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#### List of Subjects in 21 CFR Part 50

Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 50 is amended as follows:

#### PART 50—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for 21 CFR part 50 continues to read as follows:

**Authority:** 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 352, 353, 355, 360, 360c-360f, 360h-360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b-263n.

■ 2. Section 50.25 is amended by redesignating paragraphs (c) and (d) as paragraphs (d) and (e), and by adding new paragraph (c) to read as follows:

#### § 50.25 Elements of informed consent.

\* \* \* \* \*

(c) When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

\* \* \* \* \*

Dated: December 28, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-33193 Filed 1-3-11; 8:45 am]

**BILLING CODE 4160-01-P**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Parts 239 and 258

[EPA-R10-RCRA-2010-0953; FRL-9247-6]

#### Alaska: Adequacy of Alaska Municipal Solid Waste Landfill Permit Program

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** This action approves a modification to Alaska's approved Municipal Solid Waste Landfill (MSWLF) permit program. The approved modification allows the State to issue Research, Development, and Demonstration (RD&D) permits to owners and operators of MSWLFs in accordance with its State law. On March 22, 2004, EPA issued final regulations allowing RD&D permits to be issued to certain MSWLFs by approved States. On September 7, 2010, the State of Alaska submitted an application to EPA Region 10 seeking Federal approval of its RD&D requirements. After thorough review, EPA Region 10 has determined that Alaska's RD&D permit requirements are adequate through this direct final action.

**DATES:** This direct final rule will become effective March 7, 2011 without further notice unless EPA receives adverse comments on or before February 3, 2011. If adverse comments are received, EPA will publish a timely withdrawal of this direct final rule in the **Federal Register** informing the public that the rule will not take effect. EPA will then review the comments and then will publish a final rule in the **Federal Register** responding to the comments and affirming or revising its initial decision.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R10-RCRA-2010-0953, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.
- *E-mail:* [calabro.domenic@epa.gov](mailto:calabro.domenic@epa.gov).
- *Fax:* (206) 553-8509, to the attention of Domenic Calabro.
- *Mail:* Domenic Calabro, Office of Air, Waste and Toxics, U.S. EPA, Region 10, 1200 Sixth Avenue, Suite 900, Mailstop: AWT-122, Seattle, WA 98101.
- *Hand Delivery or Courier:* Deliver your comments to Domenic Calabro, Office of Air, Waste and Toxics, U.S. EPA, Region 10, 1200 Sixth Avenue, Suite 900, Mailstop: AWT-122, Seattle, WA 98101. Such deliveries are only accepted during the Office's normal hours of operation.

*Instructions:* Identify your comments as relating to Docket ID No. EPA-R10-RCRA-2010-0953. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or claimed to be other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any

disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

**Docket:** EPA has established a docket for this action under Docket ID No. EPA-R10-RCRA-2010-0953. All documents in the docket are listed on the <http://www.regulations.gov> Web site. Although it may be listed in the index, some information might not be publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the U.S. Region 10 Library, 1200 Sixth Avenue, Seattle, WA 98101 by appointment only; telephone: (206) 553-1289.

**FOR FURTHER INFORMATION CONTACT:** Domenic Calabro, Office of Air, Waste and Toxics, U.S. EPA, Region 10, 1200 Sixth Avenue, Suite 900, Mailstop: AWT-122, Seattle, WA 98101, telephone: (206) 553-6640, [calabro.domenic@epa.gov](mailto:calabro.domenic@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On March 22, 2004, EPA issued a final rule (69 FR 13242) amending the Municipal Solid Waste Landfill (MSWLF) criteria in 40 CFR part 258 to allow for Research, Development and Demonstration (RD&D) permits (69 FR 13242). That rule allows for variances from specified criteria for a limited period of time, to be implemented through State-issued RD&D permits. RD&D permits are available only in States with approved MSWLF permit programs that have been modified to incorporate RD&D permit authority. While States are not required to seek approval to allow permits under this new provision, those States that are interested in providing RD&D permits to owners and operators of MSWLFs must seek approval from EPA before issuing such permits. Approval procedures for new provisions of 40 CFR part 258 are outlined in 40 CFR 239.12.

On March 15, 2000, EPA published a final rule (65 FR 453) approving the

State of Alaska's MSWLF permit program. On September 7, 2010, Alaska applied for approval of its RD&D permit provisions which are included as part of a broader revision package and is codified as 18 AAC 60.213. The final package was adopted by the ADEC, signed and officially filed by the Lt. Governor, and took effect on September 5, 2010.

**II. Decision**

After a thorough review of Alaska's revision package, EPA has determined that the Alaska Research, Development and Demonstration (RD&D) permit provisions as set out in 18 AAC 60.213 are adequate to comply with the Federal criteria as set out in 40 CFR 258.4. The State regulations regarding RD&D permits incorporate by reference all of the requirements of 40 CFR 258.4, while specifying particular requirements which are either equivalent to or more stringent than the requirements of 40 CFR 258.4.

**III. Statutory and Executive Order Reviews**

This action approves State solid waste requirements pursuant to Resource Conversation and Recovery Act (RCRA) Section 4005 and imposes no Federal requirements. Therefore, this rule complies with applicable executive orders and statutory provisions as follows:

*1. Executive Order 12866*

This action is not a "significant regulatory action" under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the EO.

*2. Paperwork Reduction Act*

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b). This direct final rule does not establish or modify any information or recordkeeping requirements for the regulated community. EPA has determined that it is not subject to the provisions of the Paperwork Reduction Act.

*3. Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), 5 U.S.C. 601 *et seq.*, generally requires Federal agencies to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency

certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this direct final rule on small entities, small entity is defined as: (1) A small business, as codified in the Small Business Size Regulations at 13 CFR part 121; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. EPA has determined that this direct final action will not have a significant impact on small entities because the action will only have the effect of modifying pre-existing authorized requirements under State law. I certify that this action will not have a significant economic impact on a substantial number of small entities.

*4. Unfunded Mandates Reform Act*

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531-1538 for State, local, or Tribal governments or the private sector. This action imposes no new enforceable duty on any State, local or Tribal governments or the private sector. This action contains no regulatory requirements that might significantly or uniquely affect small government entities. Thus, EPA has determined that the requirements of section 203 of the UMRA do not apply to this action.

*5. Executive Order 13132: Federalism*

This action addresses a modification to Alaska's approved MSWLF permit program, which has been modified by State law to incorporate RD&D permitting authority. There are no substantial direct effects on the States, on the relationship between Federal and State governments, or on the distribution of power between among the various levels of government, as specified in Executive Order 13132. Therefore, Executive Order 13132 does not apply to this action.

*6. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have Tribal implications, as specified in Executive Order 13175. This action addresses a modification to Alaska's approved

MSWLF permit program, which has been modified by State law to incorporate RD&D permitting authority. Thus, EPA has determined that Executive Order 13175 does not apply to this rule.

*7. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks*

This action is not subject to Executive Order 13045 because it is not economically significant and it is not based on health or safety risks.

*8. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a "significant regulatory action" as defined under Executive Order 12866.

*9. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104-113, section 12(d) (15 U.S.C. 272) directs EPA to use voluntary consensus standards bodies in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus bodies. The NTTAA directs EPA to provide Congress, through the OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. EPA has determined that this action does not involve "technical standards" as defined by the NTTAA. Therefore EPA is not considering the use of any voluntary consensus standards.

*10. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This action addresses a modification to Alaska's approved MSWLF permit program, which has been modified by State law to incorporate RD&D permitting authority. EPA has determined that the action is not subject to Executive Order 12898.

*11. Congressional Review Act*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this document and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This action will be effective March 7, 2011.

**List of Subjects**

*40 CFR Part 239*

Environmental protection, Administrative practice and procedure, Intergovernmental relations, Waste treatment and disposal.

*40 CFR Part 258*

Reporting and recordkeeping requirements, Waste treatment disposal, Water pollution control.

**Authority:** This action is issued under the authority of section 2002, 4005 and 4010(c) of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912, 6945 and 6949(a).

Dated: December 22, 2010.

**Dennis J. McLerran,**

*Regional Administrator, EPA Region 10.*

[FR Doc. 2010-33196 Filed 1-3-11; 8:45 am]

**BILLING CODE 6560-50-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**44 CFR Part 67**

[Docket ID FEMA-2010-0003]

**Final Flood Elevation Determinations**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Final rule.

**SUMMARY:** Base (1% annual-chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

**DATES:** The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated in the table below.

**ADDRESSES:** The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-4064, or (e-mail) [luis.rodriquez1@dhs.gov](mailto:luis.rodriquez1@dhs.gov).

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Federal Insurance and Mitigation Administrator has resolved any appeals resulting from this notification.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in flood prone areas in accordance with 44 CFR part 60.