

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–2018–0221]

RIN 3150–AK18

List of Approved Spent Fuel Storage Casks: Holtec International HI–STORM 100 Multipurpose Canister Cask System, Certificate of Compliance No. 1014, Amendment Nos. 11 and 12

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 Holtec International HI–STORM 100 Multipurpose Canister Cask System (HI–STORM 100 System) listing within the “List of approved spent fuel storage casks” to include Amendment Nos. 11 and 12 to Certificate of Compliance No. 1014. Amendment Nos. 11 and 12 propose to revise multiple items in the Technical Specifications for multi-purpose canister models listed under Certificate of Compliance No. 1014; most of these revisions involve changes to the authorized contents. In addition, Amendment No. 11 makes several other editorial changes.

DATES: Submit comments by January 11, 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–2018–0221. 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: Yen-Ju Chen, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–1018; email: Yen-Ju.Chen@nrc.gov or Vanessa Cox, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–8342; email: Vanessa.Cox@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–2018–0221 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–2018–0221.

- *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 “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–2018–0221 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

This proposed rule is limited to the changes contained in Amendment Nos. 11 and 12 to Certificate of Compliance 1014 and does not include other aspects of the Holtec International HI–STORM 100 System design. 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 February 25, 2019. However, if the NRC receives significant adverse comments on this proposed rule by January 11, 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.

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 that 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 May 1, 2000 (65 FR 25241) that approved the Holtec International HI-STORM 100 System design and added it to the list of NRC-approved cask designs in § 72.214 as Certificate of Compliance No. 1014.

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 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
Subpart K of 10 CFR part 72, “General License for Storage of Spent Fuel at Power Reactor Sites”	55 FR 29181
10 CFR part 72, “List of Approved Spent Fuel Storage Casks: Holtec HI-STORM 100 Addition”	65 FR 25241
Letter from Holtec International to NRC, “Holtec International HI-STORM 100 Multipurpose Canister Storage System Amendment Request 1014-11” dated January 29, 2016.	ML16029A528
Letter from Holtec International to NRC, “Supporting Information for License Amendment Request 11 (1014-11) to the HI-STORM 100 CoC” dated February 16, 2016. (This letter contains five enclosures, and Enclosures 1 through 4 are proprietary information and not publicly available.).	ML16069A246
Letter from Holtec International to NRC, “Transmittal of Requests for Supplemental Information Responses Supporting HI-STORM 100 License Amendment Request 1014-11” dated June 6, 2016.	ML16159A344
Letter from Holtec International to NRC, “Submittal of Responses to NRC’s Requests for Additional Information for HI-STORM 100 License Amendment Request 1014-11” dated December 22, 2016.	ML17005A236
Letter from Holtec International to NRC, “Modification to Requested Changes on HI-STORM 100 Amendment 11 Request” dated April 22, 2016.	ML16113A394
Letter from Holtec International to NRC, “Submittal of Responses to NRC’s 2nd Round Requests for Additional Information for HI-STORM 100 License Amendment Request 1014-11” dated September 8, 2017.	ML17261A159
Letter from Holtec International to NRC, “Submittal of Supplemental Information on NRC’s Requests for Additional Information for HI-STORM 100 License Amendment Request 1014-11” dated November 10, 2017. (This package contains nine attachments, and Attachments 1, 6, 7, and 8 are proprietary information and not publicly available.).	ML17325A555
Letter from Holtec International to NRC, “Submittal of Revised Supplemental Information on NRC’s Requests for Additional Information for HI-STORM 100 License Amendment Request 1014-11” dated December 21, 2017.	ML17362A113
User Need Memorandum for Rulemaking for the Holtec International HI-STORM 100 Cask System, Amendment 11	ML18141A568
Proposed Certificate of Compliance 1014, Amendment 11, Certificate of Compliance for Spent Fuel Storage Casks	ML18141A561
Proposed Certificate of Compliance 1014, Amendment 11, Technical Specifications, Appendix A	ML18141A562
Proposed Certificate of Compliance 1014, Amendment 11, Approved Contents and Design Features, Appendix B	ML18141A563
Proposed Certificate of Compliance 1014, Amendment 11, Technical Specifications, Appendix A-100U	ML18141A564
Proposed Certificate of Compliance 1014, Amendment 11, Approved Contents and Design Features, Appendix B-100U	ML18141A565
Certificate of Compliance 1014, Amendment 11, Preliminary Safety Evaluation Report	ML18141A567

Document	ADAMS accession No./web link/ Federal Register citation
Letter from Holtec International to NRC, "Holtec International HI-STORM 100 Multipurpose Canister Storage System Amendment Request 1014-12" dated June 14, 2016.	ML16169A363
Letter from Holtec International to NRC, "Holtec International HI-STORM 100 Multipurpose Canister Storage System Amendment Request 1014-12 Supporting Calculation Packages" dated July 22, 2016. (This package contains four attachments, and Attachments 1 through 3 are proprietary information and not publicly available.)	ML16210A133
Letter from Holtec International to NRC, "HI-STORM 100 Amendment 12 Responses to Requests for Supplemental Information" dated November 4, 2016. (This package contains five attachments, and Attachment 4 is proprietary information and not publicly available.)	ML16313A216
Letter from Holtec International to NRC, "Submittal of Responses to NRC's Requests Additional Information for HI-STORM 100 License Amendment Request 1014-12" dated August 25, 2017. (This package contains 13 attachments, and Attachments 1, 5, 7, 8, 9, 10, 11, and 12 are proprietary information and not publicly available.)	ML17251A739
Letter from Holtec International to NRC, "Submittal of Responses to NRC's 2nd Round Requests Additional Information for HI-STORM 100 License Amendment Request 1014-11" dated September 8, 2017. (This package contains seven attachments, and Attachments 1, 5, and 6 are proprietary information and not publicly available.)	ML17261A159
Letter from Holtec International to NRC, "Submittal of Supplemental Information on NRC's Requests for Additional Information for HI-STORM 100 License Amendment Request 1014-12" dated November 10, 2017. (This package contains six attachments, and Attachment 1 is proprietary information and not publicly available.)	ML17326A174
Letter from Holtec International to NRC, "Submittal of Revised Supplemental Information on NRC's Requests for Additional Information for HI-STORM 100 License Amendment Request 1014-12" dated December 22, 2017.	ML17362A130
User Need Memorandum for Rulemaking for the Holtec International HI-STORM 100 Cask System, Amendment 12	ML18087A056
Proposed Certificate of Compliance 1014, Amendment 12, Certificate of Compliance for Spent Fuel Storage Casks	ML18087A057
Proposed Certificate of Compliance 1014, Amendment 12, Technical Specifications, Appendix A	ML18087A058
Proposed Certificate of Compliance 1014, Amendment 12, Approved Contents and Design Features, Appendix B	ML18087A059
Proposed Certificate of Compliance 1014, Amendment 12, Technical Specifications, Appendix A-100U	ML18087A060
Proposed Certificate of Compliance 1014, Amendment 12, Approved Contents and Design Features, Appendix B-100U	ML18087A061
Certificate of Compliance 1014, Amendment 12, Preliminary Safety Evaluation Report	ML18087A062

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-2018-0221. 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-2018-0221); (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, Spent fuel, 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 1014 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1014.
Initial Certificate Effective Date: May 31, 2000.

Amendment Number 1 Effective Date: July 15, 2002.

Amendment Number 2 Effective Date: June 7, 2005.

Amendment Number 3 Effective Date: May 29, 2007.

Amendment Number 4 Effective Date: January 8, 2008.

Amendment Number 5 Effective Date: July 14, 2008.

Amendment Number 6 Effective Date: August 17, 2009.

Amendment Number 7 Effective Date: December 28, 2009.

Amendment Number 8 Effective Date: May 2, 2012, as corrected on November 16, 2012 (ADAMS Accession No. ML12213A170); superseded by Amendment Number 8, Revision 1, Effective Date: February 16, 2016.

Amendment Number 8, Revision 1, Effective Date: February 16, 2016.

Amendment Number 9 Effective Date: March 11, 2014, superseded by Amendment Number 9, Revision 1, on March 21, 2016.

Amendment Number 9, Revision 1, Effective Date: March 21, 2016, as corrected (ADAMS Accession No. ML17236A451).

Amendment Number 10 Effective Date: May 31, 2016, as corrected (ADAMS Accession No. ML17236A452).

Amendment Number 11 Effective Date: February 25, 2019.

Amendment Number 12 Effective Date: February 25, 2019.

Safety Analysis Report Submitted by: Holtec International.

Safety Analysis Report Title: Final Safety Analysis Report for the HI-STORM 100 Cask System.

Docket Number: 72-1014.

Certificate Expiration Date: May 31, 2020.

Model Number: HI-STORM 100.

* * * * *

Dated at Rockville, Maryland, this 29th day of November 2018.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Executive Director for Operations.

[FR Doc. 2018-26878 Filed 12-11-18; 8:45 am]

BILLING CODE 7590-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 93

RIN 2120-AK39

Notification of Replacement Public Meeting on Requirement for Helicopters To Use the New York North Shore Helicopter Route

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notification of public meeting.

SUMMARY: Due to inclement weather on November 15, 2018, the FAA announces a replacement public meeting to solicit feedback concerning the New York North Shore Helicopter Rule (“the Rule”). This meeting is being held pursuant to Section 182 of the FAA Reauthorization Act of 2018. The Rule requires civil helicopter pilots operating under Visual Flight Rules (VFR), whose route of flight takes them over the north shore of Long Island between the Visual Point Lloyd Harbor (VPLYD) waypoint and Orient Point (VPOLT), to use the North Shore Helicopter Route.

DATES: The public meeting will be held on Thursday, December 13, 2018.

ADDRESSES: The public meeting will be held at Vaugh College, 8601 23rd Avenue, Flushing NY 11369. The meeting is 7:00 p.m.–9:00 p.m. EST.

FOR FURTHER INFORMATION CONTACT: Christopher Bailey, Office of Rulemaking, Federal Aviation Administration; telephone (202) 267-4158; email Christopher.Bailey@faa.gov.

SUPPLEMENTARY INFORMATION:

Purpose of the Public Meeting

The purpose of the public meeting is for the FAA to obtain feedback relevant to the Rule at subpart H of part 93, which requires civil helicopter pilots operating under VFR, whose route of flight takes them over the north shore of Long Island between the VPLYD waypoint and VPOLT, to use the North Shore Helicopter Route. The FAA will

consider comments made at the public meeting in its review of the Rule.

Public Participation and Meeting Procedures

The meeting will use a workshop format. FAA will have several stations covering a number of relevant aspects of the Rule. Each station will be staffed by an FAA representative who is able to answer questions regarding that subject. There will also be a station where the public can submit a written statement or have their oral comment transcribed. No formal presentations will be made.

Section 182 of the FAA Reauthorization Act of 2018 also calls for a written comment period on the North Shore Helicopter Rule. See docket number FAA-2018-0954 to submit written comments.

Sign and oral interpretation can be made available at the meeting, as well as an assistive listening device, if requested 3 calendar days before the meeting. The meeting will be open to all persons on a space-available basis. There will be no admission fee or other charge to attend and participate.

Issued in Washington, DC, on December 7, 2018.

Brandon Roberts,

Deputy Executive Director, Office of Rulemaking.

[FR Doc. 2018-26934 Filed 12-10-18; 4:15 pm]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. FDA-2018-N-2732]

RIN 0910-AH57

Definition of the Term “Biological Product”

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is proposing to amend its regulation that defines “biological product” to incorporate changes made by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), and to provide its interpretation of the statutory terms “protein” and “chemically synthesized polypeptide.” Under that interpretation, the term *protein* would mean any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino

acids in size. A *chemically synthesized polypeptide* would mean any alpha amino acid polymer that is made entirely by chemical synthesis and is greater than 40 amino acids but less than 100 amino acids in size. This proposed rule is intended to clarify the statutory framework under which such products are regulated.

DATES: Submit either electronic or written comments on the proposed rule by February 25, 2019.

ADDRESSES: 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 25, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of February 25, 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.

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.