

50. Section 640.22 is amended by revising paragraph (c) to read as follows:

§ 640.22 Collection of source material.

* * * * *

(c) If plateletpheresis is used, the procedure for collection shall be as described in a biologics license application or a supplement to a biologics license application, and must have the written approval of the Director, Center for Biologics Evaluation and Research, Food and Drug Administration.

* * * * *

51. Section 640.64 is amended by revising the second sentence of the introductory text of paragraph (c) to read as follows:

§ 640.64 Collection of blood for Source Plasma.

* * * * *

(c) * * * One of the following formulas shall be used in the indicated volumes, except that a different formula may be used for plasma for manufacture into noninjectable products if prior written approval is obtained from the Director of the Center for Biologics Evaluation and Research at the time of licensing or in the form of a supplement to the biologics license application for Source Plasma.

* * * * *

52. Section 640.65 is amended by revising the last sentence of paragraph (a) to read as follows:

§ 640.65 Plasmapheresis.

(a) * * * This procedure shall be described in detail in the biologics license application.

* * * * *

53. Section 640.71 is amended by revising the introductory text of paragraphs (a) and (b) and by revising paragraph (b)(1) to read as follows:

§ 640.71 Manufacturing responsibility.

(a) All steps in the manufacture of Source Plasma, including donor examination, blood collection, plasmapheresis, laboratory testing, labeling, storage, and issuing shall be performed by personnel of the licensed manufacturer of the Source Plasma, except that the following tests may be performed by personnel of a manufacturer licensed for blood or blood derivatives under section 351(a) of the Public Health Service Act, or by a clinical laboratory that meets the standards of the Clinical Laboratories Improvement Act of 1967 (CLIA) (42 U.S.C. 263a): *Provided*, The establishment or the clinical laboratory

is qualified to perform the assigned test(s).

* * * * *

(b) Such testing shall not be considered divided manufacturing, which requires two biologics licenses for Source Plasma: *Provided*, That

(1) The results of such tests are maintained by the licensed manufacturer of the Source Plasma whereby such results may be reviewed by a licensed physician as required in § 640.65(b)(2) and by an authorized representative of the Food and Drug Administration.

* * * * *

54. Section 640.74 is amended by revising paragraph (a) and the last sentence of paragraph (b)(2) to read as follows:

§ 640.74 Modification of Source Plasma.

(a) Upon approval by the Director, Center for Biologics Evaluation and Research, Food and Drug Administration, of a supplement to the biologics license application for Source Plasma, a manufacturer may prepare Source Plasma as a liquid product for a licensed blood derivative manufacturer who has indicated a need for a liquid product.

(b) * * *

(2) * * * Such evidence may be submitted by either the licensed manufacturer of the Source Plasma Liquid or the manufacturer of the final blood derivative product who has requested the Source Plasma Liquid.

* * * * *

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

55. The authority citation for 21 CFR part 660 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

56. Section 660.21 is amended by revising paragraphs (a)(3) and (d) to read as follows:

§ 660.21 Processing.

(a) * * *

(3) A lot may be subdivided into clean, sterile vessels. Each subdivision shall constitute a subplot. If lots are to be subdivided, the manufacturer shall include this information in the biologics license application. The manufacturer shall describe the test specifications to verify that each subplot is identical to other sublots of the lot.

* * * * *

(d) *Volume of final product.* Each manufacturer shall identify the possible

final container volumes in the biologics license application.

* * * * *

57. Section 660.30 is amended by revising paragraph (b) to read as follows:

§ 660.30 Reagent Red Blood Cells.

* * * * *

(b) *Source.* Reagent Red Blood Cells shall be prepared from human peripheral blood meeting the criteria of §§ 660.31 and 660.32, or from umbilical cord cells which shall be collected and prepared according to the manufacturer's biologics license application.

58. Section 660.33 is amended by revising the fifth sentence to read as follows:

§ 660.33 Testing of source material.

* * * Where fewer than three donor sources of an antibody specificity are available, test discrepancies shall be resolved in accordance with the manufacturer's biologics license application. * * *

Dated: July 22, 1998.

Michael A. Friedman,

Acting Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 98-20427 Filed 7-30-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 707 and 874

RIN 1029-AB89

Abandoned Mine Land (AML) Reclamation Program; Enhancing AML Reclamation

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule, reopening and extension of comment period.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is reopening and extending the comment period for the proposed rule, Enhancing AML Reclamation, published on June 25, 1998 (63 FR 34768). The comment period closed on July 27, 1998, and is being reopened and extended for 15 days.

DATES: *Written comments:* We will accept written comments on the proposed rule until 5 p.m., Eastern time, on August 11, 1998.

ADDRESSES: If you wish to comment, you may mail or hand deliver comments

to the Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 101, 1951 Constitution Avenue, NW, Washington, DC 20240. You may also comment via the Internet to OSM's Administrative Record at: osmrules@osmre.gov.

FOR FURTHER INFORMATION CONTACT: D. J. Growitz, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 1951 Constitution Avenue, NW, Washington, DC 20240; Telephone: 202-208-2634. E-Mail: dgrowitz@osmre.gov.

SUPPLEMENTARY INFORMATION: In response to a telephone request from a member of the public, OSM is reopening and extending the public comment period on the proposed rule, Enhancing AML Reclamation, published in the **Federal Register** on June 25, 1998 (63 FR 34768).

OSM is proposing revisions to its rules regarding the financing of Abandoned Mine Land reclamation (AML) projects that involve the incidental extraction of coal. Projections of receipts to the AML fund through the year 2004, when the authority to collect fees will expire, strongly indicate that there will be insufficient money to address all problems currently listed in the Abandoned Mine Land Inventory System. Given these limited AML reclamation resources, OSM is seeking an innovative way for AML agencies, working with contractors, to maximize available funds to increase AML reclamation.

The first revision would amend the definition of *government-financed construction* to allow less than 50 percent government funding when the construction is an approved AML project under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The existing definition requires a minimum government contribution of 50 percent to exempt government-financed construction from regulation under SMCRA.

The second revision would add a new section which would require specific consultations and concurrences with the Title V regulatory authority for AML construction projects receiving less than 50 percent government financing. These consultations and concurrences are intended to ensure the appropriateness of the project being undertaken as a Title IV AML project and not under the Title V regulatory program.

Dated: July 28, 1998.

Richard G. Bryson,

Acting Assistant Director, Program Support.
[FR Doc. 98-20505 Filed 7-30-98; 8:45 am]

BILLING CODE 4310-05-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA-071-0069b; FRL-6129-6]

Approval and Promulgation of State Implementation Plans; California State Implementation Plan Revision, Mendocino County Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the California State Implementation Plan (SIP). This action is an administrative change which revises two definitions and adds one definition in Mendocino County Air Quality Management District (MCAQMD) Rule 130, Definitions.

The intended effect of proposing approval of this rule is to incorporate changes to the definitions for clarity and consistency with revised federal and state definitions. EPA is proposing approval of this revision to be incorporated into the California SIP for the attainment and maintenance of the national ambient air quality standards (NAAQS) under title I of the Clean Air Act, as amended in 1990 (CAA or the Act). In the Final Rules Section of this **Federal Register**, the 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 this approval is set forth in the direct final rule. If no relevant adverse comments are received in response to the direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives relevant adverse comments, the direct final rule will not take effect 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. Any parties interested in commenting should do so at this time.

DATES: Comments must be received in writing by August 31, 1998.

ADDRESSES: Written comments on this action should be addressed to: Andrew Steckel, Rulemaking Office (AIR-4), Air Division, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105-3901.

Copies of the rule revisions and EPA's evaluation report of each rule are available for public inspection at EPA's Region 9 office during normal business

hours. Copies of the submitted rule revisions are also available for inspection at the following locations: Environmental Protection Agency, Air Docket (6102), 401 "M" Street, S.W., Washington, D.C. 20460
California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 "L" Street, Sacramento, CA 95812
Mendocino County Air Quality Management District, 306 East Gobbi Street, Ukiah, California 95482

FOR FURTHER INFORMATION CONTACT: Cynthia G. Allen, Rulemaking Office (AIR-4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901, Telephone: (415) 744-1189.

SUPPLEMENTARY INFORMATION: This document concerns Mendocino County Air Quality Management District Rule 130, Definitions, submitted to EPA on November 18, 1993 by the California Air Resources Board. For further information, please see the information provided in the Direct Final action that is located in the Rules Section of this **Federal Register**.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: July 8, 1998.

Felicia Marcus,

Regional Administrator, Region IX.

[FR Doc. 98-20509 Filed 7-30-98; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 98-133, RM-9314]

Radio Broadcasting Services; Zapata, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Arturo Lopez and Eleazar Trevino, proposing the allotment of Channel 274A to Zapata, Texas. The channel can be allotted to Zapata without a site restriction at coordinates 26-54-30 and 99-16-18. Concurrence of the Mexican government will be requested for this allotment.

DATES: Comments must be filed on or before September 14, 1998, and reply comments on or before September 29, 1998.

ADDRESSES: Federal Communications Commission, Washington, DC. 20554. In