representative has had access and the date of this access. A licensee or other person subject to this part shall also retain Division of Facilities and Security disclosure authorizations for 5 years beyond the date of any visit or inspection when access to classified information was permitted.

* * * * *

54. In § 95.37, paragraph (c)(1)(iv) is removed and paragraphs (c)(1)(i) and (h)(2) are revised to read as follows:

§ 95.37 Classification and preparation of documents.

* * * * *

(c) * * *

(1) * * *

(i) Derivative classifications of classified National Security Information must contain the identity of the source document or the classification guide, including the agency and office of origin, on the ''Derived From'' line and its classification date. If more than one source is cited, the ''Derived From'' line should indicate ''Multiple Sources.'' The derivative classifier shall maintain the identification of each source with the file or record copy of the derivatively classified document.

* * * * *

(h) * * *

(2) In the event of a question regarding classification review, the holder of the information or the authorized classifier shall consult the NRC Division of Facilities and Security, Information Security Branch, for assistance.

* * * * *

55. In § 95.39, the heading, paragraphs (b)(3) and (c)(2) are revised to read as follows:

§ 95.39 External transmission of classified matter.

* * * * *

(b) * * *

(3) The outer envelope or wrapper must contain the addressee's classified mailing address. The outer envelope or wrapper may not contain any classification, additional marking or other notation that indicate that the enclosed document contains classified information. The Classified Mailing Address shall be uniquely designated for the receipt of classified information. The classified shipping address for the receipt of material (e.g., equipment) should be different from the classified mailing address for the receipt of classified documents.

* * * * *

(c) * * *

(2) Confidential matter may be transported by one of the methods set forth in paragraph (c)(1) of this section, by U.S. express or certified mail. Express or certified mail may be used in transmission of Confidential documents to Puerto Rico or any United States territory or possession.

* * * * *

56. In § 95.45, paragraph (a) is revised to read as follows:

§ 95.45 Changes in classification.

(a) Documents containing classified National Security Information must be downgraded or declassified as authorized by the NRC classification guides or as determined by the NRC. Requests for downgrading or declassifying any NRC classified information should be forwarded to the NRC Division of Facilities and Security, Office of Administration, Washington, DC 20555–0001. Requests for downgrading or declassifying of Restricted Data will be forwarded to the NRC Division of Facilities and Security for coordination with the Department of Energy.

* * * * *

57. Section 95.47 is revised to read as follows:

§ 95.47 Destruction of matter containing classified information.

Documents containing classified information may be destroyed by burning, pulping, or another method that ensures complete destruction of the information that they contain. The method of destruction must preclude recognition or reconstruction of the classified information. Any doubts on methods should be referred to the CSA.

58. Section 95.53 is revised to read as follows:

§ 95.53 Termination of facility clearance.

(a) If the need to use, process, store, reproduce, transmit, transport, or handle classified matter no longer exists, the facility clearance will be terminated. The facility may deliver all documents and matter containing classified information to the Commission or to a person authorized to receive them or destroy all such documents and matter. In either case, the facility shall submit a certification of nonpossession of classified information to the NRC Division of Facilities and Security within 30 days of termination of facility clearance.

(b) In any instance where facility clearance has been terminated based on a determination of the CSA that further possession of classified matter by the facility would not be in the interest of the national security, the facility shall, upon notice from the CSA, dispose of classified documents in a manner specified by the CSA.

59. Section 95.57 is revised to read as follows:

§ 95.57 Reports.

Each licensee or other person having a facility clearance shall report to the CSA and the Regional Administrator of the appropriate NRC Regional Office listed in 10 CFR part 73, Appendix A,

(a) Any alleged or suspected violation of the Atomic Energy Act, Espionage Act, or other Federal statutes related to classified information. Incidents such as this must be reported within 1 hour of the event followed by written confirmation;

(b) Any infractions, losses, compromises or possible compromise of classified information or classified documents not falling within paragraph (a) of this section. Incidents such as these must be reported via written notification within 30 days of the incident. The report shall include details of the incident including corrective action taken;

(c) In addition, NRC requires records for all classification actions (documents classified, declassified, or downgraded) to be submitted to the NRC Division of Facilities and Security. These may be submitted on an as completed basis or every 30 days. The information may be submitted either electronically by an on-line system (NRC prefers the use of a dial-in automated system connected to the Division of Facilities and Security) or by paper copy using NRC Form 790.

Dated at Rockville, Maryland, this 16th day of July, 1998.

For the Nuclear Regulatory Commission.

L. Joseph Callan,

Executive Director for Operations.

[FR Doc. 98–20602 Filed 7–31–98; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 315 and 601

[Docket No. 98N–0040]

Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to

October 15, 1998, the comment period on a proposal rule that was published in the **Federal Register** of May 22, 1998 (63 FR 28301). The document proposed to amend the drug and biologics regulations by adding provisions that would clarify the evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis or monitoring of diseases. The agency is taking this action to provide interested persons additional time to submit comments to FDA on the proposed rule.

DATES: Written comments by October 15, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dano B. Murphy, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210, or Brian L. Pendleton, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5649.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 22, 1998 (63 FR 28301), FDA published a proposed rule to amend the drug and biologics regulations by adding provisions that would clarify the evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis and monitoring of diseases. The proposed regulations would describe certain types of indications for which FDA may approve diagnostic radiopharmaceuticals. The proposed rule would also include criteria that the agency would use to evaluate the safety and effectiveness of a diagnostic radiopharmaceutical under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. Interested persons were given until August 5, 1998, to submit comments on the proposed rule. Due to the technical nature of the proposed rule, FDA has decided to extend the comment period until October 15, 1998, to allow interested persons additional time to submit comments on the proposed rule.

Interested persons may, on or before October 15, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20596 Filed 7–31–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 095–0083; FRL–6133–7]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, Ventura County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a limited approval and limited disapproval of revisions to the California State Implementation Plan (SIP) which concern the control of the sulfur content of fuels within the Ventura County Air Pollution Control District.

The intended effect of proposing limited approval and limited disapproval of this rule is to regulate emissions of sulfur dioxide (SO_2) in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). EPA's final action on this proposed rule will incorporate it into the federally approved SIP. EPA has evaluated the rule and is proposing a simultaneous limited approval and limited disapproval under provisions of the CAA regarding EPA action on SIP submittals and general rulemaking authority because these revisions, while strengthening the SIP, also do not fully meet the CAA provisions regarding plan submissions.

DATES: Comments must be received on or before September 2, 1998.

ADDRESSES: Comments may be mailed to: Andrew Steckel, Rulemaking Office [AIR–4], Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the rule and EPA's evaluation report of the rule is available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule are also available for inspection at the following locations:

Environmental Protection Agency, Air Docket, 401 ''M'' Street, SW., Washington, DC 20460.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812.

Ventura County Air Pollution Control District, 669 County Square Drive, Ventura, CA 93003.

FOR FURTHER INFORMATION CONTACT: Stanley Tong, Rulemaking Office, [AIR–4], Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901; Telephone: (415) 744–1191.

SUPPLEMENTARY INFORMATION:

I. Applicability

The rule being proposed for approval into the California SIP is Ventura County Air Pollution Control District (VCAPCD) Rule 64, Sulfur Content of Fuels. This rule was submitted by the California Air Resources Board (CARB) to EPA on July 13, 1994.

II. Background

40 CFR 81.305 provides the attainment status designations for air districts in California. Ventura County Air Pollution Control District is listed as being in attainment for the national ambient air quality standards for sulfur dioxide (SO_2). Sulfur dioxide is formed by the combustion of fuels containing sulfur compounds.

VCAPCD adopted Rule 64, Sulfur Content of Fuels, on June 14, 1994. On July 13, 1994 the State of California submitted many rules for incorporation into its SIP, including the rule being acted on in this document. VCAPCD Rule 64 was found to be complete on September 12, 1994 pursuant to EPA's completeness criteria that are set forth in 40 CFR part 51, appendix V [1] and is being proposed for limited approval and limited disapproval. The following is EPA's evaluation and proposed action for this rule.

III. EPA Evaluation and Proposed Action

In determining the approvability of an SO_2 rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans).

While the VCAPCD is in attainment with the SO_2 NAAQS, many of the

[1] EPA adopted completeness criteria on February 16, 1990 (55 FR 5824) and, pursuant to section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).