

Warning: Potential systemic adverse effects may result from use of this device. Drugs or solutions delivered with this device have the potential to reach the blood stream and cause systemic effects. Carefully read all labeling of the drug or solution used with this device to understand all potential adverse effects and to ensure appropriate dosing information. If systemic manifestations occur, refer to the drug or solution labeling for appropriate action.

(iii) Appropriate analysis/testing must demonstrate electromagnetic compatibility, electrical safety, thermal safety, and mechanical safety.

(iv) Appropriate software verification, validation, and hazard analysis must be performed.

(v) The elements of the device that may contact the patient must be demonstrated to be biocompatible.

(vi) The elements of the device that may contact the patient must be assessed for sterility.

(vii) Performance data must support the shelf life of the elements of the device that may be affected by aging by demonstrating continued package integrity and device functionality over the stated shelf life.

Dated: September 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-22453 Filed 9-19-14; 8:45 am]

BILLING CODE 4164-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2014-0596; FRL-9916-81-Region 3]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; 2014 Amendments to West Virginia's Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of West Virginia for the purpose of amending their Legislative Rule on Ambient Air Quality Standards. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because EPA views this as a noncontroversial submittal and anticipates no adverse comments. A

detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by October 22, 2014.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2014-0596 by one of the following methods:

A. *www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. Email: fernandez.cristina@epa.gov.

C. Mail: EPA-R03-OAR-2014-0596, Cristina Fernandez, Associate Director, Office of Air Program Planning, Air Protection Division, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R03-OAR-2014-0596. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov*, 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 *www.regulations.gov* or email. The *www.regulations.gov* Web site is an "anonymous access" system, 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 email comment directly to EPA without going through *www.regulations.gov*, your email 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 *www.regulations.gov* index. 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 *www.regulations.gov* or in hard copy 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 submittal are available at the West Virginia Department of Environmental Protection, Division of Air Quality, 601 57th Street SE., Charleston, West Virginia 25304.

FOR FURTHER INFORMATION CONTACT:

Ellen Schmitt, (215) 814-5787, or by email at schmitt.ellen@epa.gov.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the "Rules and Regulations" section of this **Federal Register** publication. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

Dated: September 2, 2014.

William C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2014-22414 Filed 9-19-14; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA-HQ-SFUND-2014-0623, 0624, and 0625; FRL-9916-73-OSWER]

National Priorities List, Proposed Rule No. 61

AGENCY: Environmental Protection Agency (EPA).