DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 870 and 890

[Docket No. 98N–0009]

Medical Devices; Revocation of Exemptions from Premarket Notification for Certain Cardiovascular and Physical Medicine Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal in part.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing in part its proposed rule that published in the **Federal Register** of November 12, 1998 (63 FR 63222), to revoke the exemptions from the requirement of premarket notification of a cardiovascular device (cardiopulmonary bypass accessory equipment) and a physical medicine device (electrode cable). Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule to exempt other devices from the requirement of premarket notification.

DATES: The proposed rule that published at 63 FR 63222, November 12, 1998, is withdrawn in part for §§ 870.4200 and 890.1175 as of January 14, 2000.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION: On November 21, 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (FDAMA) into law (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(l) to the Federal Food, Drug, and Cosmetic Act (the act). Under section 206 of FDAMA, new section 510(l) of the act became effective on February 19, 1998. New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. FDA refers to devices that FDA believes meet these criteria as ''reserved.'' FDA has evaluated all class I devices to determine which device types should be subject to premarket notification requirements.

In the **Federal Register** of February 2, 1998 (63 FR 5387), FDA published a list of devices it considered reserved and that require premarket notification and a list of devices it believed met the exemption criteria in FDAMA. FDA invited comments on the February 2, 1998, notice.

FDA had proposed two rules that relate to the classification and premarket notification status of cardiopulmonary bypass accessory equipment (21 CFR 870.4200) and electrode cables (21 CFR 890.1175). In the November 12, 1998, proposed rule after reviewing the comments submitted on the February 2, 1998, notice, FDA proposed to designate which devices require premarket notification, and which are exempt, subject to limitations, under notice and comment rulemaking proceedings under new section 510(l) of the act. At that time, FDA also proposed to revoke existing exemptions for certain devices from premarket notification, including those for cardiopulmonary bypass accessory equipment and the electrode cable.

In the **Federal Register** of August 9, 1999 (64 FR 43114), FDA published a proposed rule to reclassify three devices into class II in order to make them subject to the performance standard for electrode lead wires and patient cables, including cardiopulmonary bypass accessory equipment that involves an electrical connection to the patient and the electrode cable. Because FDA believes that compliance with the performance standard for electrode lead wires and patient cables will provide adequate assurance of the safety and effectiveness of these devices, the proposal provides that these devices would be exempt from the premarket notification requirements.

Under the August 9, 1999, proposed rule, cardiopulmonary bypass accessory equipment that does not involve an electrical connection to the patient would remain in class I and would be exempt from the premarket notification requirements. FDA expects to finalize the August 9, 1999, proposed rule in the very near future. If the rule is finalized, the devices will be exempt from the premarket notification requirements and all such devices will be subject to the performance standard for electrode lead wires and patient cables, when the rule becomes effective for those devices on May 9, 2000.

If FDA were to finalize the November 12, 1998, proposed rule to revoke the existing premarket notification exemptions for cardiopulmonary bypass accessory equipment and the electrode cable, the manufacturers of these devices would have to comply with the premarket notification requirements only during the interim period until the proposed rule to make these devices class II exempt is finalized. FDA believes that there is no reason to require premarket notification for these devices during the short interval between these two final rules. Therefore, FDA is withdrawing in part its proposed rule to revoke the exemption from the premarket notification requirements for the cardiopulmonary bypass accessory equipment and the electrode cable.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the proposed rule published on November 12, 1998 (63 FR 63222) is withdrawn in part for §§ 870.4200 and 890.1175.

Dated: December 22, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–885 Filed 1–13–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 944

[SPATS No. UT–038–FOR]

Utah Regulatory Program

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

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of a proposed amendment to the Utah regulatory program (the ''Utah program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Utah's amendment proposes to change the State's rules pertaining to: Definitions of ''abandoned site,'' ''other treatment facilities,'' ''previously mined area,'' ''qualified laboratory,'' and ''significant recreational, timber, economic, or other values incompatible with coal mining and reclamation operations;'' engineering requirements for impoundments and for backfilling and grading; hydrologic requirements for impoundments; requirements for bond release applications; prime farmland acreage; inspection frequency for abandoned sites; and the period in which to pay a penalty when requesting

a formal hearing. Utah wants to revise its program to make it consistent with the corresponding Federal regulations.

DATES: Will accept written comments on this amendment until 4:00 p.m. mountain standard time on February 14, 2000. If requested, will hold a public hearing on the amendment on Tuesday February 8, 2000. Will also accept requests to speak at the hearing until 4:00 p.m. mountain standard time on January 31, 2000.

ADDRESSES: You should mail or hand deliver written comments and requests to speak at the hearing to James F. Fulton, Denver Field Division Chief, at the address listed below.

You may review copies of the Utah program, this amendment, a listing of any scheduled public hearings, and all written comments we received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Denver Field Division.

James F. Fulton, Chief, Denver Field Division, Western Regional Coordinating Center, Office of Surface Mining, 1999 Broadway, suite 3320, Denver, Colorado, 80202–5733, telephone (303) 844–1400, extension 1424.

Lowell P. Braxton, Director, Division of Oil, Gas and Mining, 1594 West North Temple, Suite 1210, P.O. Box 145801, Salt Lake City, Utah, 84114–5801 telephone (801) 538–5370.

FOR FURTHER INFORMATION CONTACT: James F. Fulton, Denver Field Division Chief; telephone: (303) 844–1400, extension 1424; e-mail: jfulton@osmre.gov.

SUPPLEMENTARY INFORMATION:

1. Background on the Utah Program

On January 21, 1981, the Secretary of the Interior conditionally approved the Utah program. You can find background information about Utah's program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Utah program can be found in the January 21, 1981, **Federal Register** (46 FR 5899). You can also find later actions concerning Utah's program and program amendments can be found at 30 CFR 944.15 and 944.30.

II. What Utah Proposes In This Amendment

By letter dated December 23, 1999, Utah sent to us an amendment (UT–038–FOR, administrative record No. UT–1133) to its program under SMCRA (30 U.S.C. 1201 *et seq.*). The State sent the amendment in response to a June 19, 1997, letter (administrative record No. UT–1093) that we sent to Utah in accordance with 30 CFR 732.17(c). The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES.** Changes to the Utah Administrative Rule (Utah Admin. R.) that the State proposes to make are summarized below.

A. Changes to Definitions at Utah Admin. R.645–100–200

1. *''Abandoned site'':* Utah proposes to revise its definition of this term by changing the conditions sites must meet to be considered abandoned and allowing the Division of Oil, Gas and Mining (the Division) to decide if it wants to inspect abandoned sites less than 12 times a year. The proposed changes also require the division to make written findings on specific topics to justify a decision to set an alternative inspection frequency;

2. ''*Other treatment facilities*'': The State proposes to change this definition to include neutralization and precipitators. Utah also proposes to include in this definition those facilities used to prevent additional contributions of dissolved solids to streamflow or runoff outside the permit area or to comply with all applicable State and Federal water quality laws and regulations;

3. ''*Previously mined area*'': Utah proposes to change its definition of this term to mean land affected by coal mining and reclamation operations prior to August 3, 1977, that has not been reclaimed to the standards of Utah Admin. R.645 or 30 CFR Chapter VII;

4. ''*Qualified laboratory*'': The State proposes to change this definition to include those facilities that can provide other services specified at Utah Admin. R.645–302–299;

5. ''*Significant recreational, timber, economic, or other values incompatible with coal mining operations*'': Utah proposes to change its definition of this term by removing the qualifying statement that damage to these values caused by mining must be beyond an operator's ability to repair or restore in order for these values' significance to be evaluated;

B. Changes to Engineering Requirements for Impoundments

1. At Utah Admin. R.645–301–514.320 and –514.330, Utah proposes to change its description of inspection requirements for impoundments that meet, and those that don't meet, the Class B or C criteria of the Natural Resources Conservation Service's (NRCS) Technical Release 60 (TR–60) or the size or other criteria of 30 CFR 77.216;

2. At Utah Admin. R.645–301–531, the State proposes to require permit applications to certain detailed design plans for siltation structures, water impoundments, and coal processing waste banks, dams, or embankments located inside the permit area;

3. At Utah Admin. R.645–301–533.100 and –533.110, Utah proposes to include references to provisions of TR–60 in its descriptions of safety factors required for different sizes and types of impoundments;

4. At Utah Admin. R.645–301–533.200 and –533.210, the State proposes to include references to provisions of TR–60 for, and expand its description of, foundation safety factors and stability, investigation, and testing requirements for different sizes and types of impoundments;

5. At Utah Admin. R.645–301–533.610, Utah proposes to include TR–60 in its rules by reference and to require impoundments meeting the Class B or C criteria of TR–60 or the size or other criteria of 30 CFR 77.216 to comply with this section of its rules. Further, at Utah Admin. R.645–301–533.610 through –533.714, Utah proposes to change its description of the information to be included in detailed design plans for various types and sizes of impoundments;

C. Changes to Engineering Requirements for Backfilling and Grading

1. At Utah Admin. R.645–533.700 and –553.800, the State proposes to revise its definitions of ''thin overburden'' and ''thick overburden'', respectively, for the purposes of surface coal mining and reclamation activities;

D. Changes to Hydrologic Requirements for Impoundments

1. At Utah Admin. R.645–301–733.100, Utah proposes to require permit applications to contain detailed design plans for water impoundments located inside the permit area;

2. At Utah Admin. R.645–301–733.210, the State proposes to allow the Division to develop design standards for impoundments not included in Utah Admin. R.645–301–533.610 (discussed previously under Part II.B.5 of this document), that ensure stability comparable to a minimum static safety factor of 1.3 in lieu of requiring engineering tests to ensure that level of safety;

3. At Utah Admin. R.645–301–742.200, Utah proposes to require siltation structures to comply with the

design criteria for sediment control measures in Utah Admin. R.645–301–742;

4. At Utah Admin. R.645–301–742.224, the State proposes to allow construction of temporary impoundments as sedimentation ponds that will contain and control all runoff from a design precipitation without using spillways, as long as they meet certain conditions;

5. At Utah Admin. R.645–301–742.225.1, for impoundments that meet the NRCS Class B or C criteria for dams in TR–60 or the size of other criteria of 30 CFR 77.216(a), Utah proposes to require them to be designed to control the probable maximum precipitation of a 6-hour event, or a greater event if specified by the Division;

6. At Utah Admin. R.645–301–742.225.2, for impoundments that don't fall under subsection –742–225.1 (described above in Part II. D.5 of this document), Utah proposes to require them to be designed to control the precipitation of the 100-year, 6-hour event, or a greater event if specified by the Division;

7. At Utah Admin. R.645–301–743.100, the State proposes to require impoundments that meet the NRCS Class B or C criteria for dams of TR–60 to comply with this section of Utah's rules and the table in TR–60 entitled, ''Minimum Emergency Spillway Hydrologic Criteria;''

8. At Utah Admin. R.645–301–743.120, Utah proposes to require impoundments that meet the NRCS Class B or C criteria for dams of TR–60 to comply with the freeboard hydrograph criteria in the TR–60 table entitled, '' Minimum Emergency Spillway Hydrologic Criteria'';

9. At Utah Admin. R.645–301–743.131.3 through –743.131.6, the State proposes spillway design precipitation events for temporary and permanent impoundments of different types and size that meet the spillway requirements of Utah Admin. R.645–301–743.130;

E. Adding Requirements for Bond Release Applications at Utah Admin. R.645–301–880.130

This proposed rule will require permittees to include in a bond release application a notarized statement certifying that all applicable reclamation activities have been completed as required by the Utah Code Annotated Section 40–10–1 *et seq.,* the regulatory program, and the approved reclamation plan. Also, each application for each phase of bond release must include this certification;

F. Adding Requirements for Prime Farmland Acreage at Utah Admin. R.645–302–316.500

This proposed rule doesn't allow a decrease in the aggregate total acreage of prime farmland after reclamation from the acreage that existed before mining. It requires Division approval of water bodies built during mining and reclamation along with the consent of all affected property owners in the permit area. Also, the proposed rule requires water bodies to be located in parts of the permit area that won't be reclaimed to prime farmland;

G. Adding an Alternative Inspection Frequency for Abandoned Sites at Utah Admin. R.645–400–132

Utah proposes to allow the Division to inspect abandoned sites on a frequency that it sets using procedures proposed under the definition of ''abandoned site'' at Utah Admin. R.645–100–200. The State's proposed definition changes are described in Part II.A of this document; and

H. Changing the Time in Which To Pay a Penalty When Requesting a Formal Hearing at Utah Admin. R.645–401–800

The State proposes to extend to 30 days the period in which a permittee, charged with a violation, must pay a reassessed or affirmed civil penalty to the Division when requesting a formal hearing. The 30-day period begins with the date of service of a conference officer's action.

III. How You Can Comment on This Amendment

Under the provisions of 30 CFR 732.17(h), we are requesting your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the Utah regulatory program.

Send Written Comments to Us

Send your written comments to us at the location shown under **ADDRESSES**. We'll make the comments, and the names and addresses of people who send us comments, available for public review during normal business hours. If you, as an individual, comment on the amendment and want us to keep your name and/or address confidential, you must state this prominently at the beginning of your comments. We'll honor your request to the extent allowed by law. However, we won't consider anonymous comments. Also, we'll make all submissions from organizations or businesses, and from individuals who identify themselves as representatives or officials of organizations or businesses, available for public review in their entirety.

Please submit Internet comments to us as an ASCII file and don't use special characters and any form of encryption. Please also include ''Attn: SPATS No. UT–R038–FOR'' and your name and return address in your Internet message. If you don't receive a confirmation that we've received your Internet message, contact the Denver Field Division at (303) 844–1400, extension 1424.

Your written comments should be specific and pertain only to the issues proposed in this rulemaking. Please explain your reasons for any changes you recommend. In the final rulemaking, we won't necessarily consider or include in the Administrative Record any comments we received after the time indicated under **DATES** or at locations other than the Denver Field Division.

Speak at a Public Hearing

If you want to speak at a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., mountain standard time on January 31, 2000. If you're disabled and need special accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We'll arrange when and where to hold a hearing with those persons who request the hearing. If no one asks for an opportunity to speak at a public hearing, we won't hold one.

To help the transcriber and ensure an accurate record, we ask, if possible, that each person who speaks at a public hearing give us a written copy of his or her testimony. The public hearing will continue on the specified date until everyone scheduled to speak and want to, you'll be allowed to after those who have been scheduled. We'll end the hearing after everyone scheduled to speak and others who want to speak have been heard.

Attend a Public Meeting

If only one person requests an opportunity to speak at a hearing, we might hold a public meeting instead. If you want to meet with us to discuss the amendment, ask for a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public. If possible, we'll post meeting notices at the locations listed under **ADDRESSES**. We'll make a written summary of each meeting part of the administrative record.

IV. Procedural Determinations

1. Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

2. Executive Order 12988

The Department of the Interior conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards don't apply to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementation Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

3. National Environmental Policy Act

This rule doesn't require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions aren't major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

4. Paperwork Reduction Act

This rule doesn't contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

5. Regulatory Flexibility Act

The Department of the Interior determined that this rule won't have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal that is the subject of this rule is based on counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect on a substantial number of small entities. Therefore, this rule will ensure that the State will implement existing requirements that OSM previously published. In determining whether this rule would have a significant economic impact, the Department relied on the data and assumptions for the corresponding Federal regulations.

6. Unfunded Mandates

OSM has determined and certifies under the Unfunded Mandates Reform Act (2 U.S.C. 1502 *et seq.*) that this rule won't impose a cost of $100 million or more in any given year on local, state, or tribal governments or private entities.

List of Subjects in 30 CFR Part 944

Intergovernmental relations, Surface mining, Underground mining.

Dated: January 6, 2000.

Brent Wahlquest,

Regional Director, Western Regional Coordinating Center.

[FR Doc. 00–970 Filed 1–13–00; 8:45 am]

BILLING CODE 4310–05–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD090–3041; FRL–6507–1]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Control of VOCs From Paper, Fabric, Vinyl, and Other Plastic Parts Coating

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revisions submitted by the State of Maryland for the purpose of amending its regulation to control volatile organic compounds (VOC) from Paper, Fabric, Vinyl, and Other Plastic Parts Coating. The regulation was revised to include Reasonable Available Control Technology (RACT) standards for sources that use flexographic printing presses to print on plastic (non-vinyl) and to limit the VOC content of the decorative coating of plastic bottles. EPA is approving these revisions to the Maryland SIP in accordance with the requirements of the Clean Air Act. 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 them as noncontroversial SIP revisions and anticipates no adverse comments. The rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated in relation to this 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 action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by February 14, 2000.

ADDRESSES: Written comments on this action should be addressed to David L. Arnold, Chief, Ozone and Mobile Sources Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103 and the Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland, 21224.

FOR FURTHER INFORMATION CONTACT: Janice M. Lewis, (215) 814–2185, at the EPA Region III office address listed above, or via e-mail at lewis.janice@epa.gov.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

Thomas C. Voltaggio,

Acting Regional Administrator, Region III.

[FR Doc. 00–617 Filed 1–13–00; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 51

[CC Docket No. 96–98; FCC 99–238]

Revision of the Commission's Rules Specifying the Portions of the Nation's Local Telephone Networks that Incumbent Local Telephone Companies Must Make Available to Competitors

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document seeks comment from interested parties on issues surrounding the ability of competitive carriers to use combinations of unbundled network elements as a