

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC-2018-0220]

RIN 3150-AK17

List of Approved Spent Fuel Storage Casks: NAC International Multi-Purpose Canister Storage System, Certificate of Compliance No. 1025, Amendment Nos. 7 and 8

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its spent fuel storage regulations by revising the NAC International Multi-Purpose Canister (NAC-MPC) Storage System listing within the “List of approved spent fuel storage casks” to include Amendment Nos. 7 and 8 to Certificate of Compliance No. 1025. Amendment No. 7 would revise the technical specifications to eliminate the requirements for the heat removal system to be operable for La Crosse Boiling Water Reactor spent fuel stored in the NAC-MPC because convective cooling is not required, and to eliminate duplicative requirements. In addition, Amendment No. 8 removes duplicative surveillance requirements in the technical specifications because these requirements are already required by the revised Technical Specification A 3.1.6, “CONCRETE CASK Heat Removal System.”

DATES: Submit comments by January 17, 2019. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking Website:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2018-0220. Address questions about NRC dockets to Carol

Gallagher; telephone: 301-415-3463; email: Carol.Gallagher@nrc.gov. For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Email comments to:* Rulemaking.Comments@nrc.gov. If you do not receive an automatic email reply confirming receipt, then contact us at 301-415-1677.

- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Bernard H. White, Office of Nuclear Material Safety and Safeguards; telephone: 301-415-6577; email: Bernard.White@nrc.gov or Gregory R. Trussell, Office of Nuclear Material Safety and Safeguards; telephone: 301-415-6244; email: Gregory.Trussell@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2018-0220 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2018-0220.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “ADAMS Public Documents” and then select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the “Availability of Documents” section.

- *NRC’s PDR:* You may examine and purchase copies of public documents at the NRC’s PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC-2018-0220 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

Because the NRC considers this action to be non-controversial, the NRC is publishing this proposed rule concurrently with a direct final rule in the Rules and Regulations section of this issue of the **Federal Register** (FR). The direct final rule will become effective on March 4, 2019. However, if the NRC receives significant adverse comments on this proposed rule by January 17,

2019, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments received in response to these proposed revisions in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC staff.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be

ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC staff to make a change (other than editorial) to the rule, Certificate of Compliance, or technical specifications.

For procedural information and the regulatory analysis, see the direct final rule published in the Rules and Regulations section of this issue of the FR.

III. Background

Section 218(a) of the Nuclear Waste Policy Act (NWPA) of 1982, as amended, requires that "the Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission." Section 133 of the NWPA states, in part, that "[the Commission] shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor."

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved

casks under a general license by publishing a final rule which added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled, "General License for Storage of Spent Fuel at Power Reactor Sites" (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled, "Approval of Spent Fuel Storage Casks," which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on March 9, 2000 (65 FR 12444), that approved the NAC-MPC Cask System design and added it to the list of NRC-approved cask designs in § 72.214 as Certificate of Compliance No. 1025.

IV. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31883). The NRC requests comment on the proposed rule with respect to the clarity and effectiveness of the language used.

V. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS accession No./ web link/ Federal Register citation
Request to Amend Certificate of Compliance No. 1025 for the NAC-MPC Storage System, dated November 14, 2017	ML17326A128
Request to Amend Certificate of Compliance No. 1025 for the NAC-MPC Storage System, dated February 12, 2018	ML18045A440
Request to Amend Certificate of Compliance No. 1025 for the NAC-MPC Storage System, dated February 28, 2018	ML18059A784
Proposed Certificate of Compliance No. 1025, Amendment No. 7	ML18255A024
Proposed Technical Specification Appendices A and B for Amendment No. 7	ML18255A022
Preliminary Safety Evaluation Report for Amendment No. 7	ML18255A026
Proposed Certificate of Compliance No. 1025, Amendment No. 8	ML18255A025
Proposed Technical Specification Appendices A and B for Amendment No. 8	ML18255A023
Preliminary Safety Evaluation Report for Amendment No. 8	ML18255A027

The NRC may post materials related to this document, including public comments, on the Federal Rulemaking website at <http://www.regulations.gov> under Docket ID NRC-2018-0220. The Federal Rulemaking website allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC-2018-0220); (2) click the "Sign up for Email Alerts" link; and (3) enter your email address and select how

frequently you would like to receive emails (daily, weekly, or monthly).

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Whistleblowing.

For the reasons set out in the preamble and under the authority of the

Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is proposing to adopt the following amendments to 10 CFR part 72:

**PART 72—LICENSING
REQUIREMENTS FOR THE
INDEPENDENT STORAGE OF SPENT
NUCLEAR FUEL, HIGH-LEVEL
RADIOACTIVE WASTE, AND
REACTOR-RELATED GREATER THAN
CLASS C WASTE**

■ 1. The authority citation for Part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 2. In § 72.214, Certificate of Compliance 1025 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1025.

Initial Certificate Effective Date: April 10, 2000.

Amendment Number 1 Effective Date: November 13, 2001.

Amendment Number 2 Effective Date: May 29, 2002.

Amendment Number 3 Effective Date: October 1, 2003.

Amendment Number 4 Effective Date: October 27, 2004.

Amendment Number 5 Effective Date: July 24, 2007.

Amendment Number 6 Effective Date: October 4, 2010.

Amendment Number 7 Effective Date: March 4, 2019.

Amendment Number 8 Effective Date: March 4, 2019.

SAR Submitted by: NAC International, Inc.

SAR Title: Final Safety Analysis Report for the NAC Multi-Purpose Canister System (NAC-MPC System).

Docket Number: 72-1025.

Certificate Expiration Date: April 10, 2020.

Model Number: NAC-MPC.

* * * * *

Dated at Rockville, Maryland, this 4th day of December, 2018.

For the Nuclear Regulatory Commission.

Margaret M. Doane,
Executive Director for Operations.

[FR Doc. 2018-27286 Filed 12-17-18; 8:45 am]

BILLING CODE 7590-01-P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2018-N-3952]

Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies; New Date for Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of new date for public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a new date for the public hearing to discuss its efforts to eliminate youth electronic cigarette (e-cigarette) use as well as other tobacco product use, with a focus on the potential role of drug therapies to support youth e-cigarette cessation and the issues impacting the development of such therapies. FDA is also extending the comment period.

DATES: The public hearing will be held on January 18, 2019, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early depending on the level of public participation. Persons seeking to present at the public hearing must register by January 8, 2019. Persons seeking to speak at the public hearing must register by January 15, 2019. Persons seeking to attend, but not present at, the public hearing must register by January 15, 2019. Section III provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until February 1, 2019.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993-0002. Entrance for public hearing participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 1, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end

of February 1, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date. You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-3952 for "Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies; Public Hearing; Request for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9