required under paragraphs (i)(1), (i)(2), and (i)(3) of this section must be removed or otherwise obscured.

(j) A tie-tag attached to the container may be used for providing the information required by paragraphs (e)(1)(iii), (e)(2)(ii), and (e)(3), (h), or (i)(1), (i)(2), and (i)(3) of this section.

4. Section 606.122 is amended by:

a. Revising the section heading;

b. Revising the introductory text;

c. Revising paragraphs (e), (f), (m)(2), (m)(4), and (m)(5); and

d. Revising the introductory text in paragraphs (k), (l), (m), and (n).

The revisions read as follows:

§ 606.122 Circular of information.

A circular of information must be available for distribution if the product is intended for transfusion. The circular of information must provide adequate directions for use, including the following information:

* * * * *

(e) A statement that the product was prepared from blood that was found negative when tested for communicable disease agents, as required under § 610.40 of this chapter (include each test that was performed).

(f) The statement: “Warning: The risk of transmitting infectious agents is present. Careful donor selection and available laboratory tests do not eliminate the hazard.”

* * * * *

(k) For Red Blood Cells, the circular of information must contain:

* * * * *

(l) For Platelets, the circular of information must contain:

* * * * *

(m) For Plasma, the circular of information must contain:

(1) * * *

(2) Instructions to thaw the frozen product at a temperature appropriate for the product.

(3) When applicable, instructions to begin administration of the product within a specified time after thawing.

* * * * *

(5) A statement that this product has the same risk of transmitting infectious agents as Whole Blood; other plasma volume expanders without this risk are available for treating hypovolemia.

(n) For Cryoprecipitated AHF, the circular of information must contain:

* * * * *

6. Section 606.170 is amended by revising paragraph (b) to read as follows:

§ 606.170 Adverse reaction file.

* * * * *

(b) When a complication of blood collection or transfusion is confirmed to be fatal, the Director, Office of Compliance and Biologics Quality, CBER, must be notified by telephone, facsimile, express mail, or electronically transmitted mail as soon as possible. A written report of the investigation must be submitted to the Director, Office of Compliance and Biologics Quality, CBER, by mail, facsimile, or electronically transmitted mail (for mailing addresses, see § 600.2 of this chapter), within 7 days after the fatality by the collecting facility in the event of a donor reaction, or by the facility that performed the compatibility tests in the event of a transfusion reaction.

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

7. The authority citation for 21 CFR part 610 continues to read as follows:


8. Section 610.40 is amended by revising paragraphs (h)(2)(i)(B) and (i) to read as follows:

§ 610.40 Test requirements.

* * * * *

(h) * * *

(2) * * *

(i) * * *

(B) You must appropriately label such blood or blood components as required under § 606.121 of this chapter, and with the “BIOHAZARD” legend;

* * * * *

(i) Syphilis testing.

In addition to the testing otherwise required under this section, you must test by a serological test for syphilis under §§ 640.5(a), 640.14, 640.22(a), 640.33(a), 640.53(a), and 640.65(b)(1) and (b)(2) of this chapter.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

9. The authority citation for 21 CFR part 640 continues to read as follows:


§ 640.70 [Removed]

10. Section 640.70 is removed.

11. Section 640.74 is amended by revising paragraph (b)(4) to read as follows:

§ 640.74 Modification of Source Plasma.

* * * * *

(b) * * *

(4) The label affixed to each container of Source Plasma Liquid shall contain, in addition to the information required by § 606.121 of this chapter, but excluding § 606.121(e)(5)(ii) of this chapter, the name of the manufacturer of the final blood derivative product for whom it was prepared.

* * * * *

Dated: December 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–33554 Filed 12–30–11; 8:45 am]

BILLING CODE 4160–01–P
Amend § 1915.8, by adding to the paper the entries “1915.83, 1915.87, 1915.88, and 1915.89” in the proper numerical sequence as follows:

§ 1915.8 OMB control numbers under the Paperwork Reduction Act.

<table>
<thead>
<tr>
<th>29 CFR citation</th>
<th>OMB control No.</th>
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<tbody>
<tr>
<td>1915.83</td>
<td>1218–0259</td>
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<td>1915.87</td>
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<td>1915.89</td>
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52


Approval and Promulgation of Air Quality Implementation Plans; State of New Jersey; Regional Haze State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving the revision to the New Jersey State Implementation Plan, submitted by the State of New Jersey. The revision addresses Clean Air Act requirements and EPA’s rules for states to prevent and remedy future and existing anthropogenic impairment of visibility in mandatory Class I areas through a regional haze program. EPA’s approval includes but is not limited to New Jersey’s plans to implement Reasonable Progress Goals, Best Available Retrofit Technologies on eligible sources, as well as New Jersey’s Subchapter 9, Sulfur in Fuels rule and source-specific SIP revisions.

DATES: Effective Date: This rule is effective on February 2, 2012.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R02–OAR–2011–0607. All documents in the docket are listed on the www.regulations.gov Web site. Although listed in the index, some information is not publicly available, e.g., 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 or in hard copy at the Environmental Protection Agency, Region II Office, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007–1866. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (212) 637–4249.

FOR FURTHER INFORMATION CONTACT: Robert F. Kelly, State Implementation Planning Section, Air Programs Branch, EPA Region 2, 290 Broadway, New York, New York 10007–1866. The telephone number is (212) 637–4249. Mr. Kelly can also be reached via electronic mail at kelly.bob@epa.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents
I. What action is EPA taking?
II. Did NJ adopt BART requirements consistent with EPA’s proposal?
III. What comments did EPA receive in response to its proposal?
IV. What are EPA’s conclusions?
V. Statutory and Executive Order Reviews

I. What action is EPA taking?

EPA is approving a revision to New Jersey’s State Implementation Plan (SIP) submitted on July 28, 2009, that addressed progress toward reducing regional haze for the first implementation period ending in 2018. The initial submittal was supplemented by a December 9, 2010 submittal transmitting New Jersey’s adopted regulation Subchapter 9 Sulfur in Fuel, lowering the sulfur content in fuel oil, a March 2, 2011 submittal which included Best Available Retrofit Technologies (BART) determinations and controls, and a December 7, 2011 submittal including Air Pollution Control Operating Permits for sources that require BART reductions, as listed in the regulatory section of this action.

EPA determined that New Jersey’s Regional Haze Plan contains the emission reductions needed to achieve New Jersey’s share of emission reductions that were determined to be reasonable through the regional planning process. Furthermore, New Jersey’s Regional Haze Plan ensures that emissions from the State will not interfere with the Reasonable Progress Goals (RPGs) for neighboring States’ Class I areas. Thus, EPA is approving into the SIP the Regional Haze Plan submitted by New Jersey on July 28, 2009 and supplemented on December 9, 2010, March 2, 2011, and December 7, 2011 as satisfying the requirements of the Clean Air Act. EPA is taking this action pursuant to Section 110 of the Act.