

when finalized, will answer frequently asked questions relating to the requirements of the Accredited Third-Party Certification Program established in 21 CFR part 1, subpart M (21 CFR 1.600 through 1.695, 21 CFR 1.700 through 1.725), and is intended to assist the accreditation bodies', third-party certification bodies', and eligible entities' understanding of the TPP regulation and program requirements.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information under the TPP regulation in 21 CFR part 1, subpart M have been approved under OMB control number 0910–0750.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: April 25, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–09232 Filed 4–28–22; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 913

[SATS No. IL–111–FOR; Docket ID: OSM–2022–0002; S1D1S SS08011000 SX064A000 222S180110; S2D2S SS08011000 SX064A000 22XS501520]

#### Illinois 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:** We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Illinois regulatory program (hereinafter, the

Illinois program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The amendment proposes the removal of revegetation success standards and statistically valid sampling techniques from inclusion in the approved regulatory program as allowed by the 2006 *Topsoil Redistribution and Revegetation Success Standards Final Rule*. This amendment also updates references and makes minor editorial changes. This document gives the times and locations that the Illinois program and this proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

**DATES:** We will accept written comments on this amendment until 4:00 p.m., Central Standard Time (c.s.t.), May 31, 2022. If requested, we may hold a public hearing or meeting on the amendment on May 24, 2022. We will accept requests to speak at a hearing until 4:00 p.m., c.s.t. on May 16, 2022.

**ADDRESSES:** You may submit comments, identified by SATS No. IL–111–FOR, by any of the following methods:

- *Mail/Hand Delivery:* William L. Joseph, Chief, Alton Field Division, Office of Surface Mining Reclamation and Enforcement, 501 Belle Street, Suite 216, Alton, Illinois 62002–6169.

- *Fax:* (618) 463–6470.

- *Federal eRulemaking Portal:* The amendment has been assigned Docket ID: OSM–2022–0002. If you would like to submit comments, go to <https://www.regulations.gov>. Follow the instructions for submitting comments.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Public Comment Procedures” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to review copies of the Illinois program, this amendment, a listing of any scheduled public hearings or meetings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE’s Alton Field Division or the full text of the program amendment is available for you to read at [www.regulations.gov](http://www.regulations.gov).

William L. Joseph, Chief, Alton Field Division, Office of Surface Mining

Reclamation and Enforcement, 501 Belle Street, Suite 216, Alton, Illinois 62002–6169, Telephone: (618) 463–6463, Email: [bjoseph@osmre.gov](mailto:bjoseph@osmre.gov).

In addition, you may review a copy of the amendment during regular business hours at the following location: Office of Mines and Minerals, Illinois Department of Natural Resources, One Natural Resources Way, Springfield, IL 62702–1271, Telephone: (618) 439–9111.

**FOR FURTHER INFORMATION CONTACT:** William L. Joseph, Chief, Alton Field Division. Telephone (618) 463–6463, Email: [bjoseph@osmre.gov](mailto:bjoseph@osmre.gov).

#### SUPPLEMENTARY INFORMATION:

- I. Background on the Illinois Program
- II. Description of the Proposed Amendment
- III. Public Comment Procedures
- IV. Statutory and Executive Order Reviews

#### I. Background on the Illinois Program

Subject to OSMRE’s oversight, Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its approved, State program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7).

On the basis of these criteria, the Secretary of the Interior conditionally approved the Illinois program on June 1, 1982. You can find background information on the Illinois program, including the Secretary’s findings, the disposition of comments, and conditions of approval of the Illinois program in the June 1, 1982, **Federal Register** (47 FR 23858). You can also find later actions concerning the Illinois program and program amendments at 30 CFR 913.10, 913.15, and 913.17.

#### II. Description of the Proposed Amendment

By letter dated February 4, 2022 (Administrative Record No. IL–5119), Illinois sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). The amendment proposes the removal of revegetation success standards and sampling techniques from inclusion in the approved regulatory program as allowed by the 2006 *Topsoil Redistribution and Revegetation Success Standards Final Rule* (71 FR 51684). This change was driven by recent fluctuations in available datasets for their Agricultural Lands Productivity Formula. No longer including these standards and techniques in their regulations and providing them as a

separate publicly available document as approved in the 2006 OSMRE rule will provide the ability to be more responsive to changes in dataset availability. Illinois would not be required to process a formal regulation amendment in order to remain compliant if data for a particular crop and/or area is not available. Illinois could process changes to their locally available document instead. This amendment also updates references and makes minor editorial changes. The full text of the program and/or plan amendment is available for you to read at the locations listed above under **ADDRESSES** or at [www.regulations.gov](http://www.regulations.gov).

### III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking 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 State program.

#### *Electronic or Written Comments*

If you submit written or electronic comments on the proposed rule during the 30-day comment period, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

#### *Public Availability of Comments*

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

#### *Public Hearing*

If you wish to speak at the public hearing, contact the person listed under

**FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., c.s.t. on May 16, 2022. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

#### *Public Meeting*

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

### IV. Statutory and Executive Order Reviews

#### *Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review*

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB) will review all significant rules. Pursuant to OMB guidance, dated October 12, 1993, the approval of State program amendments is exempted from OMB review under Executive Order 12866. Executive Order 13563, which reaffirms and supplements Executive Order 12866, retains this exemption.

#### *Other Laws and Executive Orders Affecting Rulemaking*

When a State submits a program amendment to OSMRE for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the

proposed amendment, its text or a summary of its terms, and an opportunity for public comment. We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

### List of Subjects in 30 CFR Part 913

Intergovernmental relations, Surface mining, Underground mining.

**Alfred L. Clayborne,**

*Regional Director, Interior Regions 3, 4, and 6.*

[FR Doc. 2022–09190 Filed 4–28–22; 8:45 am]

**BILLING CODE 4310–05–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 100

[Docket Number USCG–2022–0161]

RIN 1625–AA08

### Special Local Regulation; Back River, Baltimore County, MD

**AGENCY:** Coast Guard, Homeland Security (DHS).

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to establish temporary special local regulations for certain waters of Back River. This action is necessary to provide for the safety of life on these navigable waters located in Baltimore County, MD, during a high-speed power boat event on July 16, 2022 (alternate date on July 17, 2022). This proposed rulemaking would prohibit persons and vessels from being in the regulated area unless authorized by the Captain of the Port Maryland-National Capital Region or the Coast Guard Event Patrol Commander. We invite your comments on this proposed rulemaking.

**DATES:** Comments and related material must be received by the Coast Guard on or before May 31, 2022.

**ADDRESSES:** You may submit comments identified by docket number USCG–2022–0161 using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the