criteria and to be suitable for distribution.

3. Section 600.14 is amended by revising the section heading and paragraph (a) and by adding new paragraph (c) to read as follows:

§ 600.14 Reporting of errors and accidents.

(a) Except as provided in paragraph (c) of this section, the Director, Office of Compliance (HFM–650), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448, shall be notified as soon as possible but not to exceed 45 calendar days, of errors or accidents in the manufacture of products that may affect the safety, purity, or potency of any biological product made available for distribution.

* * * * *

(c) In lieu of the requirements of paragraph (a) of this section, all manufacturers of blood and blood components shall submit reports to FDA in accordance with § 606.171 of this chapter.

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

4. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 505, 510, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374); secs. 215, 351, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263a, 264).

5. Section 606.3 is amended by adding new paragraphs (k) and (l) to read as follows:

§ 606.3 Definitions.

* * * * *

(k) *Error and accident* means:

(1) An event that represents a deviation from current good manufacturing practice (CGMP), applicable standards, or established specifications that may affect the safety, purity, or potency of blood or blood components, including source plasma, or otherwise cause the product to be in violation of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, or

(2) An unexpected or unforeseeable event that may affect the safety, purity, or potency of blood or blood components, including source plasma, or otherwise cause the product to be in violation of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

(l) *Made available for distribution* means that the blood or blood component, including source plasma, has been determined to meet all release criteria and to be suitable for distribution.

6. Section 606.171 is added to subpart I to read as follows:

§ 606.171 Error and accident reporting, blood and blood components.

All establishments as defined in § 607.3(c) of this chapter shall notify the Director, Office of Compliance (HFM–600), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448, as soon as possible but not to exceed 45 calendar days, of errors or accidents in the manufacture of blood or blood components, including source plasma, that may affect the safety, purity, or potency of any blood or blood component made available for distribution.

Dated: June 25, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–25129 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[ME–046–6996b; A–1–FRL–5894–7]

Approval and Promulgation of Air Quality Implementation Plans; Maine; (General Conformity Rule)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Maine for the purpose of implementing General Conformity (Section 176(c)(4)(C) of the Clean Air Act (CAA) and its regulations 40 CFR part 51, Subpart W). The Maine SIP incorporates by reference the criteria and procedures set forth at 40 CFR part 51, Subpart W. This SIP revision establishes and requires federal actions to conform to all applicable implementation plans developed pursuant to Section 110 and Part D of the CAA. In the Final Rules Section of this **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment 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 that direct final rule, no further activity is contemplated in relation to this proposed rule. 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 on this proposal. Any parties interested in commenting on this proposal should do so at this time.

DATES: Comments must be received on or before October 23, 1997.

ADDRESSES: Comments may be mailed to Susan Studlien, Deputy Director, Office of Ecosystem Protection (mail code CAA), U.S. Environmental Protection Agency, Region I, JFK Federal Bldg., Boston, MA 02203. Copies of the State submittal are available for public inspection during normal business hours, by appointment at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, Region I, One Congress Street, 11th floor, Boston, MA and the Bureau of Air Quality Control, Department of Environmental Protection, 71 Hospital Street, Augusta, ME 04333.

FOR FURTHER INFORMATION CONTACT: Donald O. Cooke, (617) 565–3508, at the EPA Region I address above.

SUPPLEMENTARY INFORMATION: For additional information, see the direct final rule which is located in the Rules Section of this **Federal Register**.

Authority: 42 U.S.C. 7401—7671q.

Dated: September 9, 1997.

John P. DeVillars,

Regional Administrator, Region I.

[FR Doc. 97–25229 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA58–4039; AD–FRL–5897–2]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Pennsylvania Power—New Castle NO_X RACT Proposal; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of the comment period.

SUMMARY: EPA is reopening the comment period for a proposed rule published on August 18, 1997 (62 FR 43959). In the August 18 document, EPA proposed to disapprove the April 19, 1995 Pennsylvania Department of