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

Environmental Protection proposal for nitrogen oxide reasonably available control technology (NO_X RACT) for the Pennsylvania Power—New Castle plant located in Lawrence County. At the request of Paul, Hastings, Janofsky & Walker LLP, attorneys representing Pennsylvania Power—New Castle plant, EPA is extending the comment period through November 18, 1997.

DATES: Comments must be received on or before November 18, 1997.

ADDRESSES: Comments may be mailed to David L. Arnold, Chief, Ozone/CO and Mobile Sources Section, Mailcode 3AT21, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107.

FOR FURTHER INFORMATION CONTACT: Cynthia H. Stahl, U.S. EPA Region III, (215) 566–2180.

Dated: September 16, 1997.

W. Michael McCabe,

Regional Administrator, Region III.

[FR Doc. 97–25224 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[Region 2 Docket No. NY24–2–172a; FRL–5892–4]

Approval and Promulgation of Implementation Plans; Reasonably Available Control Technology for Oxides of Nitrogenfor Specific Sources in the State of New York

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to approve three (3) State Implementation Plan (SIP) revisions submitted by the State of New York related to development of reasonably available control technologies for oxides of nitrogen from various sources in the State. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP revisions, as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision 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. The EPA will not institute a secondcomment period on this rulemaking. Any parties interested in commenting on this **Federal Register** should do so at this time.

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

ADDRESSES: All comments should be addressed to: Ronald Borsellino, Chief, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, New York, New York 10007–1866.

Copies of the State submittal are available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007–1866.

New York Department of Environmental Conservation, Division of Air Resources, 50 Wolf Road, Albany, New York 12233.

FOR FURTHER INFORMATION CONTACT: Ted Gardella or Rick Ruvo, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–4249.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the rules section of this **Federal Register**.

Dated: September 2, 1997.

William J. Muszynski,

Acting Regional Administrator.

[FR Doc. 97–25231 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 86

[FRL–5897–5]

Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines; Voluntary Standards for Light-Duty Vehicles; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: The U.S. Environmental Protection Agency is extending the comment period on the Supplemental Notice of Proposed Rulemaking (SNPRM) which takes comment on the few remaining issues necessary to finalize the regulations for the National LEV program, and which appeared in the **Federal Register** on August 22, 1997 (62 FR 44754). The public comment period was to end on September 22, 1997. The purpose of this document is to extend the comment period an additional 7 days beyond that, to end on September 29, 1997. This extension of the comment period is provided to allow commenters additional time to respond to the SNPRM.

DATES: EPA will accept public comments on the Supplemental Notice of Proposed Rulemaking until September 29, 1997.

ADDRESSES: Written comments should be submitted (in duplicate if possible) to: the EPA, Air Docket, Room M–1500 (Mail Code 6102), Waterside Mall, Attn: Docket A–95–26, 401 M Street, SW., Washington, DC 20460. Materials relevant to this rulemaking are contained in Docket No. A–95–26. The docket is located at The Air Docket, 401 M Street, SW., Washington, DC 20460, and may be viewed in room M–1500 between 8:00 a.m. and 5:30 p.m., Monday through Friday. The telephone number is (202) 260–7548 and the facsimile number is (202) 260–4400. A reasonable fee may be charged by EPA for copying docket material.

FOR FURTHER INFORMATION CONTACT: Karl Simon, Office of Mobile Sources, U.S. Environmental Protection Agency, 401 M Street SW, Washington, DC 20460. Telephone (202) 260–3623; Fax (202) 260–6011; e-mail simon.karl@epamail.epa.gov.

Dated: September 17, 1997.

Richard D. Wilson,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 97–25233 Filed 9–22–97; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Chapter IV

[OMC–029–N]

RIN 0938–AI25

Medicare Program; Solvency Standards for Provider-Sponsored Organizations; Intent To Form Negotiated Rulemaking Committee

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Intent to form negotiated rulemaking committee and notice of meetings.