

No objections to the proposed temporary deviation were raised.

Vessels that can transit the bridge, while in the closed-to-navigation position, may continue to do so at any time.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: January 27, 2012.

**D.H. Sulouff,**

*District Bridge Chief, Eleventh Coast Guard District.*

[FR Doc. 2012-3102 Filed 2-9-12; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2012-0006]

#### Drawbridge Operation Regulations; Merrimack River, Amesbury, MA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the 1st Lt. Derek S. Hines Memorial Bridge, mile 5.8, across the Merrimack River at Amesbury (Newburyport), Massachusetts. The deviation is necessary to facilitate bridge rehabilitation and repairs. This deviation allows the bridge to remain in the closed position for four months.

**DATES:** This deviation is effective from February 13, 2012 through May 11, 2012.

**ADDRESSES:** Documents mentioned in this preamble as being available in the docket are part of docket USCG-2012-0006 and are available online at [www.regulations.gov](http://www.regulations.gov), inserting USCG-2012-0006 in the "Keyword" and then clicking "Search". They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Mr. Joe Arca, Project Officer, First Coast Guard District,

[joe.m.arca@uscg.mil](mailto:joe.m.arca@uscg.mil) or telephone (212) 668-7165. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366-9826.

**SUPPLEMENTARY INFORMATION:** The 1st Lt. Derek S. Hines Memorial Bridge, across the Merrimack River, mile 5.8, at Amesbury (Newburyport), Massachusetts, has a vertical clearance in the closed position of 13 feet at mean high water and 20 feet at mean low water. The drawbridge operation regulations are listed at 33 CFR 117.605(c).

The owner of the bridge, Massachusetts Department of Transportation, requested a temporary deviation from the regulations to facilitate bridge rehabilitation repairs, replacement of operating machinery, structural steel, and highway deck on the swing span.

Under this temporary deviation the bridge may remain in the closed position from February 13, 2012 through May 11, 2012.

The bridge rarely opens during the time period this temporary deviation will be in effect. In addition, mariners may use an alternate channel to the south under the Chain Bridge, which is a fixed highway bridge that provides 28 feet of vertical clearance at mean high water and 35 feet of vertical clearance at mean low water.

In accordance with 33 CFR 117.35(e), the bridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: February 1, 2012.

**Gary Kassof,**

*Bridge Program Manager, First Coast Guard District.*

[FR Doc. 2012-3101 Filed 2-9-12; 8:45 am]

**BILLING CODE 9110-04-P**

## ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA-R03-OAR-2011-0623; FRL-9628-7]

#### Approval and Promulgation of Air Quality Implementation Plans; Maryland; Preconstruction Permitting Requirements for Electric Generating Stations in Maryland

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

**ACTION:** Final rule.

**SUMMARY:** EPA is granting limited approval of a State Implementation Plan

(SIP) revision submitted by the Maryland Department of the Environment (MDE). This SIP revision revises and supplements the Maryland SIP by adding the preconstruction permitting requirements for electric generating stations that are required to receive a Certificate of Public Convenience and Necessity (CPCN) from the Maryland Public Service Commission (PSC) before commencing construction or modification. The SIP revision also requires electric generating stations to obtain a preconstruction permit from MDE when a CPCN is not required under the PSC regulations and statutes. EPA is granting limited approval of these revisions to Maryland's preconstruction program for electric generating stations in accordance with the requirements of the Clean Air Act (CAA).

**DATES:** *Effective Date:* This final rule is effective on March 12, 2012.

**ADDRESSES:** EPA has established a docket for this action under Docket ID Number EPA-R03-OAR-2011-0623. All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (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 through [www.regulations.gov](http://www.regulations.gov) or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submission are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

**FOR FURTHER INFORMATION CONTACT:** David Talley, (215) 814-2117, or by email at [talley.david@epa.gov](mailto:talley.david@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Throughout this document, whenever "we," "us," or "our" is used, we mean EPA. The PSC is an agent of the State of Maryland and is an independent unit in the Executive Branch of the government of the State of Maryland. The PSC regulates public utilities including electric generating stations owned by electric companies doing business in Maryland and is empowered by the State of Maryland to issue CPCNs

for the construction and modification of electric generating stations. On August 4, 2011 (76 FR 47090), EPA published a notice of proposed rulemaking (NPR) for the State of Maryland. The NPR proposed approval of changes to the Code of Maryland Administrative Regulations (COMAR), specifically the MDE regulations at COMAR 26.11.02.09 and 26.11.02.10. The NPR also proposed to approve into the Maryland SIP for first time the following: (1) Maryland statutory provisions at Md. Code Ann., Public Utilities Cos. sections 7–205 (2006), 7–207 (2007), 7–207.1 (2007) and 7–208 (2001); and (2) PSC regulations at COMAR 20.79.01.01; 20.79.01.02; 20.79.01.06; 20.79.01.07; 20.79.02.01; 20.79.02.02; 20.79.02.03; 20.79.03.01; and 20.79.03.02. The formal SIP revision (#11–01) was submitted by MDE on May 13, 2011. EPA initially proposed full approval of the submission.

However, in response to comments received on that proposal, a portion of the submission has been withdrawn by MDE. On December 20, 2011, MDE withdrew COMAR 20.79.01.07 (regarding the PSC's waiver authority for CPCNs) from its Maryland SIP revision submission. EPA is now granting limited approval of the remainder of the MDE SIP submission for electric generating stations which includes COMAR 26.11.02.09 and 26.11.02.10, applicable parts of sections 7–205, 7–207, 7–207.1 and 7–208 of the Md. Code Ann., and applicable parts of COMAR 20.79.01.01; 20.79.01.02; 20.79.01.06; 20.79.02.01; 20.79.02.02; 20.79.02.03; 20.79.03.01; and 20.79.03.02. See Sections III, IV and V below for more detail.

In our August 4, 2011 notice of proposed rulemaking, EPA proposed to include a July 15, 2011 letter from the Secretary of MDE in the Maryland SIP. Because MDE's July 15, 2011 letter addressed COMAR 20.79.01.07 which MDE has subsequently withdrawn from our consideration, EPA is not including the July 15, 2011 Letter in our limited approval of the May 13, 2011 Maryland SIP submission (as amended on December 20, 2011).

## II. Summary of SIP Revision

Under the CAA, major stationary sources of air pollution are required to obtain a permit to construct prior to commencing construction or modification activities. The Maryland statutory provisions at sections 7–205, 7–207, 7–207.1, and 7–208 of the Md. Code Ann. and the PSC's regulations identified above require electric generating stations in Maryland to obtain a CPCN from the PSC prior to

construction or modification activities which would require a permit under the CAA. The CPCNs serve as the mechanism for the State to implement Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR) requirements for electric generating stations in Maryland. EPA is limitedly approving Maryland's SIP revision request to add the statutory and regulatory requirements that require electric generating stations to obtain a CPCN prior to construction or modification. These requirements were not previously in the Maryland SIP; therefore, our limited approval corrects deficiencies in the Maryland SIP and strengthens the SIP.

Previously, the Maryland SIP at COMAR 26.11.02.09 and 26.11.02.10 exempted electric generating stations constructed or modified by electric generating companies from MDE's permitting regulations. However, the State of Maryland has since modified Md. Code Ann., Environment Section 2–402(3) and COMAR 26.11.02.09 and 26.11.02.10 so that electric generating stations that are not required to obtain CPCNs from the PSC remain subject to MDE's preconstruction permitting requirements. Therefore, the SIP regulations were inconsistent with Maryland's present statutory and regulatory provisions in that they do not preserve MDE's permitting authority for electric generating stations that are not required otherwise to obtain a CPCN. MDE's May 13, 2011 SIP revision request included the amended MDE regulations, COMAR 26.11.02.09 and 26.11.02.10. Our limited approval of the May 13, 2011 SIP revision request, as amended on December 20, 2011, eliminates the inconsistency between the Maryland SIP and Maryland's present statutory and regulatory provisions regarding MDE's ability to permit electric generating stations when the electric generating stations do not receive CPCNs.

Section 110(a)(2)(C) of the CAA, 42 U.S.C. section 7410(a)(2)(C), requires the state SIP to have a program for regulation of construction and modification of stationary sources to assure that national ambient air quality standards (NAAQS) are achieved, including a permit program as required by Part C of Title I of the CAA for PSD and Part D of Title I of the CAA for NSR. Our limited approval of Maryland's SIP revision of May 13, 2011, as amended on December 20, 2011, ensures that the Maryland SIP has a permit program for the construction and modification of electric generating stations as required by Parts C and D of Title I of the CAA and ensures that the SIP provides for the

attainment and maintenance of the NAAQS. Included in the May 13, 2011 proposed SIP revision is section 7–208(f) of the Md. Code Ann. which specifically requires the PSC to include in CPCNs the requirements of federal and state environmental laws and standards as identified by MDE. EPA's limited approval ensures the Maryland SIP is adequate to prevent significant deterioration of air quality in areas designated as attainment or unclassifiable as required by sections 110(a) and 161 of the CAA, 42 U.S.C. sections 7410(a) and 7471, and 40 CFR 51.166. EPA's limited approval of the Maryland permitting program for electric generating stations also ensures that the Maryland SIP meets plan requirements for nonattainment areas as required by Part D of Title I of the CAA. Because the provisions in the May 13, 2011 SIP submission, as amended on December 20, 2011, strengthen the Maryland SIP, EPA limitedly approves them into the Maryland SIP.

## III. Limited Approval

*Why is EPA granting only “Limited Approval” of Maryland’s preconstruction program for electric generating stations for the Maryland SIP?*

In general, EPA has determined that MDE's May 13, 2011 submission (#11–01), as amended by MDE's December 20, 2011 letter removing COMAR 20.79.01.07, strengthens Maryland's SIP by containing a permit program as required by Parts C and D of Title I of the CAA. However, we acknowledge that for the reasons stated below, the May 13, 2011 submission (as amended on December 20, 2011) does not fully meet all CAA requirements for SIPs. Therefore, EPA is granting limited approval in accordance with section 110(k) of the CAA, 42 U.S.C. section 7410(k).

### A. Completeness Determinations

The May 13, 2011 Maryland SIP submission, as amended December 20, 2011, does not contain a requirement for the PSC to conduct completeness determinations for CPCN applications. Pursuant to 40 CFR 51.166(q)(1), a state SIP must require the permitting authority “to notify all applicants within a specified time period as to the completeness of the application or any deficiency in the application or information submitted.” See 40 CFR 51.166(q)(1). However, as discussed more thoroughly in EPA's Response to Comments in Section IV below, we believe the PSC is complying with this requirement in its practice for issuing

CPCNs such that the impact on CPCN applicants is minimized.

#### *B. Permit Documents in One Location for Public Access*

The May 13, 2011 Maryland SIP submission, as amended December 20, 2011, does not contain a requirement for the PSC to make available for public inspection in one location the documents from a CPCN applicant and the reviewing agency's analysis of the effect on air quality from the proposed construction or modification at an electric generating station. Pursuant to 40 CFR 51.161(a) and (b)(1), a state SIP shall provide for the "[a]vailability for public inspection in at least one location in the area affected of the information submitted by the owner or operator and of the State or local agency's analysis of the effect on air quality." See 40 CFR 51.161(a) and (b)(1). As discussed more thoroughly in EPA's Response to Comments in Section IV below, EPA believes the PSC provides in its practice the opportunity for public review of this information through the availability of such documents on its Web site. Therefore, the impact on the public's opportunity to comment meaningfully is minimized. When the PSC amends its regulations to include the requirements of 40 CFR 51.161(a) and (b)(1) and 51.166(q)(1), MDE may submit the revised regulations for EPA's consideration for full approval of the permitting program for electric generating stations in the Maryland SIP.

#### **IV. EPA's Response to Comments Received on the Proposed Action**

EPA received a single set of relevant comments on its August 4, 2011 (76 FR 47090) proposed action to approve revisions to the Maryland SIP. These comments, provided by the Environmental Integrity Project (hereinafter referred to as "the Commenter"), raised concerns with regard to EPA's August 4, 2011 proposed action. A full set of these comments is provided in the docket for today's final action. A summary of the comments and EPA's responses are provided below.

Generally, the Commenter raised four areas of concern. First, the Commenter asserts that the proposed revision to the Maryland SIP does not require compliance with NSR requirements in the CAA. Second, the Commenter asserts the proposed revision to the Maryland SIP allows the PSC, the air permitting agency for electric generating stations in Maryland, to waive or modify regulatory requirements. Third, the Commenter asserts the proposed Maryland SIP revision does not meet

minimum requirements in the CAA for public participation, does not protect the public's right to review and comment on draft permits, and does not require the PSC to respond to comments. Finally, the Commenter asserts the proposed Maryland SIP revision does not contain formal requirements for completeness determinations. EPA's response to these four comments is provided below.

*Comment 1:* The Commenter asserts the proposed revision to the Maryland SIP "does not clearly and unambiguously mandate compliance with New Source Review standards under the Clean Air Act." The Commenter cites to section 110(a)(2)(C) of the CAA, 42 U.S.C. section 7410(a)(2)(C), which requires SIPs to include a permit program as required by parts C and D of the CAA for PSD and NSR. The Commenter also cites to 40 CFR 51.166(j) which includes requirements that SIPs provide certain requirements, including, but not limited to, requirements that major stationary sources or major modifications meet applicable emission limitations under 40 CFR parts 60 and 61 and apply best available control technology (BACT) for each regulated NSR pollutant they would have the potential to emit in significant amounts or for each regulated NSR pollutant for which there is a significant net emissions increase. The Commenter cites to 40 CFR 51.166(a)(1)(7)(ii) (requiring each SIP to incorporate requirements of 40 CFR 51.166(j)–(r)) and to section 165(a)(2) of the CAA, 42 U.S.C. section 7475(a)(2), which requires major emitting facilities to receive permits prior to construction.

*Response 1:* EPA does not agree with the Commenter that the Maryland SIP revision does not meet the above requirements. Section 110(a)(2)(C) of the CAA, 42 U.S.C. section 7410(a)(2)(C), requires each SIP to include a permits program as required in parts C and D of the CAA (42 U.S.C. sections 7470–7492 and 7501–7515). 40 CFR 51.166 provides further details on the requirements for the permits programs. EPA believes the statutory and regulatory requirements in the May 13, 2011 Maryland SIP submission, as amended December 20, 2011, fulfill the requirements of section 110(a)(2)(C) and 165(a)(2) of the CAA and 40 CFR 51.166.

Pursuant to Md. Code Ann., Public Utilities Cos. sections 7–205 and 7–207, electric generating stations may not be modified or constructed without receiving prior approvals from the PSC through the PSC's issuance of a permit which is known as a CPCN. Section 7–207 requires electric generating stations to obtain CPCNs from the PSC prior to

construction. Section 7–205 requires electric generating stations to obtain approval from the PSC prior to commencing a modification to the generating station. "Approval" as used in the Maryland statutory provision (section 7–205) means a CPCN issued pursuant to sections 7–207 and 7–208. See COMAR 20.79.01.02(4). The Maryland statutory provisions in sections 7–207 and 7–208 which EPA proposed to include in the Maryland SIP contain specific requirements for the issuance of CPCNs. In particular, section 7–208(f)(1) states that the PSC shall include in each certificate it issues "(i) the requirements of the federal and State environmental laws and standards that are identified by the Department of the Environment; and (ii) the methods and conditions that the Commission determines are appropriate to comply with those environmental laws and standards." Section 7–208(f)(2) provides that the PSC "may not adopt any method or condition under paragraph (1)(ii) of this subsection that the Department of the Environment determines is inconsistent with federal and State environmental laws and standards."

The Maryland regulatory provisions EPA is limitedly approving in the SIP revision further fulfill the Clean Air Act requirements for SIPs. COMAR 20.79.03.02 contains the requirements for applications for CPCNs and requires applicants for CPCNs to include in CPCN applications a description of the effect on air quality including the ability of the applicant to comply with PSD and NSR provisions, a description of the impact on PSD areas and nonattainment areas, and all information and forms required by MDE regulations for permits to construct and operating permits under COMAR 26.11. Further, COMAR 20.79.01 contains additional requirements for electric generating stations applying for CPCNs including requirements for when modifications need CPCNs.

EPA disagrees with the Commenter's claim that the Maryland SIP revision does not meet the requirements of 40 CFR 51.166. EPA believes the revision meets 40 CFR 51.166 through the statutory and regulatory requirements identified above. As previously discussed, COMAR 20.79.03.02 requires CPCN applicants to identify relevant requirements of the CAA. Section 7–208(f) requires inclusion of federal environmental laws and standards identified by MDE which is the Maryland environmental agency which implements PSD and NSR as well as all requirements of the CAA for all sources in Maryland except electric generating

stations. Because the Maryland SIP as implemented through MDE requires sources to apply BACT or Lowest Achievable Emissions Rate at COMAR 26.11.06.14 and 26.11.17, because CPCN applicants identify requirements of the CAA needed for construction or modification projects, and because the emissions standards and standards of performance under 40 CFR Parts 60 and 61 would be identified by MDE through section 7–208(f), EPA believes the Maryland SIP revision meets the requirements of 40 CFR 51.166 as specifically identified by the Commenter, except as discussed below regarding 40 CFR 51.161(b)(1) and 51.166(q)(1) (relating to availability of permit documents and completeness determinations).

EPA believes that the statutory provisions in sections 7–205, 7–207, and 7–208 and the regulatory provisions in COMAR 20.79 contain the required and necessary permits program for PSD and NSR as required in sections 110(a)(2)(C) and 165(a)(2) of the CAA, 42 U.S.C. sections 7410(a)(2)(C) and 7475(a)(2), and by 40 CFR 51.166. The Maryland provisions included in the SIP revision require CPCNs prior to construction or modification of electric generating stations. See sections 7–205, 7–207, and 7–208. In addition, section 7–208(f) specifically requires the PSC to include in CPCNs federal environmental requirements identified by MDE. MDE implements the SIP approved PSD and NSR permit program for sources other than electric generating stations in Maryland through COMAR 26.11.06.14 and 26.11.17.

*Comment 2:* The Commenter asserts the proposed revisions to the Maryland SIP contain a provision which allows the PSC authority to waive CAA requirements in COMAR 20.79. See COMAR 20.79.01.07. The Commenter asserts that the CAA requires a SIP to unambiguously require an applicant for a CPCN to comply with NSR requirements such as BACT. The Commenter asserts that the PSC has “extremely broad authority to waive or modify any of the regulatory provisions in Title 20, Subchapter 79, which governs the CPCN application process.” The Commenter asserts that the letter submitted by the Secretary of MDE to the Regional Administrator of EPA Region III on July 15, 2011 stating that MDE would ensure that the PSC does not issue waivers or modifications not in compliance with the CAA and federal regulations was not sufficient to serve as a binding requirement on the state to ensure CPCN applicants comply with NSR requirements. The Commenter asserts that section 7–208(f) is

insufficient to show that NSR requirements will be included in all CPCNs because section 7–208 “appears to apply only to the construction of an EGU when either (1) associated overhead transmission lines designed to carry a voltage in excess of 69,000 volts are also being constructed; or (2) the entity constructing the EGU is exercising the right of condemnation in connection therewith.” See section 7–208(a).

*Response 2:* EPA notes that in a December 20, 2011 letter from Robert M. Summers, Secretary of MDE, to Shawn M. Garvin, Regional Administrator, EPA Region III, MDE officially withdrew COMAR 20.79.01.07 from MDE’s proposal for inclusion in the Maryland SIP. In taking final action on Maryland’s proposed SIP revision, EPA is acting on the remaining statutes and regulations submitted by Maryland. Therefore, EPA’s limited approval of the PSC permitting program for electric generating stations does not include COMAR 20.79.01.07 and that provision is not included in the Maryland SIP.

Nevertheless, EPA disagrees with the Commenter in general on the waiver issue and believes the Letter from Robert M. Summers, Secretary of MDE, to Shawn M. Garvin, Regional Administrator, EPA Region III (July 15, 2011) provides assurances that MDE will ensure that its sister Maryland agency, the PSC, will include all necessary PSD and NSR requirements as required by section 7–208(f). EPA believes that the PSC’s waiver authority in COMAR 20.79.01.07 is clearly restricted by the statutory restraint on the PSC’s CPCN authority in section 7–208(f) which provides that the PSC *shall* include federal environmental laws and standards identified by MDE in CPCNs. This statutory restraint is clearly evident from the plain language of the statute. The July 15, 2011 Letter from Robert M. Summers to EPA confirms the statutory limitation on the PSC’s waiver authority. EPA has given considerable weight to the Summers’ July 15, 2011 letter because MDE has expertise in interpreting Maryland law. Presently, EPA has no reason to believe the PSC will exercise its waiver authority to issue CPCN’s without environmental requirements identified by MDE contrary to section 7–208(f). In addition, as of December 20, 2011, the PSC’s waiver authority in COMAR 20.79.01.07 was removed from Maryland’s proposed SIP revision and is therefore not included in EPA’s limited approval of the Maryland permitting program for electric generating stations. Therefore, EPA believes the Maryland SIP revision

meets the requirements of the CAA for the limited approval.

Additionally, EPA disagrees with the Commenter that section 7–208 does not apply to the construction and modification of all electric generating stations in Maryland. EPA believes the Commenter’s assertion is contrary to established Maryland case law. Section 7–207 was originally codified as Maryland Ann. Code, Article 78, section 54A (1968), and section 7–208 was previously codified as Maryland Ann. Code, Article 78, section 54B (1971). In *Baltimore Gas & Electric Co. v. Dept. of Health & Mental Hygiene*, 284 Md. 216, 225–26 (1979), the Maryland Court of Appeals interpreted Maryland Ann. Code, Article 78, sections 54A and 54B as providing a comprehensive plan for the erection of new power plants. The Maryland Court of Appeals stated section 54A prohibited construction of a generating station or overhead transmission line without first obtaining a CPCN and also found that section 54B (the predecessor of Md. Ann. Code, Public Utilities Co. section 7–208) simply provided the procedures for obtaining a CPCN under section 54A (now codified as section 7–207). *Id.* Likewise, today, section 7–207 requires CPCNs prior to construction of electric generating stations, and section 7–208 provides the detailed requirements for those CPCNs.

Further, COMAR 20.79.01.02(B)(4) clearly confirms that CPCNs issued for modification projects would be CPCNs issued pursuant to requirements in sections 7–207 and 7–208. Because Maryland case law found that Maryland Ann. Code, Article 78, sections 54A and 54B (now codified as sections 7–207 and 7–208) apply to construction of electrical generating stations or transmission lines and because the Maryland regulations included in the SIP revision state that section 7–208 applies also to modifications, EPA does not believe the Commenter’s assertion is valid or a correct interpretation of Maryland law.

*Comment 3:* The Commenter asserts the proposed Maryland SIP revisions do not meet minimum standards for public participation set forth in the CAA and do not protect the public’s right to review and comment on a draft CPCN. The Commenter also states the PSC does not allow for sufficient time for response to public comments. The Commenter asserts the proposed SIP revision does not contain a formal process for ensuring the PSC responds to comments and asserts the letter from H. Robert Erwin, Jr., General Counsel, PSC, to Robert M. Summers, Secretary, MDE (January 25, 2011) is inadequate to

establish an independent obligation under the SIP on the PSC to respond to comments during the CPCN permitting process. The Commenter asserts that the CAA requires a public hearing and an opportunity for public comment during the NSR permit process and that the permitting agency must make available to the public information submitted by the owner or operator of the applicant as well as the permit agency's analysis of the effect on air quality and the draft approval in at least one location. *See* 40 CFR 51.161(a), 51.161(b), and 51.166(q). The Commenter states the SIP must provide at least 30 days for public comments. 40 CFR 51.161(b)(2). The Commenter asserts that the Md. Code Ann., Pub. Util. Cos. section 7-207(d) and related regulations do not meet these requirements.

*Response 3:* EPA agrees with the Commenter that the CAA does require public participation in NSR permitting, including the right to review documents. However, EPA disagrees with the Commenter regarding the proposed Maryland SIP revision because EPA believes the Maryland SIP revision meets the requirements of the CAA for public participation with the exception of the requirement for the SIP to require the permitting agency to make available to the public in at least one location information submitted by the owner or operator of the applicant as well as the permit agency's analysis of the effect on air quality and the draft approval. *See* 40 CFR 51.161(a) and (b)(1).

Sections 7-207(c) and (d) and 7-208(d) contain the CAA's public participation requirements for SIPs. As discussed above, sections 7-207 and 7-208 apply to CPCNs for construction as well as for modification of electric generating stations. Section 7-207(c) and (d) require the PSC to provide notice of an application for a CPCN to all interested persons, to provide an opportunity for public comment, and to hold a public hearing on the CPCN application. Section 7-207(d) also requires weekly notice of the public hearing and opportunity for comment in a newspaper of general circulation in the four weeks prior to a hearing. Section 7-208(d) requires the PSC to provide notice to all interested persons upon receipt of an application for a CPCN and to hold a public hearing as required by section 7-207 upon publication of proper notice.

However, EPA agrees with the Commenter that a SIP must require the permitting agency to make available to the public in at least one location information submitted by the permit applicant as well as the permit agency's

analysis of the effect on air quality and the draft approval. *See* 40 CFR 51.161(a) and (b)(1). As explained in this rulemaking, EPA is granting limited approval to the Maryland SIP revision until such time as MDE submits a statutory or regulatory requirement that meets the requirements of 40 CFR 51.161(a) and (b)(1). EPA is granting this limited approval to the Maryland SIP revision because EPA believes the PSC in practice is providing the public with full access to the public information submitted by a CPCN applicant as well as the PSC's and MDE's analysis of the effect on air quality from an application. All public records relevant to a CPCN application and the PSC's official actions on those applications are available to the public for review and download through access to the PSC's publicly available Web page at <http://www.psc.state.md.us/>. The purpose of providing an opportunity for public review is served by this method of availability such that EPA is granting a limited approval until the PSC and MDE include such a requirement in a request for SIP revision.

In addition, we gain additional assurance that the public will have available for inspection information submitted by a CPCN applicant and associated PSC analyses through the PSC's statutory obligation to comply with the Maryland Public Information Act, Md. Code Ann., State Government sections 10-611 to 10-630. The Maryland Public Information Act applies to all branches of the Maryland state government and provides persons the right to review the available records that are disclosable by the State and the right to obtain copies of those records. This statute provides that all persons are entitled to access to information about the affairs of government and the official acts of public officials and employees. *See* Maryland Public Information Act, section 10-612(a). The Maryland Public Information Act permits persons to inspect public records at any reasonable time within thirty days of a request and provides a process for persons to challenge the withholding of public documents. *See* Maryland Public Information Act, sections 10-614 and 10-623.

EPA believes these statutory obligations as well as the practice of making documents publicly available over the PSC's Web page meet the intent of the requirements for SIPs in the CAA and in the regulations at 40 CFR 51.161 and 51.166. Hence, EPA is granting limited approval to this SIP revision until such time as Maryland submits a statutory or regulatory requirement meeting 40 CFR 51.161(a) and (b)(1).

The Commenter also addressed the PSC's obligations to respond to public comments. In reviewing SIPs submitted for approval, EPA must follow the requirements in section 110 of the CAA and in 40 CFR 51.161 and 51.166. The Maryland SIP revision meets these requirements. As discussed above, EPA believes the Maryland SIP revision provides for public hearings for CPCNs and an opportunity for public comment as required by section 165(a)(2) of the CAA and 40 CFR 51.161. The PSC in its practice makes available to the public all information including the CPCN application as required by 40 CFR 51.161(a) and (b) and 51.166(q) through complying with Md. Code Ann., Public Utilities Cos. sections 7-207 and 7-208 and complying with its statutory mandate in the Maryland Public Information Law. In addition, the PSC provides further public access to documents relevant to CPCN obligations via its publically-available docket on the PSC's Web site. While the Maryland Public Information Law and the PSC's Web site are not included in the SIP revision, EPA believes that the PSC is obligated to act in accordance with these obligations and that the PSC's practice in using the Web site strengthens public participation.

If these public access provisions and policies were to be repealed or substantially changed, EPA would reevaluate the limited approval of the SIP revision.

EPA reviews SIPs for their compliance with requirements in the CAA and in the implementing regulations. EPA agrees with the Commenter that responding to comments is essential to ensuring adequate public participation. However, EPA disagrees with the Commenter that the Maryland provisions for electric generating stations are not SIP approvable. EPA has previously stated that adequate public participation and comment requires air permitting agencies to address and respond to public comment. *See In the Matter of Onyx Environmental Services*, Petition V-2005-1 at 7 (February 1, 2006) (citing *Home Box Office v. FCC*, 567 F.2d 9, 35 (DC Cir. 1977) (stating "the opportunity to comment is meaningless unless the agency responds to significant points raised by the public"). *See also In the Matter of Citgo Refining and Chemicals Co. L.P.*, Petition VI-2007-01 at 7 (May 28, 2009) (stating permitting authorities have a responsibility to respond to significant comments); *In the Matter of Kerr-McGee Gathering, LLC*, Petition VIII-2007 at 4; *In the Matter of Wheelabrator, Baltimore L.P.*, Permit 24-510-01-886 at 7 (April 14, 2010).

EPA believes an essential correlative in taking public comment on permits is responding to those comments such that an adequate record of the permit issuer's rationale is created. Responding to public comments ensures meaningful public participation in permitting as intended by the Clean Air Act.

In response to EPA's concerns regarding the PSC's responding to comments on CPCN applications, the General Counsel for the PSC did state in his January 25, 2011 letter to EPA referred to previously that interested persons would be able to raise to a PSC Hearing Examiner, during a prehearing scheduling conference which is part of the CPCN review process, any failure by the PSC to respond to public comments and the need for adequate time for the PSC to respond to comments in a scheduling order. *See* Robert Erwin's January 25, 2011 letter to MDE. In addition, the PSC's General Counsel stated that the failure to respond to comments could be brought to the PSC's attention before a CPCN becomes final during the CPCN approval hearing process. *Id.* EPA believes the commitment to respond to comments from the PSC's General Counsel as evidenced in the General Counsel's January 25, 2011 letter satisfies EPA's concerns that the PSC will respond to public comments on CPCN applications. EPA believes the Maryland SIP revision provides for full public participation as required by sections 110 and 165 of the CAA and its implementing regulations at 40 CFR 51.161 and 51.166 (with the exception of providing public access to documents in one location as discussed above). *See id.*

**Comment 4:** Finally, the Commenter asserts that the proposed Maryland SIP revision does not contain a requirement that the permit reviewing authority (the PSC) shall notify all permit applicants within a specified time period as to the completeness of the permit application or any deficiency in the application as required in 40 CFR 51.166(q)(1).

**Response 4:** EPA agrees with the Commenter that the Maryland SIP revision does not formally contain a requirement directly meeting 40 CFR 51.166(q)(1). EPA is granting limited approval to the PSC permitting program in the Maryland SIP until Maryland submits a regulation meeting 40 CFR 51.166(q)(1) (as well as 40 CFR 51.161(a) and (b)(1) as discussed previously). However, EPA has granted limited approval because EPA is satisfied that the PSC is meeting this requirement in practice. EPA believes the revised Maryland SIP as implemented by the PSC will appropriately address CPCN completeness determinations.

According to 40 CFR 51.166(q)(1), a SIP shall provide that the "reviewing authority shall notify all applicants within a specified time period as to the completeness of the application or any deficiency in the application or information submitted." EPA believes the General Counsel's January 25, 2011 letter addresses this issue. *See* Robert Erwin's January 25, 2011 letter to MDE. The PSC's General Counsel stated in the January 25, 2011 letter that parties should raise the issue of completeness determinations with the PSC Hearing Examiner at the Prehearing Scheduling Conference which is held during the CPCN application review process. The General Counsel stated that the PSC's Hearing Examiner for each CPCN application would hear argument and make a determination as to completeness of applications and subsequently either order an incomplete CPCN application be supplemented or make a finding on the record that a CPCN application was complete. *See id.* We believe the PSC provides adequate opportunities during the CPCN application process for parties to raise the issue of incomplete CPCN applications.

In addition, the statutory and regulatory provisions in the proposed Maryland SIP revision support EPA's belief that the PSC will act on completeness determinations. Pursuant to section 7-205(d), the PSC must render a decision on a CPCN application within 150 days of the filing of the CPCN application. *See* Md. Code Ann., Public Util. Cos. section 7-205(d). In addition, section 7-207(d) provides the requirements for the PSC to hold public hearings on CPCN applications, and section 7-208(e) follows along with the requirements in section 7-207(d) by requiring the PSC to grant or deny CPCN applications within 90 days of the conclusion of the hearings on the CPCN applications. Finally, the PSC's implementing regulations at COMAR 20.79.02.03, require the PSC to impose a schedule of procedural dates to ensure timely completion of the CPCN application process. Reading these statutory and regulatory provisions together with the PSC General Counsel's January 25, 2011 letter, EPA believes the Maryland SIP revision together with the PSC's implementation as described above satisfies the intent of 40 CFR 51.166(q)(1) sufficient for EPA to provide limited approval to the Maryland SIP revision until Maryland submits a regulation from the PSC for SIP approval formally addressing the requirements of 40 CFR 51.166(q)(1).

Furthermore, EPA believes the requirements of 40 CFR 51.166(q)(1) are

intended to protect the interests of permit applicants in receiving timely review of permit applications. EPA does not believe that the Commenter is adversely affected by the PSC's failure to do a completeness determination on a particular CPCN. EPA has no reason to believe that the PSC is not conducting completeness determinations as discussed by the PSC's General Counsel and has received no adverse comment on this issue from the regulated and impacted community of electric generating stations.

Finally, EPA notes that the Commenter included additional statements in its Comments relating to CPCNs issued previously by the PSC and the federal enforceability of those CPCNs. To the extent that these comments do not relate to the Maryland SIP revision and are not relevant to EPA's limited approval of the SIP revision, EPA is not responding to those Comments here.

## V. Final Action

EPA is granting limited approval in accordance with section 110(k) of the CAA, 42 U.S.C. section 7410(k), of MDE's May 13, 2011 SIP submission (#11-01), as amended on December 20, 2011 with the removal of COMAR 20.79.01.07, because the submission as amended strengthens Maryland's SIP. When the PSC adopts amended regulations which meet the requirements of 40 CFR 51.161(a) and (b)(1) and 51.166(q)(1), MDE may request full SIP approval of the permitting program for construction and modification of electric generating stations in Maryland.

## V. Statutory and Executive Order Reviews

### A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions

of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- 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);

- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct

costs on tribal governments or preempt tribal law.

#### *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. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

#### *C. Petitions for Judicial Review*

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 10, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action.

This action pertaining to preconstruction requirements for Electric Generating Stations in Maryland may not be challenged later in

proceedings to enforce its requirements. (See section 307(b)(2).)

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

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

Dated: January 31, 2012.

**W.C. Early,**

*Acting, Regional Administrator, Region III.*

40 CFR part 52 is amended as follows:

#### **PART 52—[AMENDED]**

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

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

#### **Subpart V—Maryland**

■ 2. In § 52.1070, the table in paragraph (c) is amended by:

■ a. Revising the heading of the table.

■ b. Revising the existing entries for COMAR 26.11.02.09 and 26.11.02.10.

■ c. Adding entries for COMAR 20.79.01, 20.79.02 and 20.79.03 in numerical order after the existing entry for COMAR 03.03.06.06.

■ d. Adding new entries for “Public Utility Companies Article of the Annotated Code of Maryland” at the end of the table.

The amendments read as follows:

#### **§ 52.1070 Identification of plan.**

\* \* \* \* \*

(c)\* \* \*

#### **EPA-APPROVED REGULATIONS, TECHNICAL MEMORANDA, AND STATUTES IN THE MARYLAND SIP**

Code of Maryland administrative regulations (COMAR) citation	Title/subject	State effective date	EPA approval date	Additional explanation/citation at 40 CFR 52.1100
*	*	*	*	*
<b>26.11.02 Permits, Approvals, and Registrations</b>				
26.11.02.09 .....	Sources Subject to Permits to Construct and Approvals.	11/16/09	2/10/12 [Insert page number where the document begins].	Revised 26.11.02.09A(1), (2); limited approval.
26.11.02.10 .....	Sources Exempt from Permits to Construct and Approvals.	11/16/09	2/10/12 [Insert page number where the document begins].	Revised 26.11.02.10A; limited approval.



## EPA-APPROVED REGULATIONS, TECHNICAL MEMORANDA, AND STATUTES IN THE MARYLAND SIP—Continued

Code of Maryland administrative regulations (COMAR) citation	Title/subject	State effective date	EPA approval date	Additional explanation/citation at 40 CFR 52.1100
*	*	*	*	*
<b>20.79.01 Applications Concerning the Construction or Modification of Generating Stations and Overhead Transmission Lines—General</b>				
20.79.01.01A, .01C, and .01D.	Scope .....	12/28/09	2/10/12 [Insert page number where the document begins].	Added; limited approval.
20.79.01.02A and .02B(1) through (13), (14)(a), (15), (16), and (18) through (20).	Definitions .....	12/28/09	2/10/12 [Insert page number where the document begins].	Added; limited approval.
20.79.01.06 .....	Modifications to Facilities at a Power Plant.	12/28/09	2/10/12 [Insert page number where the document begins].	Added; limited approval.
<b>20.79.02 Applications Concerning the Construction or Modification of Generating Stations and Overhead Transmission Lines—Administrative Provisions</b>				
20.79.02.01 .....	Form of Application .....	2/10/97	2/10/12 [Insert page number where the document begins].	Added; limited approval.
20.79.02.02 .....	Distribution of Application ....	2/10/97; 11/8/04	2/10/12 [Insert page number where the document begins].	Added; limited approval.
20.79.02.03 .....	Proceedings on the Application.	2/10/97; 11/8/04	2/10/12 [Insert page number where the document begins].	Added; Limited approval.
<b>20.79.03 Applications Concerning the Construction or Modification of Generating Stations and Overhead Transmission Lines—Details of Filing Requirements—Generating Stations</b>				
20.79.03.01 .....	Description of Generating Station.	2/10/97; 11/8/04	2/10/12 [Insert page number where the document begins].	Added; limited approval.
20.79.03.02A and .02B(1) and (2).	Environmental Information ...	2/10/97; 11/8/04	2/10/12 [Insert page number where the document begins].	Added; limited approval.
*	*	*	*	*
Annotated Code of Maryland citation	Title/subject	State effective date	EPA approval date	Additional explanation/citation at 40 CFR 52.1100
<b>Public Utility Companies Article of the Annotated Code of Maryland</b>				
Section 7–205 .....	Electric Companies—Modification of Power Plant.	7/01/06	2/10/12 [Insert page number where the document begins].	Added; limited approval.
Section 7–207(a), (b)(1), (c), (d), and (e).	Generating Stations or Transmission Lines—General Certification Procedure.	7/01/07	2/10/12 [Insert page number where the document begins].	Added; limited approval.
Section 7–207.1(a) and (e) ..	Generating Stations or Transmission Lines—On-site Generated Electricity; Approval Process.	7/01/07	2/10/12 [Insert page number where the document begins].	Added; limited approval.
Section 7–208 (a)(1), (b) through (f), and (h)(2).	Generating Stations or Transmission Lines—Joint Construction of Station and Associated Lines.	7/01/01	2/10/12 [Insert page number where the document begins].	Added; limited approval.

\* \* \* \* \*

[FR Doc. 2012–2984 Filed 2–9–12; 8:45 am]

BILLING CODE 6560–50–P



**DEPARTMENT OF HEALTH AND HUMAN SERVICES****42 CFR Part 171****[Docket No. CDC–2012–0003]****RIN 0920–AA47****Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples**

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

**ACTION:** Direct final rule and request for comments.

**SUMMARY:** Through this Direct Final Rule, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) is establishing a user fee for filovirus testing of all nonhuman primates that die during HHS/CDC-required 31-day quarantine period for any reason other than trauma. We are amending regulations to establish a filovirus testing service at HHS/CDC because testing is no longer being offered by the only private, commercial laboratory that previously performed these tests. This testing service will be funded through user fees. The direct final rule does not impose any new burdens on the regulated community because the testing of non-human primates for filovirus is a long-standing requirement and the amount of the user fee is consistent with the amount previously charged commercially. HHS/CDC is therefore publishing a direct final rule because it does not expect to receive any significant adverse comment and believes that the establishment of an HHS/CDC testing program and imposition of user fees are non-controversial. However, in this **Federal Register**, HHS/CDC is simultaneously publishing a companion notice of proposed rulemaking that proposes identical filovirus testing and user fee requirements. If HHS/CDC does not receive any significant adverse comment on this direct final rule within the specified comment period, it will publish a notice in the **Federal Register** confirming the effective date of this final rule within 30 days after the comment period on the direct final rule ends and withdraw the notice of proposed rulemaking. If HHS/CDC receives any timely significant adverse comment, it will withdraw the direct final rule in part or in whole by publication of a document in the **Federal Register** within 30 days after the comment period ends and proceed with notice and comment under the

notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. A significant adverse comment is one that explains: Why the direct final rule is inappropriate, including challenges to the rule's underlying premise or approach; or why the direct final rule will be ineffective or unacceptable without a change.

**DATES:** The direct final rule is effective on March 12, 2012 unless significant adverse comment is received by April 10, 2012. If we receive no significant adverse comment within the specified comment period, we intend to publish a notice confirming the effective date of the final rule in the **Federal Register** within 30 days after the end of the comment period on this direct final rule. If we receive any timely significant adverse comment, we will withdraw this final rule in part or in whole by publication of a notice in the **Federal Register** within 30 days after the comment period ends.

**ADDRESSES:** You may submit comments, identified by “RIN 0920–AA47”: by any of the following methods:

- **Internet:** Access the Federal e-rulemaking portal at <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Mail:** Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–03, Atlanta, Georgia 30333, ATTN: NHP DFR.

**Instructions:** All submissions received must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking. All comments will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Public Participation” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, please go to <http://www.regulations.gov>. Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Time, at 1600 Clifton Road NE., Atlanta, Georgia 30333. Please call ahead to 1–866–694–4867 and ask for a representative in the Division of Global Migration and Quarantine (DGMQ) to schedule your visit. To download an electronic version of the rule, access <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** For questions concerning this direct final rule: Ashley A. Marrone, JD, Centers for

Disease Control and Prevention, 1600 Clifton Road NE., Mailstop E–03, Atlanta, Georgia 30333; telephone 404–498–1600. For information concerning program operations: Dr. Robert Mullan, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop E–03, Atlanta, Georgia 30333; telephone 404–498–1600.

**SUPPLEMENTARY INFORMATION:**

This preamble is organized as follows:

- I. Public Participation
- II. Background
- III. Rationale for Direct Final Rule
- IV. User Fees
- V. Services and Activities Covered by User Fees
- VI. Analysis of User Fee Charge (Cost to Government)
- VII. Payment Instructions
- VIII. Regulatory Analysis
- IX. References

**I. Public Participation**

Interested persons are invited to participate in this rulemaking by submitting written views, opinions, recommendations, and data. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you do not wish to be disclosed publicly. Comments are invited on any topic related to this direct final rule.

**II. Background**

Filoviruses belong to a family of viruses known to cause severe hemorrhagic fever in humans and nonhuman primates (NHPs). So far, only two members of this virus family have been identified: Ebola virus and Marburg virus. Five species of Ebola virus have been acknowledged: Zaire, Sudan, Reston, Ivory Coast, and Bundibugyo. Most strains of Ebola virus can be highly fatal in humans, and while the Reston strain is the only strain of filovirus that has *not* been reported to cause disease in humans, it can be fatal in monkeys. (<http://www.cdc.gov/ncidod/dvrd/spb/mnpages/dispages/filoviruses.htm>).

Ebola hemorrhagic fever was first recognized in 1976, when two epidemics occurred in southern Sudan and in Zaire. Since that time, multiple outbreaks have occurred, mostly in Central Africa, and all have been associated with high (45–90%) case-fatality rates in humans (for an updated