

or assisted reproduction catheters, to aspirate, incubate, infuse, and/or maintain temperature. This generic type of device may include:

(1) Powered aspiration pumps, used to provide low flow, intermittent vacuum for the aspiration of eggs (ova).

(2) Syringe pumps (powered or manual), used to activate a syringe to infuse or aspirate small volumes of fluid during assisted reproduction procedures.

(3) Collection tube warmers, used to maintain the temperature of egg (oocyte) collection tubes at or near body temperature. A dish/plate/microscope stage warmer is a device used to maintain the temperature of the egg (oocyte) during manipulation.

(4) Embryo incubators, used to store and preserve gametes and/or embryos at or near body temperature.

(5) Cryopreservation instrumentation and devices, used to contain, freeze and maintain gametes and/or embryos at an appropriate freezing temperature.

(b) *Classification.* Class II (special controls) (premarket notification guidance and voluntary standards).

§ 884.6400 Assisted reproduction microtools.

(a) *Identification.* Assisted reproduction microtools are pipettes or other devices used in the laboratory to denude, micromanipulate, hold or transfer human gametes or embryos for assisted hatching, intracytoplasmic sperm injection (ICSI), embryo biopsy or other assisted reproduction methods, including preimplantation diagnosis.

(b) *Classification.* Class II (special controls) (premarket notification guidance and voluntary standards).

§ 884.6500 Assisted reproduction micropipette fabrication instruments.

(a) *Identification.* Assisted reproduction micropipette fabrication devices are instruments intended to pull, bevel, or forge a micropipette or needle for intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF), or other similar procedures.

(b) *Classification.* Class II (special controls) (premarket notification guidance and voluntary standards).

§ 884.6600 Assisted reproduction micromanipulators and microinjectors.

(a) *Identification.* Assisted reproduction micromanipulators are devices intended to control the position of an assisted reproduction microtool. Assisted reproduction microinjectors are any device intended to control aspiration or expulsion of the contents of an assisted reproduction microtool.

(b) *Classification.* Class II (special controls).

§ 884.6700 Assisted reproduction labware.

(a) *Identification.* Assisted reproduction labware consists of laboratory equipment or supplies intended to prepare, store, manipulate, or transfer human gametes or embryos for in vitro fertilization (IVF) or other assisted reproduction techniques. These include syringes, IVF tissue culture dishes, IVF tissue culture plates, pipette tips, dishes, plates, and other vessels that come into physical contact with gametes, embryos or tissue culture media.

(b) *Classification.* Class II (special controls).

§ 884.6800 Assisted reproduction water and water purification systems.

(a) *Identification.* Assisted reproduction water purification systems are devices specifically intended to generate high quality sterile, pyrogen-free, distilled, deionized water for reconstitution of media used for aspiration, incubation, transfer or storage of gametes or embryos for in vitro fertilization (IVF) or other assisted reproduction procedures. It may also be intended as the final rinse for labware or other assisted reproduction devices that will contact the gametes or embryos. This also includes bottled water ready for reconstitution available from a vendor that is specifically intended for reconstitution of media used for aspiration, incubation, transfer or storage of gametes or embryos for IVF or other assisted reproduction procedures.

(b) *Classification.* Class II (special controls).

§ 884.6900 Reproductive media and supplements.

(a) *Identification.* Reproductive media and supplements are products that are used for assisted reproduction procedures. Media include liquid and powder versions of various substances that come in direct physical contact with human gametes or embryos (including water, or oil used to cover the media) for the purposes of preparation, maintenance, transfer or storage, and supplements are specific reagents added to media to enhance specific properties of the media (e.g., proteins, sera, antibiotics, etc.).

(b) *Classification.* Class II (special controls) (premarket notification guidance and voluntary standards).

§ 884.7000 Assisted reproductive microscopes and microscope accessories.

(a) *Identification.* Assisted reproduction microscopes and microscope accessories (excluding microscope stage warmers, which are

classified under Assisted Reproduction Accessories) are optical instruments used to enlarge images of gametes or embryos. Variations of microscopes and accessories used for these purposes would include phase contrast microscopes, fluorescence microscopes, dissecting microscopes, and inverted stage microscopes.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

Dated: August 26, 1997.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 97-23449 Filed 9-2-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 934

[ND-032-FOR; Amendment No. XXII]

North Dakota Regulatory Program

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

ACTION: Proposed rule; reopening and extension of public comment period on proposed amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of a revision to a previously proposed amendment to the North Dakota regulatory program (hereinafter, the "North Dakota program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The revision for North Dakota's proposed rules pertain to individual civil penalties. The amendment is intended to revise the North Dakota program to be consistent with the corresponding Federal regulations.

DATES: Written comments must be received by 4:00 p.m., m.d.t., September 19, 1997.

ADDRESSES: Written comments should be mailed or hand delivered to Guy Padgett at the address listed below.

Copies of the North Dakota program, the proposed revision to the proposed amendment, the proposed amendment, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed

amendment by contacting OSM's Casper Field Office.

Guy Padgett, Director, Casper Field Office, Office of Surface Mining Reclamation and Enforcement, 100 East "B" Street, Room 2128, Casper, Wyoming 82601-1918, Telephone: (307) 261-6550, Internet: gpadgett@osmre.gov

James R. Deutsch, Director, Reclamation Division, Public Service Commission, Bismarck, North Dakota 58505-0480, Telephone: (701) 328-2400

FOR FURTHER INFORMATION CONTACT:
Guy Padgett, Telephone: (307) 261-6550.

SUPPLEMENTARY INFORMATION:

I. Background on the North Dakota Program

On December 15, 1980, the Secretary of the Interior conditionally approved the North Dakota program. General background information on the North Dakota program, including the Secretary's findings, the disposition of comments, and conditions of approval of the North Dakota program can be found in the December 14, 1980, **Federal Register** (45 FR 82214). Subsequent actions concerning North Dakota's program and program amendments can be found at 30 CFR 934.15, 934.16, and 934.30.

II. Proposed Amendment

By letter dated April 12, 1995, North Dakota submitted a proposed amendment to its program (amendment No. XXII, administrative record No. ND-W-1) pursuant to SMCRA. (30 U.S.C. 1201 *et seq.*) North Dakota submitted the proposed amendment in response to the required program amendments at 30 CFR 934.16(y) and (z).

OSM announced receipt of the proposed amendment in the May 2, 1995 **Federal Register** (60 FR 21484), provided an opportunity for a public hearing or meeting on its substantive adequacy, and invited public comment on its adequacy (administrative record No. ND-W-04). Because no one requested a public hearing or meeting, none was held. The public comment period ended on June 1, 1995.

During its review of the proposed amendment, OSM identified concerns and notified North Dakota of the concerns by letter dated August 28, 1995 (administrative record No. ND-W-12). North Dakota responded in a letter dated October 19, 1995.

Subsequently, on July 30, 1997, OSM notified North Dakota by telephone of an additional concern (administrative record No. ND-W-17). In response, North Dakota proposed a revision to its

proposed coal exploration regulations at North Dakota Administrative Code (NDAC) 43-02-001 (administrative record No. ND-W-18).

Specifically, North Dakota proposes to further revise its proposed regulations at NDAC 43-02-01 dealing with individual civil penalties, from: "any director, officer, or agent of such corporation who willfully and knowingly authorized or carried out such violation * * *." (emphasis added); to: "any director, officer, or agent of such corporation who willfully or knowingly authorized or carried out such violation * * *." (emphasis added). The only change is that the word "and" would be replaced by the word "or." According to North Dakota, the intent of the resulting requirement in North Dakota's regulations at NDAC 43-02-01 is that it would then be consistent with the requirement in North Dakota's statute at NDCC 38-12.1-08, upon which the requirement in North Dakota's regulations is based.

III. Public Comment Procedures

OSM is reopening the comment period on the proposed program amendment to provide the public an opportunity to reconsider the adequacy of the proposed amendment in light of the additional material submitted. In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed revision to the proposed amendment satisfies the applicable program criteria of 30 CFR 732.15. If the revision and the amendment are deemed adequate, they will become part of the North Dakota program.

Written comments should be specific, pertain only to the issue proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Casper Field Office will not necessarily be considered in the final rulemaking or included in 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 has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that this rule meets the

applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such 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 submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

3. National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute 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 does not 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 has determined that this rule will not 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 upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

6. Unfunded Mandates

This rule will not impose a cost of \$100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 934

Intergovernmental relations, Surface mining, Underground mining.

Dated: August 27, 1997.

Russell F. Price,

Acting Regional Director, Western Regional Coordinating Center.

[FR Doc. 97-23423 Filed 9-3-97; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF TRANSPORTATION**Coast Guard****33 CFR Part 117**

[CGD08-97-004]

RIN 2115-AE47

Drawbridge Operation Regulation for the Minnesota River

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rule making.

SUMMARY: The Coast Guard proposes removing the 24 hour advance notice requirement from the regulation governing operation of drawbridges over the Minnesota River between the mouth and LeSueur, MN. This action is being taken to update the regulation to reflect existing conditions and to ensure the reasonable needs of navigation are met. The change will require drawbridges on that reach of the river to open on demand in accordance with the general drawbridge operating regulations under 33 CFR 117 Subpart A.

DATES: Comments must be received on or before November 3, 1997.

ADDRESSES: Comments may be mailed to Director, Western Rivers Operations (ob), Eighth Coast Guard District, 1222 Spruce Street, St. Louis, MO 63103-2832, Attention: Bridge Administrator. Comments may also be delivered to Room 2.107f at the above address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (314) 539-3900, extension 378.

The Bridge Branch, Director Western Rivers Operations, maintains the public docket for this rulemaking. Comments will become part of the public docket and the docket will be available for inspection or copying in room 2.107f at the above address.

FOR FURTHER INFORMATION CONTACT:

Roger K. Wiebusch, Bridge Administrator, Director Western Rivers Operations, 314-539-3900, extension 378.

SUPPLEMENTARY INFORMATION:**Request for Comments**

The Coast Guard encourage interested persons to participate in this rulemaking by submitting written data, views, or arguments. The Coast Guard is soliciting comments on the regulation change until November 3, 1997. The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Bridge Administrator at the address under **ADDRESSES**. The request should include the reasons why a hearing would be beneficial. If it determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at the time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The proposed change will ensure the regulation reflects favorable existing drawbridge operating practices. Coordination between the Coast Guard, waterway users and owners of the only affected drawbridge at Savage, MN, Mile 14.3 on the Minnesota River, have resulted in the bridge being operated in a manner that meets the needs of both navigation and the railroad. (All written correspondence regarding this coordination is available in the public docket). Operation of the Savage Drawbridge will revert to the existing general drawbridge regulations found in 33 CFR, 117 Subpart A, i.e. it will open on demand. Approval of this proposal will eliminate an obsolete and undesirable drawbridge regulation and ensure continued favorable drawbridge operation practices.

Discussion of Change

This proposed rule will remove the requirement in 33 CFR 117.663, paragraph (a), that currently requires river traffic to provide 24 hours advance notice for drawbridge operation. All bridges below (downstream of) LeSueur, MN will now operate under the general bridge requirements found in 33 CFR 117 Subpart A, i.e. will have to open upon demand. The only bridge that will be affected is the railroad drawbridge at Savage, MN. The proposed rule will maintain the existing language in the second paragraph of 33 CFR 117.663 stating that the draws of bridges above LeSueur, MN need not be opened for the passage of vessels.

Regulatory Evaluation

This rule is not a significant regulatory action under 3(f) of Executive Order 12866 and does not require an assessment of potential cost and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. The proposed rule affects one drawbridge and is not expected to significantly alter the day-to-day activities of any businesses.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this change, if adopted, will have a significant economic impact on a substantial number of small entities. "Small entities" may include (1) small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and (2) governmental jurisdictions with populations of less than 50,000. Because the proposed rule affects only one drawbridge and requires the bridge to open upon demand, the Coast Guard expects the impact of this change to be minimal. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this change, if adopted, will not have a significant economic impact on a substantial number of small entities. If, however, you think that your business or organization qualifies as a small entity and that this proposed rule will have a significant economic impact on your business or organization, please submit a comment (See **ADDRESSES**) explaining why you think it qualifies and in what way and to what degree this proposed rule will economically affect it.

Collection of Information

This proposed rule contains no collection of information requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that this change does not have sufficient federalism