

additional costs to state, local, or tribal governments, or to the private section, will result from this action.

Under 5 U.S.C. 801(a) (1) (A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 52

Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, and Sulfur dioxide.

Note: Incorporation by reference of the State Implementation Plan was approved by the Director of the Federal Register on July 1, 1982.

Dated: August 9, 1996.

Felicia Marcus,

Regional Administration.

Subpart F of Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Subpart F—California

Authority: 42 U.S.C. 7401–7671q.

1. Section 52.220 is amended by adding paragraphs (c)(179)(i)(E) and (c)(193)(i)(D) to read as follows:

§ 52.220 Identification of Plan.

* * * * *

- (c) * * *
- (179) * * *
- (i) * * *

(E) Siskiyou County Air Pollution Control District.

(I) Rules 1.2 (except section V1), 1.4, 2.1, 2.2, 2.10, 4.1, 4.6, 6.1, and Appendix A, adopted on January 24, 1989.

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- (193) * * *
- (i) * * *

(D) Glenn County Air Pollution Control District.

(I) Section 51, adopted on March 16, 1993.

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[FR Doc. 96–28195 Filed 11–1–96; 8:45 am]

BILLING CODE 6560–50–M

40 CFR Part 70

[AD–FRL–5643–5]

Withdrawal of Direct Final Rule for Interim Approval of Operating Permits Program; South Coast Air Quality Management District, California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to an adverse comment, EPA is withdrawing the direct final rule for the interim approval of the South Coast Air Quality Management District title V operating permits program. EPA published the direct final rule on August 29, 1996, 61 FR 45330. As stated in that Federal Register document, if adverse or critical comments were received by September 30, 1996, the effective date would be delayed and notice would be published in the Federal Register. EPA subsequently received adverse comments on that direct final rule. EPA will address the comments received in a subsequent final action in the near future. EPA will not institute a second comment period on this document.

EFFECTIVE DATE: Withdrawal of the direct final rule becomes effective on November 4, 1996.

FOR FURTHER INFORMATION CONTACT: Ginger Vagenas, Operating Permits Section (A–5–2), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1252.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final rule located in the final rules section of the August 29, 1996 Federal Register, and in the short informational document located in the proposed rule section of the August 29, 1996 Federal Register.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: October 21, 1996.

Felicia Marcus,

Regional Administrator.

Therefore, the amendment to 40 CFR part 70, appendix A which added paragraph (dd) to the California entry is withdrawn.

[FR Doc. 96–28245 Filed 11–1–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 266

Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities

CFR Correction

In Title 40 of the Code of Federal Regulations, parts 260 to 299, revised as of July 1, 1996, § 266.100 is corrected by adding paragraphs (c)(3)(i)(B)–(D) as follows:

§ 266.100 Applicability.

* * * * *

- (c) * * *
- (3) * * *
- (i) * * *
- (A) * * *

(B) The waste does not exhibit the Toxicity Characteristic of § 261.24 of this chapter for an organic constituent; and

(C) The waste is not a hazardous waste listed in subpart D of part 261 of this chapter because it is listed for an organic constituent as identified in appendix VII of part 261 of this chapter; and

(D) The owner or operator certifies in the one-time notice that hazardous waste is burned under the provisions of paragraph (c)(3) of this section and that sampling and analysis will be conducted or other information will be obtained as necessary to ensure continued compliance with these requirements. Sampling and analysis shall be conducted according to paragraph (c)(1)(ii) of this section and records to document compliance with paragraph (c)(3) of this section shall be kept for at least three years.

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BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 50

Policies of General Applicability

CFR Correction

In title 42 of the Code of Federal Regulations, parts 1 to 399, revised as of October 1, 1995, page 171, §§ 50.604 through 50.606 are added as follows:

§ 50.604 Institutional responsibility regarding conflicting interests of investigators.

Each Institution must:

(a) Maintain an appropriate written, enforced policy on conflict of interest

that complies with this subpart and inform each Investigator of that policy, the Investigator's reporting responsibilities, and of these regulations. If the Institution carries out the PHS-funded research through subgrantees, contractors, or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with this subpart, either by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with this subpart.

(b) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

(c)(1) Require that by the time an application is submitted to PHS each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):

(i) That would reasonably appear to be affected by the research for which PHS funding is sought; and

(ii) In entities whose financial interests would reasonably appear to be affected by the research.

(2) All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with this subpart for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application for the funding to which this subpart applies, that:

(1) There is an effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS,

(2) Prior to the Institution's expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the institution and assure that the interest has been managed, reduced or eliminated in accordance with this subpart; and, for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification;

(3) The Institution agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias; and

(4) The Institution will otherwise comply with this subpart.

§ 50.605 Management of conflicting interests.

(a) The designated official(s) must: Review all financial disclosures; and determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

(1) Public disclosure of significant financial interests;

(2) Monitoring of research by independent reviewers;

(3) Modification of the research plan;

(4) Disqualification from participation in all or a portion of the research funded by the PHS;

(5) Divestiture of significant financial interests; or

(6) Severance of relationships that create actual or potential conflicts.

(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an Institution may require the management of other conflicting financial interests, as the Institution deems appropriate.

§ 50.606 Remedies.

(a) If the failure of an Investigator to comply with the conflict of interest

policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that suspension of funding under 45 CFR 74.62 is necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this subpart, the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 14

[CGD 94-004]

RIN 2115-AE72

Electronic Records of Shipping Articles and Certificates of Discharge

AGENCY: Coast Guard, DOT.

ACTION: Final rule.