NR 407.10(3)(c) state that WDNR must provide the applicant

notice of WDNR's determination that the source is covered under the general permit; a description of any information that is missing from the application for the general permit; or notice of WDNR's determination that the source does not qualify for coverage and the reasons for that determination.

EPA's 1995 guidance also specifies that the rule establishing the general permit program must require that: "(1) General permits apply to a specific and narrow category of sources; (2) sources electing coverage under general permits where coverage is not mandatory, provide notice or reporting to the permitting authority; (3) general permits provide specific and technically accurate (verifiable) limits that restrict the potential to emit; (4) general permits contain specific compliance requirements; (5) limits in general permits are established based on practicably enforceable averaging times; and, (6) violations of the permit are considered violations of the state and federal requirements and result in the source being subject to major source requirements." *Id.* at 6.

With respect to the first requirement above, NR 406.16(1)(b) and NR 407.10(1)(b) contain criteria to define the types of sources for which WDNR can issue general construction and operation permits. These criteria serve to describe and narrow the sources for which WDNR may establish general permits.

Regarding compliance with the second requirement of the 1995 guidance, sources electing to be covered by Wisconsin's non-mandatory general construction or operation permits must submit applications to the WDNR, upon which the agency must act.

Wisconsin's general permit program satisfies requirements 3 to 5 of the 1995 guidance regarding emission limits, compliance requirements, and averaging times. NR 406.16(1)(d) and NR 407.10(1)(d) require that the general construction and operation permits contain applicability criteria, emission limits, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions appropriate for the stationary source category.

Regarding the sixth requirement, that violations of the permit should be considered violations of the applicable requirement that result in the source becoming subject to major source requirements, both NR 406.16(1)(d) and NR 407.10(1)(d) state that the general construction and operation permit include terms and conditions required to comply with the Act and required to assure compliance with applicable

provisions in Wisconsin's statutes and regulations. In addition, NR 406.10, which is an existing provision of the Wisconsin SIP that addresses violations of a construction permit, states that a source that fails to construct and operate a stationary source in accordance with conditions imposed by the WDNR under Wisconsin statute s. 285.65 (which requires the establishment of permit conditions to ensure compliance with Wisconsin regulations and the Act) shall be considered in violation of Wisconsin statute 285.60. Wisconsin statute s. 285.60 requires air pollution control permits for new or modified sources, specifically a construction permit for commencing construction, reconstruction, replacement or modification of a stationary source, and an operation permit before any person can operate a new source or a modified source. Further, NR 407.09(1)(f), operation permit content, requires that permits include the following provision: The permittee must comply with all conditions of the permit and any noncompliance with the operation permit constitutes a violation of the statutes and is grounds for enforcement action; for permit suspension, revocation or revision; or for denial of a permit renewal application. The WDNR also retains the discretion to determine whether violations of a registration or general permit result in the source becoming subject to major source permitting requirements.

With respect to EPA's 1989 rulemaking criteria discussed above, EPA has determined that Wisconsin's general permit program meets these criteria, as outlined below.

1. Wisconsin submitted the regulations and administrative framework for the general permit rule, under NR 400, NR 406, NR 407, and NR 410, as a revision to its SIP on July 28, 2005. EPA's approval of this section would provide legal support for these permit programs and, would satisfy the first criterion.

2. Wisconsin's rule imposes a legal obligation that permit holders adhere to the terms and limitations of the permits. NR 406.10, violations of a construction permit, states that a source that fails to construct and operate a stationary source in accordance with conditions imposed by the WDNR under Wisconsin statute s. 285.65, (which requires the establishment of permit conditions to ensure compliance with Wisconsin regulations and the Act,) shall be considered in violation of Wisconsin statute s. 285.60, (which requires the air pollution control permit.) Also, NR 407.09(1)(f), an existing SIP provision that addresses operation permit content,

requires that permits include the following provision: The permittee must comply with all conditions of the permit and any noncompliance with the operation permit constitutes a violation of the statutes and is grounds for enforcement action; for permit suspension, revocation or revision; or for denial of a permit renewal application. This satisfies the second approval criterion that the permittee must comply with the permit conditions.

3. The permit program requires that all emissions, limitations, controls and other requirements imposed by permits will be at least as stringent as any other applicable limitation or requirement contained in the SIP or enforceable under the SIP. NR 406.16(1)(d) and NR 407.10(1)(d) both require that the general permit contain applicability criteria, emission caps and limitations, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions appropriate for the source category; and, that the permit terms and conditions shall include those required to comply with the Act and those required to assure compliance with applicable provisions in Wisconsin's rules (ch. 285, Stats., and chs. NR 400 to 499.) This provision satisfies the third criterion.

4. The limitations, controls, and requirements in the permits will be permanent, quantifiable and otherwise enforceable as a practical matter. As discussed above, Wisconsin's general permit rule requires that WDNR provide a 30-day public comment on the proposed general permit, and it specifies that the general permit will contain applicability criteria, emission caps and limitations, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions appropriate for the source category. During the comment period, EPA has the opportunity to review the permit to ensure that the limitations, controls, and requirements in the permits are permanent, quantifiable and otherwise enforceable as a practical matter. Additionally, the general construction permits do not expire. For general operation permits, NR 407.10(1)(e) states that a general operation permit issued to a part 70 source category may not exceed 5 years, and that general operation permits issued to a non-part 70 source category shall only expire if an expiration date is requested by the source owner or operator, or if the WDNR finds that expiring coverage would significantly improve the likelihood of continuing

compliance with applicable requirements, compared to coverage that does not expire. Although the general operation permits can expire, the expiration ends the source's right to operate unless the permittee has submitted a timely and complete renewal application or WDNR has issued a renewed operation permit. Based on the reasons above, the fourth criterion is met.

5. As discussed previously, Wisconsin's rule requires that the general permits are issued subject to public participation under NR 406.16(1)(c) and NR 407.10(1)(c), for construction and operation permits, respectively. EPA has determined that, in cases where standardized permits have been adopted, EPA and the public need not be involved in their application to individual sources as long as the standard permits themselves have been subject to notice and opportunity to comment. EPA's 1995 guidance, on page 10. Specifically, EPA's 1995 guidance states that "since the rule establishing the program does not provide the specific standards to be met by the source, each general permit, but not each application under each general permit, must be issued pursuant to public and EPA notice and comment." *Id.* Wisconsin's general permit rule satisfies this criterion.

Sources of HAPs may also be eligible for coverage under Wisconsin's general permit rule. NR 406.16(2) and NR 407.10(2), which describe the sources which are ineligible for coverage under a general construction or general operation permit, do not include sources of HAPS. Therefore, EPA is evaluating Wisconsin's general permit program under section 112(l) of the Act for the purposes of creating federally enforceable limitations on the potential to emit HAPs.

Several EPA guidance documents address this issue, including EPA's November 3, 1993, guidance document, "Approaches to Creating Federally Enforceable Emissions Limits," which states on page 2 that a state permit program could be extended to create federally enforceable limits for emissions of HAPs if the program were approved pursuant to section 112(l) of the Act. Also, EPA's 1995 guidance states on page 4 that a mechanism available to limit potential to emit is a general permit program approved into the SIP or under Section 112(1). Wisconsin's general permit program may limit HAP emissions in permits and therefore must also be evaluated with the approval criteria for programs limiting potential to emit of HAPs under 40 CFR part 63, subpart E, the

regulations promulgated to implement section 112(l) of the Act. 40 CFR 63.91(a)(5) states, "[t]he Administrator may, under the authority of section 112(l) and this subpart, also approve a State program designed to establish limits on the potential to emit hazardous air pollutants listed pursuant to section 112 of the Act."

Section 112(l) allows EPA to approve a state's permit program only if it meets the following statutory criteria for approval under section 112(l)(5): (1) It contains adequate authority to assure compliance with any section 112 standards, regulations, or requirements established under section 112, (2) it provides for adequate authority and resources to implement the program, (3) it provides for an expeditious schedule for assuring compliance with section 112 requirements, and, (4) it is otherwise in compliance with Agency guidance and is likely to satisfy the objectives of the Act.

EPA has determined that Wisconsin's general permit program meets these 112(l) criteria as outlined below:

First, Wisconsin's general permit program contains adequate authority to assure compliance with section 112 standards or requirements. Both NR 406.16(1)(d) and NR 407.10(1)(d) state that the general construction or operation permit shall contain applicability criteria, emission limits, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions; and that the permit terms and conditions shall include those required to comply with the Act and those required to assure compliance with applicable provisions in Wisconsin's regulations.

Furthermore, Wisconsin Statutes s. 285 provides the authority for Wisconsin to administer and enforce all of its permit programs. Section 285.11 specifies that the WDNR shall: "(1) Promulgate rules implementing and consistent with this chapter and statute 299.15; \* \* \* (18) Adopt and apply objective performance measurements, for the subunit of the department that administers this chapter, relating to the issuance of permits under subchapter VII and to overall performance of the subunit." In addition, section 285.13 specifies WDNR's powers, including "\* \* \* (2) Issue orders to effectuate the purposes of this chapter and statute 299.15 and enforce the same by all appropriate administrative and judicial proceedings."

For criterion 2, regarding adequate resources, NR 410.03(1)(a)(6) requires WDNR to collect fees from sources subject to 40 CFR Part 70 that are

covered under the general construction permit. The general operation permit program also requires fees to be collected, as described in the July 26, 2005, State budget. The State anticipates that its new fee structure, adopted in this budget, will provide sufficient resources to administer the general permit program. WDNR has submitted this revised fee structure along with a fee sufficiency demonstration to EPA for review. EPA will monitor the State's implementation of the permit program to assure that adequate resources continue to be available.

Wisconsin's general permit program also meets the third requirement for an expeditious schedule to assure compliance. Nothing in this program would allow a source to avoid or delay compliance with federal HAPs requirements if it fails to obtain the appropriate federally enforceable limit by the relevant deadline.

Fourth, Wisconsin's general permit program is consistent with the objectives of the section 112 program, since its purpose is to enable sources to obtain federally enforceable limits on potential to emit. This is also consistent with the intent of the guidance documents discussed above.

Based on the discussion above, EPA has determined that Wisconsin's general permit program is approvable under section 112(l). By approving Wisconsin's general permit program, EPA recognizes it as a federally enforceable method of limiting a source's potential to emit HAPs.

#### *B. Evaluation of the Registration Permit Rule*

The registration permit rule establishes the general framework for the registration permits by setting certain criteria for developing the permits and criteria under which sources would qualify for coverage under the permits. Specific terms and conditions will be established during the development of each registration permit, which will then be standard for all sources that are covered under the permit.

In the past, Wisconsin has placed federally enforceable synthetic minor limitations on sources through individual permits issued pursuant to a federally approved program. WDNR is now establishing standardized federally enforceable synthetic minor permits. EPA has the authority to enforce the terms of these permits if the permit program under which they are issued is approved into the SIP. EPA has acknowledged this approach for creating emission limitations and discussed various criteria that must be considered

for approval in several policy and guidance documents related to creating federally enforceable emissions limits and approval of SIPs.

As discussed above, various regulatory options exist for the creation of federally enforceable limits on potential to emit. Several guidance documents, including EPA's November 3, 1993, memorandum, "Approaches to Creating Federally Enforceable Emission Limits," summarize these options. Major NSR permits, minor NSR permits (if EPA has approved the NSR program into the SIP and the program meets certain procedural requirements), and operating permits based on programs approved into the SIP pursuant to the criteria in the June 28, 1989 **Federal Register** (54 FR 27274), are available regulatory mechanisms.

EPA's April 14, 1998, memorandum "Potential to Emit (PTE) Guidance for Specific Source Categories" also discusses on page 2 approaches that permitting authorities can use to establish enforceable emission limits which ensure that a source's potential emissions are below the major source threshold, such as using a general permit. Under its registration permit program, Wisconsin establishes permits which, like general permits, contain standardized conditions that will cap or limit source or unit emissions below a certain threshold. The guidance states that sources wishing to be subject to the standard permit must provide a notification to the permitting agency, and must comply with the standard terms and conditions. Wisconsin's registration permit program specifically requires sources to apply for coverage under NR 406.17(4) and NR 407.105(4), for registration construction and operation permits, respectively.

EPA's April 14, 1998 memorandum states that, "[i]n making any change to a minor NSR program, the State or local agency needs to address air quality impact considerations in addition to those discussed here." *Id.* at 6. Additionally, Section 110 of the Act specifies that permit programs must ensure that the NAAQS are protected.

NR 406.17(3)(c) and NR 407.105(3)(c) for registration construction and operation permits, respectively, state that a source is ineligible for coverage under a registration permit if the emissions unit or units cause or exacerbate, or may cause or exacerbate, a violation of any ambient air quality standard or ambient air increment, as determined by the WDNR through an air quality assessment.

EPA's 1995 guidance, as discussed in Section A, above, outlines general permit rule requirements. Again, this

guidance states on page 3 that "[a]lthough this concept [of general permits] is generally thought of as an element of Title V permit programs there is no reason that a state or local agency could not submit a general permit program as a SIP submittal aimed at creating synthetic minor sources." The guidance further states on page 4 that "[a]nother mechanism available to limit potential to emit is a general permit program approved into the SIP or under section 112(1)."

This guidance document further states that, although general permit programs can be separate from Title V permit programs, the issuance of general permits should comply with Title V procedures. That is, all general permits must meet certain legal and practical requirements for federal enforceability. The guidance states on page 4 "[w]ith respect to legal sufficiency, the operating permit regulations provide that once the general permit has been issued, after opportunity for public participation and, EPA and affected State review, the permitting authority may grant or deny a sources request to be covered by a general permit without further public participation or EPA or affected State review." Because Wisconsin's registration permit program is essentially a general permit that will contain standardized emissions limitations, we have evaluated it using the criteria from EPA's 1995 guidance discussed above. Wisconsin's registration construction permit rule provides for public participation at NR 406.17(1)(b), which states that WDNR shall use the applicable procedures in Wisconsin Statutes s. 285.61 to issue registration construction permits. NR 407.105(1)(b) states that WDNR shall use the applicable procedures in Statutes s. 285.62 to issue registration operation permits. Both of these statutes require that the WDNR distribute a notice of the availability of the proposed registration permit and of the WDNR's analysis and preliminary determination, a notice of the opportunity for public comment and a notice of the opportunity to request a public hearing.

Wisconsin's registration permit rules also provides that the WDNR may grant or deny a source's request to be covered by a registration permit. Both the registration construction and operation permit rules, at NR 406.17(1)(b) and NR 407.105(1)(b), respectively, state that the WDNR shall prepare an air quality analysis and a preliminary determination on the approvability of the proposed registration permit. NR 406.17(2) and NR 407.105(2) establish the criteria that the WDNR will use to determine if a facility is eligible for

coverage under a registration permit. Additionally, NR 406.17(4)(c) and NR 407.105(4)(c) require that WDNR provide notice of its determination that the source is covered under the registration permit; a description of any information that is missing from the application for coverage under the registration permit; or a notice of its determination that the source does not qualify for coverage, and the reasons for that determination.

EPA's 1995 guidance specifies that the rule establishing the general permit program must require that: "(1) General permits apply to a specific and narrow category of sources; (2) sources electing coverage under general permits where coverage is not mandatory, provide notice or reporting to the permitting authority; (3) general permits provide specific and technically accurate (verifiable) limits that restrict the potential to emit; (4) general permits contain specific compliance requirements; (5) limits in general permits are established based on practicably enforceable averaging times; and (6) violations of the permit are considered violations of the state and federal requirements and result in the source being subject to major source requirements." For the reasons explained previously, EPA will evaluate Wisconsin's registration permit program based upon these general permit program criteria with respect to establishing emissions limits.

For the first criterion, registration permits will be available to types of sources that have low actual emissions and that meet other criteria. These types of sources may elect to limit their emissions to specified levels.

Because coverage under Wisconsin's registration permit program is not mandatory, and sources electing to be covered by a general permit must submit an application to the WDNR which the agency must act on, the registration permit program complies with the second requirement.

For requirements 3 to 5, regarding emission limits, compliance requirements, and averaging times, both NR 406.17(1)(c) and NR 407.105(1)(c) require the registration construction or operation permit to contain applicability criteria, emission limits, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions.

Regarding criterion 6, that violations of the permit should be considered violations of the applicable requirement, both NR 406.17(1)(c) and NR 407.105(1)(c) state that the permit must include terms and conditions required

to comply with the Act and required to assure compliance with applicable provisions in Wisconsin's statutes and regulations. In addition, NR 406.10, which governs violations of a construction permit, states that a source that fails to construct and operate a stationary source in accordance with conditions imposed by the WDNR under Wisconsin statutes. 285.65 (which requires the establishment of permit conditions to ensure compliance with Wisconsin regulations and the Act) will be considered in violation of Wisconsin statutes. 285.60, (which requires the air pollution control permit.) Also, NR 407.09(1)(f), operation permit content, requires permits to provide that the permittee must comply with all conditions of the permit and that any noncompliance with the operation permit constitutes a violation of the statutes and is grounds for enforcement action; for permit suspension, revocation or revision; or for denial of a permit renewal application. Therefore, EPA concludes that the portion of the Wisconsin's SIP which deals with registration permits complies with the 1995 guidance.

With respect to EPA's 1989 rulemaking criteria, discussed above, EPA has determined that Wisconsin's registration permit program meets these criteria as outlined below:

1. Wisconsin submitted the regulations and administrative framework for the registration permit rule, under NR 400, NR 406, NR 407, and NR 410, as a revision to its SIP on July 28, 2005. EPA's approval of this section would provide legal support for these permit programs and, would satisfy the first criterion.

2. Wisconsin's rule imposes a legal obligation that permit holders adhere to the terms and limitations of the permits. Existing SIP provision NR 406.10, violations of a construction permit, states that a source that fails to construct and operate a stationary source in accordance with conditions imposed by the WDNR under Wisconsin statutes. 285.65, (which requires the establishment of permit conditions to ensure compliance with Wisconsin regulations and the Act), shall be considered in violation of Wisconsin statutes. 285.60, (which requires the air pollution control permit.) Also, existing SIP provision NR 407.09(1)(f), operation permit content, requires that permits provide that the permittee must comply with all conditions of the permit, and any noncompliance with the operation permit constitutes a violation of the statutes and is grounds for enforcement action; for permit suspension, revocation or revision; or for denial of

a permit renewal application. This satisfies the second approval criterion which requires that permit holders abide by the permit conditions.

3. The registration permit program requires that all emissions, limitations, controls, and other requirements imposed by permits will be at least as stringent as any other applicable limitation or requirement contained in the SIP or enforceable under the SIP. NR 406.17(1)(c) and NR 407.105(1)(c) require that the registration construction and operation permits contain applicability criteria, emission caps and limitations, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions; and, that the permit terms and conditions shall include those required to comply with the Act and those required to assure compliance with applicable provisions in Wisconsin's rules (ch. 285, Stats., and chs. NR 400 to 499.) This provision satisfies the third criterion.

4. This criterion provides that limitations, controls, and requirements in the permits are permanent, quantifiable and otherwise enforceable as a practical matter. As discussed above, Wisconsin's registration rule requires that a 30-day public comment period be held on the proposed registration permit, and it specifies that the registration permit will contain applicability criteria, emission caps and limitations, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions. During the comment period, EPA has the opportunity to review the permits to ensure that the limitations, controls, and requirements in the permits are permanent, quantifiable and otherwise enforceable as a practical matter. Additionally, the registration permits do not expire. The registration permit program meets the fourth criterion for permit program approval.

5. As discussed previously, Wisconsin's rule requires that the registration construction and registration operation permits are issued subject to public participation under NR 406.17(1)(b) and NR 407.105(1)(b), respectively. EPA has determined that, in cases where standardized permits have been adopted, EPA and the public need not be involved in their application to individual sources as long as the standard permits themselves have been subject to notice and opportunity to comment. Specifically, EPA's 1995 guidance states on page 10, "since the rule establishing the program does not provide the specific standards

to be met by the source, each general permit, but not each application under each general permit, must be issued pursuant to public and EPA notice and comment.”

Sources of HAPs also may be eligible for coverage under Wisconsin’s registration permit rule. NR 406.17(2)(a)(1) and NR 407.105(2)(a)(1), the criteria for issuance of registration construction and operation permits, respectively, specify that the actual emissions from sources will not exceed 25% of any major source threshold in NR 407.02(4). NR 407.02(4) includes sources that emit HAPs listed under section 112(b) of the Act. NR 406.17(3) and 407.105(3), which describe types of sources which are ineligible for coverage under registration construction and operation permits, does not include sources of HAPs. Furthermore, NR 406.17(3)(d) states that sources ineligible for registration construction permits include an emission unit or units subject to a standard or regulation under section 111 or 112 of the Act, other than those contained in the registration construction permit or those determined by WDNR not to preclude eligibility for the registration construction permit. Therefore, EPA is evaluating Wisconsin’s registration permit program under section 112(l) of the Act for the purposes of creating federally enforceable limitations on the potential to emit HAPs.

As discussed above, several EPA guidance documents address the creation of limitations on the potential to emit HAPs, including EPA’s November 3, 1993, guidance document, “Approaches to Creating Federally Enforceable Emissions Limits.” This guidance states on page 2 that a state permit program could be extended to create federally enforceable limits for emissions of HAPs if the program were approved pursuant to section 112(l) of the Act. Also, EPA’s 1995 guidance on page 4 states that a mechanism available to limit potential to emit is a general permit program approved into the SIP or under Section 112(1). Wisconsin may establish a registration permit to cap or limit HAP emissions in permits and, therefore, is eligible under the 1995 guidance for evaluation under 40 CFR part 63, subpart E, the regulations promulgated to implement section 112(l) of the Act, as a program that the state can use to limit a source’s potential to emit HAPs. 40 CFR 63.91(a)(5) states that “[t]he Administrator may, under the authority of section 112(l) and this subpart, also approve a State program designed to establish limits on the potential to emit hazardous air

pollutants listed pursuant to section 112 of the Act.”

As discussed above, section 112(l) allows EPA to approve a state’s permit program only if it meets the following the statutory criteria for approval under section 112(l)(5): (1) It contains adequate authority to assure compliance with any section 112 standards or requirements, (2) it provides for adequate resources, (3) it provides for an expeditious schedule for assuring compliance with section 112 requirements, and, (4) it is otherwise likely to satisfy the objectives of the Act. EPA has determined that Wisconsin’s registration permit program meets these 112(l) criteria as outlined below.

First, Wisconsin’s registration permit program contains adequate authority to assure compliance with section 112 standards or requirements. NR 406.17(1)(c) and NR 407.105(1)(c) both state that a registration construction or operation permit must contain applicability criteria, emission caps and limitations, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions; and that the permit terms and conditions shall include those required to comply with the Act and those required to assure compliance with applicable provisions in Wisconsin’s regulations.

Furthermore, Wisconsin Statutes s. 285 provides the authority for Wisconsin to administer and enforce all of its permit programs. Section 285.11 specifies that the WDNR shall: “(1) Promulgate rules implementing and consistent with this chapter and statute 299.15; \* \* \* (18) Adopt and apply objective performance measurements, for the subunit of the department that administers this chapter, relating to the issuance of permits under subchapter VII and to overall performance of the subunit.” In addition, section 285.13 specifies WDNR’s powers, including “\* \* \* (2) Issue orders to effectuate the purposes of this chapter and statute 299.15 and enforce the same by all appropriate administrative and judicial proceedings.”

For criterion 2, regarding adequate resources, NR 410.03(1)(a)(7) provides that sources subject to 40 CFR part 70 must pay fees for coverage under a registration construction permit. The registration operation permit also requires fees to be collected, as described in the July 26, 2005, state budget. The State anticipates that its new fee structure, adopted in this budget, will provide sufficient resources to administer the registration permit program. WDNR has submitted this

revised fee structure along with a fee sufficiency demonstration to EPA for review. EPA will monitor the State’s implementation of the permit program to assure that adequate resources continue to be available.

Regarding the third requirement, Wisconsin’s registration permit program provides for an expeditious schedule for assuring compliance. Nothing in this program would allow a source to avoid or delay compliance with the Federal requirement if it fails to obtain the appropriate federally enforceable limit by the relevant deadline.

Fourth, Wisconsin’s registration permit program is consistent with the objectives of the section 112 program, since its purpose is to enable sources to obtain federally enforceable limits on potential to emit. This also is consistent with the intent of the guidance documents discussed above.

Based on the discussion above, EPA has determined that Wisconsin’s registration permit program is approvable under section 112(l). By approving Wisconsin’s registration permit program, EPA recognizes the program as a federally enforceable method of limiting a source’s potential to emit HAPs.

### *C. Evaluation of the Clarification to Grain Elevator Exemption*

EPA reviewed Wisconsin’s permit exemption with regard to its potential emissions and with respect to relevant EPA guidance, such as EPA’s November 14, 1995, memorandum, “Calculating the Potential to Emit (PTE) for Grain Handling Facilities.” The WDNR provided EPA with additional documentation regarding its grain storage and grain handling facilities exemption in a May 31, 2005, internal memorandum which contains its PTE calculations for these permit exemptions. This document demonstrates and clarifies the following: Only non-part 70 sources are eligible for the air operation permit exemptions; only non-NSPS sources are eligible for the air construction and operation permit exemptions; air emission calculations for the “worst case” facility exempt from operation permit requirements demonstrate that the Particulate Matter (PM–10) emission rate is 29.6 tons per year, which is below the 100 tons per year part 70 major source threshold level; air emission calculations for the “worst case” facility exempt from construction permit requirements demonstrate that the PM–10 emission rate is 8.8 tons per year; and sources subject to PSD are excluded from the construction permit exemptions in ch. NR 406, Wis. Adm.

Code. Based on this information, EPA is proposing to approve these exemptions.

*D. Evaluation of the Changes to Definitions, References, and Numbering*

Several definitions were created or amended due to the creation of the general and registration permit programs. In addition, several regulatory citations were revised as well as other administrative changes related to the registration and general permit programs. All of the changes, as described in Part I, Section D, "Changes to Definitions, References, and Numbering", are consistent with Wisconsin's statutes and the Act.

**IV. What Action Is EPA Taking Today?**

EPA is proposing to approve revisions to Wisconsin SIP rules NR 400, 406, 407, and 410 submitted by the State on July 28, 2005. EPA also is soliciting comment on this proposed approval.

**V. Statutory and Executive Order Reviews**

*Executive Order 12866; Regulatory Planning and Review*

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget.

*Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use*

Because it is not a "significant regulatory action" under Executive Order 12866 or a "significant energy action," this action also is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001).

*Regulatory Flexibility Act*

This action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

*Unfunded Mandates Reform Act*

Because this action proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or

significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

*Executive Order 13175 Consultation and Coordination With Indian Tribal Governments*

This proposed action does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

*Executive Order 13132 Federalism*

This proposed action does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Act.

*Executive Order 13045 Protection of Children From Environmental Health and Safety Risks*

This proposed approval is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not a significant regulatory action under executive order 12866.

*National Technology Transfer Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTA), 15 U.S.C. 272, requires federal agencies to use technical standards that are developed or adopted by voluntary consensus to carry out policy objectives, so long as such standards are not inconsistent with applicable law or otherwise impracticable. In reviewing program submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Act. Absent a prior existing requirement for the state to use voluntary consensus standards, EPA has no authority to disapprove a program submission for failure to use such standards, and it would thus be inconsistent with applicable law for EPA to use voluntary consensus

standards in place of a program submission that otherwise satisfies the provisions of the Act. Therefore, the requirements of section 12(d) of the NTTA do not apply.

*Civil Justice Reform*

As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), 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.

*Governmental Interference With Constitutionally Protected Property Rights*

EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) 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, and has determined that the rule's requirements do not constitute a taking.

*Paperwork Reduction Act*

This proposed action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: September 12, 2005.

**Bharat Mathur,**

*Acting Regional Administrator, Region 5.*

[FR Doc. 05-18722 Filed 9-19-05; 8:45 am]

**BILLING CODE 6560-50-P**

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**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**44 CFR Part 67**

**[Docket No. FEMA-D-7638]**

**Proposed Flood Elevation Determinations**

**AGENCY:** Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.