

# Rules and Regulations

Federal Register

Vol. 81, No. 3

Wednesday, January 6, 2016

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 72

[NRC-2015-0156]

RIN 3150-AJ63

### List of Approved Spent Fuel Storage Casks: Holtec International HI-STORM 100 Cask System; Amendment No. 9, Revision 1

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Direct final rule.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is amending its spent fuel storage regulations by revising the Holtec International ("Holtec," or "the applicant") HI-STORM 100 Cask System listing within the "List of Approved Spent Fuel Storage Casks" to include Amendment No. 9, Revision 1, to Certificate of Compliance (CoC) No. 1014. Amendment No. 9, Revision 1, changes cooling time limits for thimble plug devices (TPDs), removes certain testing requirements for the fabrication of Metamic HT neutron-absorbing structural material, and reduces certain minimum guaranteed values (MGV) used in bounding calculations for this material. Amendment No. 9, Revision 1, also changes fuel definitions to classify certain boiling water reactor (BWR) fuel within specified guidelines as undamaged fuel.

**DATES:** The direct final rule is effective March 21, 2016, unless significant adverse comments are received by February 5, 2016. If the direct final rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the **Federal Register**. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only of

comments received on or before this date. Comments received on this direct final rule will also be considered to be comments on a companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**.

**ADDRESSES:** You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2015-0156. Address questions about NRC dockets to Carol Gallagher, telephone: 301-415-3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Email comments to:* [Rulemaking.Comments@nrc.gov](mailto: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:** Robert D. MacDougall, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-5175, email: [Robert.MacDougall@nrc.gov](mailto:Robert.MacDougall@nrc.gov); U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

#### **SUPPLEMENTARY INFORMATION:**

#### **Table of Contents**

- I. Obtaining Information and Submitting Comments
- II. Procedural Background
- III. Background
- IV. Discussion of Changes
- V. Voluntary Consensus Standards
- VI. Agreement State Compatibility

#### VII. Plain Writing

VIII. Environmental Assessment and Final Finding of No Significant Environmental Impact

IX. Paperwork Reduction Act Statement

X. Regulatory Flexibility Certification

XI. Regulatory Analysis

XII. Backfitting and Issue Finality

XIII. Congressional Review Act

XIV. Availability of Document

### **I. Obtaining Information and Submitting Comments**

#### *A. Obtaining Information*

Please refer to Docket ID NRC-2015-0156 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 Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2015-0156.

- *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](mailto: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-2015-0156 in the subject line of 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, 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. Procedural Background

This rule is limited to the changes contained in Amendment No. 9, Revision 1, to CoC No. 1014 and does not include other aspects of the Holtec HI-STORM 100 Cask System design. The NRC is using the “direct final rule” procedure to issue this amendment because it represents a limited and routine change to an existing CoC and is expected to be noncontroversial. Adequate protection of public health and safety continues to be ensured. The amendment to the rule will become effective on March 21, 2016. If the NRC receives significant adverse comments on this direct final rule by February 5, 2016, the NRC will publish a **Federal Register** notice withdrawing the direct final rule, and will address the comments in a subsequent **Federal Register** notice for a final rule based on the companion proposed rule published in the Proposed Rule section of this issue of the **Federal Register**. Absent the need for significant modifications to the proposed revisions that would require republication, the NRC will not initiate a second comment period on this action.

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, CoC, or Technical Specifications.

For detailed instructions on filing comments, please see the **ADDRESSES** section of this document.

## III. Background

Section 218(a) of the Nuclear Waste Policy Act (NWPA) of 1982, as amended, requires that “the Secretary [of the U.S. 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 [U.S. 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 “[t]he 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 to add 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 (65 FR 25241; May 1, 2000) that approved the HI-STORM 100 Cask System design and added it to the list of NRC-approved cask designs in 10 CFR 72.214, “List of approved spent fuel storage casks,” as CoC No. 1014. Most recently, the NRC issued a final rule effective on March 11, 2014 (78 FR 78165), that approved the HI-STORM 100 Cask System design amendment subject to this rulemaking and added it to the list of NRC-approved cask designs in 10 CFR 72.214 as CoC No. 1014, Amendment No. 9.

## IV. Discussion of Changes

On July 1, 2014, Holtec submitted a request to the NRC to revise CoC No. 1014 to supersede Amendment 9 with

Amendment 9, Revision 1. Amendment No. 9, Revision 1, changes cooling time limits for TPDs, removes certain testing requirements for the fabrication of Metamic HT, and reduces certain MGVs used in bounding calculations for this material. Amendment No. 9, Revision 1, also changes fuel definitions to classify certain boiling water reactor (BWR) fuel within specified guidelines as undamaged fuel. The changes to the CoC and Technical Specifications (TS) Appendices are identified with revisions bars in the margin of each document.

As a revision, the CoC and its associated TS will supersede the previous version of the CoC No. 1014, Amendment No. 9 CoC and its TSs in their entirety. A revision in lieu of a new amendment is justified on the grounds that:

- Equipment for CoC No. 1014, Amendment No. 9, cask systems has been placed in service by several general licensees, all of whom were made aware of Holtec’s revision request and supported it;
- No new canisters are being requested to be added to CoC No. 1014, Amendment No. 9, cask systems;
- No new systems, components, or structures are requested to be added to CoC No. 1014, Amendment No. 9, cask systems;
- The requested changes have minor field and administrative implementation impacts on general licensees; and
- The requested changes are applicable to CoC No. 1014, Amendment No. 9, in their entirety.

Each of the applicant’s proposed changes is discussed below.

### 1. Reduced Cooling Time Limit for TPDS

The TPDs are a form of non-fuel hardware inserted into guide tubes used in some pressurized water reactor (PWR) fuel assemblies and made radioactive by exposure to neutrons during reactor operation. Supporting its proposal to reduce the cooling time limits for TPDs, the applicant noted that TPDs are not considered in any of the thermal analyses of CoC No. 1014, Amendment No. 9, so that in order to comply with this amendment, general licensees must perform an evaluation under 10 CFR 72.212 to ensure that maximum fuel storage decay heat limits are met. The applicant stated that, currently, cooling times for TPDs exposed to typical fuel burnups in a reactor core are long, preventing many TPDs from being stored in the dry multi-purpose canisters (MPC) that contain spent fuel and non-fuel hardware with “activation products,” or components or constituents made radioactive by

exposure to neutrons in the reactor core. The applicant proposed to reduce the required cooling times so that general license users can have greater flexibility to store a larger population of TPDs.

The principal activation product from the irradiation of TPDs in a reactor core is Cobalt-60 (Co-60), which has a half-life (the time it takes to lose half its radioactivity) of 5 years. The applicant calculated that the Co-60 source for a TPD with a five-year cooling time after exposure to a fuel burnup of 63,000 megawatt-days per metric ton of uranium (MWD/MTU) or less is 141 curies. The maximum Co-60 activity of TPDs is 240 curies. The applicant selected 141 curies Co-60 as the design basis Co-60 activity for each TPD, so that any TPD can be stored in a HI-STORM MPC so long as the TPD has a cooling time of 5 years or greater after a burnup of 63,000 MWD/MTU or less, as required by the TSs.

The applicant also calculated the dose rates from a HI-STORM 100 overpack with an MPC for BWR and for PWR fuels using allowable burnup and cooling times from the proposed Revision 1 to CoC No. 1014, Amendment No. 9. These calculated dose rates were less than the allowable values in the TSs for the currently-approved Amendment No. 9.

The NRC staff reviewed the applicant's proposed revisions to its final safety analysis report (FSAR) and finds that the proposed change would have no impact on a fuel rod's internal pressure or cladding temperatures. The NRC staff finds the storing of TPDs to be acceptable because, as non-fuel components, they present no risk of rupturing and releasing fission products, fission product gases, or any other material detrimental to the internals of the cask. Nor would the storage of TPDs prevent the retrieval of spent fuel from a cask. General licensees will, however, continue to be required under 72.212 to evaluate and ensure that cell heat loads per canister remain below the applicable limits as listed in the FSAR and TSs prior to loading.

## 2. Removing or Revising Certain Metamic-HT Fabrication Testing Requirements

Metamic-HT is a neutron-absorbing structural material used for internal components of MPCs, which hold spent fuel assemblies and other radioactive fuel components inside storage casks. The applicant proposed changing Metamic-HT fabrication testing requirements to: Remove testing using a 1-inch collimated neutron beam; remove Charpy V-notch and lateral expansion testing; remove thermal conductivity

testing; revise testing requirements for fuel basket welds; change re-testing criteria when a component fails to meet an MGV by requiring only the failed property to be re-tested (not all MGVs); and add the ability to conduct 100% testing of an MGV property within a lot if a sample within the lot fails re-testing. According to the applicant, these changes are to improve Metamic-HT testing, or ease undue burden, because some testing requirements were overly conservative and created a lengthy testing process, while others did not affect the safety analysis.

The requirement for the use of a 1-inch neutron beam is based on Interim Staff Guidance (ISG)-23, "Application of ASTM Standard Practice C1671-07 when performing technical reviews of spent fuel storage and transportation packaging licensing actions." ISG-23 concludes that a beam between 1 cm and 2.54 cm is acceptable for qualification and acceptance testing of neutron absorbing materials. The ISG also states, however, that "a visual inspection should be conducted on all neutron absorbing materials intended for service," and that as part of that visual inspection, "it is important to ensure that there are no defects that might lead to problems in service; such as delaminations or cracks that could appear on clad neutron absorbing materials." The staff finds that in this instance, a visual inspection of all neutron-absorbing materials intended for service, along with other fabrication testing measures called for in ISG-23, such as minimum plate thickness testing, will provide adequate assurance against significant defects in Metamic HT without the need for neutron beam testing.

The Charpy V-notch test is a measure of a given material's toughness under impact loading to study temperature-dependent ductile-to-brittle transitions. As temperature decreases, a metal's ability to absorb the energy of an impact—its ductility—decreases, and at some temperature, its ductility may suddenly drop almost to zero. This sharp transition to brittleness is essentially unidentified in metals with a face-centered cubic (FCC) crystal structure, however, and Metamic-HT is an aluminum composite with an FCC-based metal matrix. The staff therefore concludes that the Charpy V-notch test is not necessary for Metamic-HT.

Proposing to remove the thermal conductivity testing requirement for Metamic-HT during fabrication, the applicant noted that there is little variability in this material's thermal conductivity when fabricated according to the manufacturing manual.

The NRC staff evaluated the applicant's proposal and finds that the thermal conductivity of Metamic-HT is stable for normal operating temperatures (200 °C to 500 °C), so that removal of this testing requirement would have no impact on any of the previously approved NRC staff evaluations. The proposed change is therefore considered acceptable.

The applicant also intends to employ a new qualified welding process called Friction Stir Welding (FSW), for external basket joints. Allowing the use of FSW of the Metamic HT basket does not change the safety basis as evaluated by the staff in HI-STORM 100, Amendment No. 9, with respect to basket structural performance. Since the basket corners utilize the same welded joint configuration specified in amendment No. 9 and prior amendments, the primary consideration is that of weld process and qualification, rather than structural performance of the weld itself.

Based on its review of the application, the staff determined that the methods used to qualify the weld joint were sufficiently robust to demonstrate a structural performance comparable to the welding method described in previous amendments. The loading conditions and the fully supported boundary conditions of the peripheral basket panels result in calculated joint stresses below their full capacity. The staff therefore concludes that this margin accounts for any differences in welding procedures, should they arise in the future. The staff's conclusions in this regard only apply to the basket corner welds and shim arrangement defined by this revision.

## 3. Changing Minimum Guaranteed Values for Metamic-HT Analyses

Using the guidance of the American Society of Mechanical Engineers (ASME) Section II, Mandatory Appendix 5, "Guideline on the Approval of New Materials Under the ASME Boiler and Pressure Vessel Code," Holtec determined the mechanical properties of Metamic-HT at ambient and various other higher and lower temperatures. It then analyzed its test data using statistical methods to determine minimum, average, and mean values of the material's structural properties. In addition, the applicant established a design value MGV for each of the various properties. An MGV is an arbitrary value for any given property below the lowest measured value from the test data. The MGV is then demonstrated or guaranteed to be exceeded for every manufactured lot of Metamic HT through lot testing.

The MGVs for Metamic-HT are used in calculations to demonstrate that structural components made with this material will satisfy engineering requirements, such as stress or deflection limits to ensure acceptable hardness of the component in service. Using MGV values produces a bounding calculation for any given engineering requirement.

To support its proposal for reducing some of these MGVs, Holtec used differing MGV values in structural calculations for developing stress/strain curves from finite element analysis, a method of computing displacements, stresses, and strains at defined points along the length, width, or within a cross-section of a given component.

Holtec's calculations determined that a positive margin of safety for basket performance criteria remains even with an average reduction of approximately 10 percent in MGVs for material yield stress, ultimate strength, and Young's modulus, a measure of a material's elasticity (ability to resume its original dimensions) under lengthwise tension or compression. The applicant also reported a calculated reduction of 20 percent of the MGV for area criteria measured during a tensile test. Positive margins remain in the criteria for peak stress, maximum deflection, and crack propagation. These minimum values are guaranteed to be met by the imposition of a sampling test plan based on the standards for critical service parts. The applicant also proposed to add the ability to conduct 100 percent testing of an MGV property within a lot if a sample fails re-testing.

This is the same change Holtec made to the HI-STORM 100 Flood/Wind (FW) Multipurpose MPC Storage System, CoC—No. 1032 using an acceptable evaluation that complied with 10 CFR 72.48, "Changes, tests, and experiments." The NRC staff reviewed these results and finds the proposed changes acceptable, because an adequate safety margin remains for basket performance criteria even with the reduced MGVs.

#### 4. New Spent Fuel Definitions

Holtec proposed to add new definitions for "undamaged fuel assembly," and "repaired/reconstituted fuel assembly" to provide further clarity for cask system users and greater consistency with NRC guidance for classifying fuel. In addition, the applicant says that these definitions will help some BWR users who have older, low-enriched, channeled BWR fuel with potential cladding defects that these users want to load for dry storage without prior placement in a damaged

fuel container. A discussion of the definition changes follows.

##### 4.a. Definition of "Undamaged Fuel Assembly"

The applicant proposed the new definition for "undamaged fuel assembly" to read: "(a) a fuel assembly without known or suspected cladding defects greater than pinhole leaks or hairline cracks and that can be handled by normal means; or b) a BWR fuel assembly with an intact channel and a maximum average initial enrichment of 3.3 percent U-235 by weight (wt-percent) that has no known or suspected grossly breached spent fuel rods and can be handled by normal means." Under this definition, an "undamaged fuel assembly" may be a repaired and reconstituted fuel assembly.

The applicant noted that with the currently approved definition, inspections to classify the fuel cladding of channeled BWR fuel as undamaged may be prohibitively costly and/or unjustifiable for maintaining worker radiation exposures as low as reasonably achievable. Holtec also noted, however, that a particular subset of older, less-enriched fuel has been shown to remain subcritical even with significant cladding damage and rearrangement of the fuel rods inside the channel. If this fuel does not have gross cladding breaches (defined as breaches larger than pinhole leaks or hairline cracks), can be handled by normal means, and has enrichment less than or equal to 3.3 weight-percent, Holtec asserted, the fuel does not require a damaged fuel container and is not limited to certain basket locations in the HI-STORM 100 Cask System's MPC model 68 designed for BWR fuel.

Under the NRC's ISG-1, "Classifying the Condition of Spent Nuclear Fuel for Interim Storage and Transportation Based on Function," undamaged fuel may contain some cladding defects if it is safeguarded from high temperatures and/or oxidation and does not contain gross cladding breaches. Because HI-STORM 100 Cask System MPCs are backfilled with helium and shown to keep peak fuel cladding temperatures below the limits in ISG 11, "Cladding Considerations for the Transportation and Storage of Spent Fuel," the staff has determined that this fuel is protected during storage from temperatures that would lead to gross ruptures. Also, as long as the fuel meets ISG-1 and does not already contain a gross breach, the staff concludes that there are no means for the release of fuel fragments during storage. In addition, fuel that contains an assembly defect may be considered undamaged under ISG-1 if the fuel can

still meet fuel-specific and system-related functions. The NRC staff will therefore also consider repaired and/or reconstituted assemblies meeting these functions as undamaged under the applicant's proposed revised definition.

##### 4.b. Definition of "Repaired/Reconstituted Fuel Assembly"

As part of Amendment No. 9, Revision 1, Holtec proposed a new definition for a repaired or reconstituted fuel assembly as one that "contains dummy fuel rod(s) that displaces [sic] an amount of water greater than or equal to the original fuel rod(s) and/or which contains structural repairs so it can be handled by normal means." The applicant proposed this definition for clarification purposes and as a subset of the definition of "undamaged fuel." It is a common practice to repair a nuclear fuel assembly by removing a damaged fuel rod and replacing it with a dummy rod to allow the assembly to be returned to the reactor core. The NRC has approved this use in specific applications, and has provided guidance to 10 CFR part 50 licensees to ensure that the repair is performed within the requirements of the licensee's 10 CFR part 50 TSs and does not create an unreviewed safety question. Because a repaired/reconstituted fuel assembly is restored to a condition within the bounds of its original design and safety analysis, the NRC staff finds this type of assembly to be a subset of "undamaged fuel," and concludes that the applicant's proposed definition is consistent with ISG-1 and therefore acceptable.

#### 5. Conclusions

As documented in its Safety Evaluation Report (SER), the NRC staff performed a detailed safety evaluation of this proposed CoC amendment request. There are no significant changes to cask design requirements in the proposed CoC amendment. Considering the specific design requirements for each accident condition, the design of the cask would prevent loss of containment, shielding, and criticality control. If there is no loss of containment, shielding, or criticality control, the environmental impacts would be not be significant. This amendment does not reflect a significant change in design or fabrication of the cask. In addition, any resulting occupational exposures or offsite dose rates from the implementation of Amendment No. 9, Revision 1, would remain well within 10 CFR part 20 radiation safety limits. Therefore, the proposed CoC changes will not result in any radiological or non-radiological environmental impacts that significantly

differ from the environmental impacts evaluated in the environmental assessment (EA) supporting the May 1, 2000, final rule approving the original HI-STORM 100 Cask System CoC. There will be no significant changes in the types or amounts of any effluent released, no significant increase in individual or cumulative radiation exposures, and no significant increase in the potential for or consequences of radiological accidents.

This direct final rule revises the HI-STORM 100 Cask System listing in 10 CFR 72.214 by adding Amendment No. 9, Revision 1, to CoC No. 1014. The revision consists of the changes previously described, as set forth in the revised CoC and TSs. The revised TSs are identified in the SER.

The revised HI-STORM 100 Cask System design, when used under the conditions specified in the CoC, the TSs, and the NRC's regulations, will meet the requirements of 10 CFR part 72; therefore, adequate protection of public health and safety will continue to be ensured. When this direct final rule becomes effective, persons who hold a general license under 10 CFR 72.210 may load spent nuclear fuel into HI-STORM 100 Cask Systems that meet the criteria of Amendment No. 9, Revision 1, to CoC No. 1014 under 10 CFR 72.212.

#### V. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires that Federal agencies use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC will revise the Holtec HI-STORM 100 Cask System design listed in § 72.214, "List of Approved Spent Fuel Storage Casks." This action does not constitute the establishment of a standard that contains generally applicable requirements.

#### VI. Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), this rule is classified as Compatibility Category "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended, or the provisions of 10 CFR. Although

an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain requirements using mechanisms consistent with the particular State's administrative procedure laws, but classifying an NRC rule as Category "NRC" does not confer regulatory authority on the State.

#### VII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and 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).

#### VIII. Environmental Assessment and Finding of No Significant Environmental Impact

##### A. The Action

The action is to amend 10 CFR 72.214 to revise the Holtec HI-STORM 100 Cask System listing within the "List of Approved Spent Fuel Storage Casks" to include Amendment No. 9, Revision 1, to CoC No. 1014. Under the National Environmental Policy Act (NEPA) of 1969, as amended, and the NRC's regulations in subpart A of 10 CFR part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," the NRC has determined that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement (EIS) is not required. The NRC has made a finding of no significant impact on the basis of this EA.

##### B. The Need for the Action

The need for this direct final rule is to allow users of HI-STORM 100 Cask Systems under Amendment 9, Revision 1, to load for dry storage under a general license some PWR fuel assemblies with shorter cooling times for TPDs, and some BWR fuel assemblies that would otherwise have to remain in spent fuel storage pools. Specifically, Amendment No. 9, Revision 1, changes cooling time limits for TPDs, removes certain testing requirements for the fabrication of Metamic HT neutron-absorbing structural material, and reduces certain MGVs used in bounding calculations for this material. Amendment No. 9, Revision 1, also changes fuel definitions to classify certain BWR fuel within specified guidelines as undamaged fuel, which could avert the worker radiation exposures that would otherwise be

necessary to put this fuel into containers before loading them into MPCs.

#### C. Environmental Impacts of the Action

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent fuel under a general license in cask designs approved by the NRC. The potential environmental impact of using NRC-approved storage casks was initially analyzed in the EA for the 1990 final rule. The EA for this Amendment No. 9, Revision 1, tiers off of that EA for the July 18, 1990, final rule. Tiering on past environmental assessments is a standard process under NEPA. As stated in the Council on Environmental Quality's 40 Frequently Asked Questions, the tiering process makes each EIS/EA of greater use and meaning to the public as the plan or program develops without duplication of the analysis prepared for the previous impact statement.

Holtec HI-STORM 100 Cask Systems are designed to mitigate the effects of design basis accidents that could occur during storage. Design basis accidents account for human-induced events and the most severe natural phenomena reported for the site and surrounding area. Postulated accidents analyzed for an independent spent fuel storage installation, the type of facility at which a holder of a power reactor operating license would store spent fuel in casks in accordance with 10 CFR part 72, include tornado winds and tornado-generated missiles, a design basis earthquake, a design basis flood, an accidental cask drop, lightning effects, fire, explosions, and other incidents.

Considering the specific design requirements for each accident condition, the design of the cask would prevent loss of confinement, shielding, and criticality control. If there is no loss of confinement, shielding, or criticality control, the environmental impacts would be insignificant. This revision does not reflect a significant change in design or fabrication of the cask. There are no significant changes to cask design requirements in the proposed CoC revision. In addition, because there are no significant design or process changes, any resulting occupational exposures or offsite doses from the implementation of Amendment No. 9, Revision 1, would remain well within 10 CFR part 20 radiation protection limits. Therefore, the proposed CoC changes will not result in any radiological or non-radiological environmental impacts that differ significantly from the environmental impacts evaluated in the EA supporting the July 18, 1990, final rule. There will

be no significant change in the types or amounts of any effluent released, no significant increase in individual or cumulative radiation exposures, and no significant increase in the potential for or consequences of radiological accidents. The NRC staff documented these safety findings in the SER.

#### *D. Alternative to the Action*

The alternative to this action is to deny approval of Amendment No. 9, Revision 1, and end the direct final rule. Consequently, any 10 CFR part 72 general licensee that seeks to load spent fuel into a HI-STORM 100 Cask System in accordance with the changes described in proposed Amendment No. 9, Revision 1, would have to request an exemption from the requirements of 10 CFR 72.212 and 72.214. Under this alternative, interested licensees would have to prepare, and the NRC would have to review, each separate exemption request, thereby increasing the administrative burden on the NRC and the costs to each licensee. The environmental impacts of this no-action alternative would therefore be the same as or more than those for the action itself.

#### *E. Alternative Use of Resources*

Approval of Amendment No. 9, Revision 1, to CoC No. 1014 would result in no irreversible commitments of resources.

#### *F. Agencies and Persons Contacted*

No agencies or persons outside the NRC were contacted in connection with the preparation of this EA.

#### *G. Finding of No Significant Impact*

The environmental impacts of the action have been reviewed as required by the NRC's 10 CFR part 51 regulations. Based on the foregoing EA, the NRC concludes that this direct final rule entitled, "List of Approved Spent Fuel Storage Casks: Holtec International HI-STORM 100 Cask System; Amendment No. 9, Revision 1," will not have a significant effect on the human environment. Therefore, the NRC has determined that an EIS for this direct final rule is not necessary.

### **IX. Paperwork Reduction Act Statement**

This rule does not contain any information collection requirements, and is therefore not subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### *Public Protection Notification*

The NRC may not conduct or sponsor, and a person is not required to respond

to, a request for information or an information collection requirement unless the requesting document displays a currently valid Office of Management and Budget control number.

### **X. Regulatory Flexibility Certification**

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects only nuclear power plant licensees and Holtec. These entities do not fall within the definition of small entities set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

### **XI. Regulatory Analysis**

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent nuclear fuel under a general license in cask designs approved by the NRC. Any nuclear power reactor licensee can use NRC-approved cask designs to store spent nuclear fuel if it notifies the NRC in advance, the spent fuel is stored under the conditions specified in the cask's CoC, and the conditions of the general license are met. A list of NRC-approved cask designs is provided in 10 CFR 72.214. On May 1, 2000 (65 FR 25241), the NRC issued an amendment to 10 CFR part 72 that approved the HI-STORM 100 Cask System design by adding it to the list of NRC-approved cask designs in 10 CFR 72.214.

On July 1, 2014, Holtec submitted an application to revise the HI-STORM 100 Cask System as described in Section III, "Discussion of Changes," of this document.

The alternative to this action is to withhold approval of Amendment No. 9, Revision 1, and to require any 10 CFR part 72 general licensee seeking to load spent nuclear fuel into a HI-STORM 100 Cask System under the changes described in Amendment No. 9, Revision 1, to request an exemption from the requirements of 10 CFR 72.212 and 72.214. Under this alternative, each interested 10 CFR part 72 licensee would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee.

Approval of the direct final rule is consistent with previous NRC actions. Further, as documented in the SER and the EA, the direct final rule will have no adverse effect on public health and safety or the environment. This direct

final rule has no significant identifiable impact or benefit on other Government agencies. Based on this regulatory analysis, the NRC concludes that the requirements of the direct final rule are commensurate with the NRC's responsibilities for public health and safety and the common defense and security. No other available alternative is believed to be as satisfactory, and therefore, this action is recommended.

### **XII. Backfitting and Issue Finality**

For the reasons set forth below, the NRC has determined that the backfit rule (10 CFR 72.62) does not apply to this direct final rule, and therefore, a backfit analysis is not required.

This direct final rule revises CoC No. 1014, Amendment No. 9, for the Holtec HI-STORM 100 Cask System, as currently listed in 10 CFR 72.214, "List of Approved Spent Fuel Storage Casks." Amendment No. 9, Revision 1, reduces cooling time limits for TPDs in some fuel assemblies, removes a thermal conductivity testing requirement for the fabrication of Metamic HT neutron-absorbing structural material, and reduces the MGVs used in bounding calculations for this material. Amendment No. 9, Revision 1, also changes fuel definitions to classify certain BWR fuel within specified guidelines as undamaged fuel.

According to the certificate holder, casks have been manufactured under Amendment No. 9, the subject of this revision. Although Holtec (applicant, certificate holder) has manufactured some casks under the existing CoC No. 1014, Amendment No. 9, that is being revised by this direct final rule, Holtec, as the certificate holder, is not subject to backfitting protection under 10 CFR 72.62. Moreover, Holtec requested the change and requested to apply it to the existing casks manufactured under Amendment No. 9. Therefore, even if the certificate holder were deemed to be an entity protected from backfitting, this request represents a voluntary change and is not backfitting for Holtec.

Under 10 CFR 72.62, general licensees are entities that are protected from backfitting, and in this instance, Holtec has provided casks under CoC No. 1014, Amendment No. 9, to general licensees at the Braidwood, Byron, Farley, Hatch, and Vogtle reactor facilities. General licensees are required, pursuant to 10 CFR 72.212, to ensure that each cask conforms to the terms, conditions, and specifications of a CoC, and that each cask can be safely used at the specific site in question. Because the casks purchased and delivered under CoC No. 1014 Amendment No. 9, must now be evaluated under 10 CFR 72.212

consistent with the revisions in CoC No. 1014 Amendment 9, Revision 1, this change in the evaluation method and criteria constitutes a change in a procedure required to operate an independent spent fuel storage installation (ISFSI) and, therefore, would constitute backfitting under 10 CFR 72.62(a)(2).

In this instance, however, the affected general licensees voluntarily indicated their willingness to comply with the revised CoC. In order to provide these general licensees adequate time to implement the revised CoC, it now also incorporates a condition that provides general licensees 180 days from the effective date of Revision 1 to implement the changes authorized by this revision and to perform the

required evaluation. Therefore, although the general licensees are entities that are protected from backfitting, this request represents a voluntary change and is not backfitting for the general licensees.

In addition, the changes in CoC No. 1014, Amendment 9, Revision 1, do not apply to casks manufactured to the initial CoC 1014 or subsequent Amendments of CoC 1014. These changes therefore have no effect on current ISFSI general licensees using casks manufactured to the initial CoC 1014 or other amendments of CoC No. 1014. Thus, the NRC approval of CoC No. 1014, Amendment No. 9, Revision 1, does not constitute backfitting for general licensed users of the Holtec HI-STORM 100 Cask System that were manufactured to the initial CoC No.

1014 or to other amendments of CoC No. 1014, under 10 CFR 72.62, 10 CFR 50.109(a)(1), or the issue finality provisions in 10 CFR part 52.

For these reasons, no backfit analysis or additional documentation addressing the issue finality criteria in 10 CFR part 52 has been prepared by the NRC.

**XIII. Congressional Review Act**

The Office of Management and Budget has not found this to be a major rule as defined in the Congressional Review Act.

**XIV. 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.
Proposed CoC 1014 Amendment No. 9, Revision 1 .....	ML15156A941
Proposed CoC 1014 Amendment No. 9, Revision 1 Technical Specifications, Appendix A .....	ML15156A956
Proposed CoC 1014 Amendment No. 9, Revision 1 Technical Specifications, Appendix B .....	ML15156A970
Proposed CoC 1014 Amendment No. 9, Revision 1 Technical Specifications, Appendix A-100U .....	ML15156A982
Proposed CoC 1014 Amendment No. 9, Revision 1 Technical Specifications, Appendix B-100U .....	ML15156B000
Preliminary CoC 1014 Amendment No. 9, Revision 1 Safety Evaluation Report .....	ML15156B011
Request for Revision Application dated July 1, 2014 .....	ML14182A486
Notification by general licensees of voluntary acceptance of Revision 1 requirements dated August 28, 2015 .....	ML15240A233
Interim Staff Guidance 1, Classifying the Condition of Spent Nuclear Fuel for Interim Storage and Transportation Based on Function.	ML071420268
Interim Staff Guidance 11, Revision 3, Cladding Considerations for the Transportation and Storage of Spent Fuel .....	ML033230335
Interim Staff Guidance 23, Application of ASTM Standard Practice C1671-07 when performing technical reviews of spent fuel storage and transportation packaging licensing actions.	ML103130171

The NRC may post materials related to this document, including public comments, on the Federal rulemaking Web site at <http://www.regulations.gov> under Docket ID NRC-2015-0156. The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC-2015-0156); (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, Criminal penalties, Hazardous waste, Indians, Intergovernmental relations, Manpower training programs, Nuclear energy, Nuclear materials, Occupational safety and health, 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 adopts 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 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.

Section 72.44(g) also issued under Nuclear Waste Policy Act secs. 142(b) and 148(c), (d) (42 U.S.C. 10162(b), 10168(c), (d)).

Section 72.46 also issued under Atomic Energy Act sec. 189 (42 U.S.C. 2239); Nuclear Waste Policy Act sec. 134 (42 U.S.C. 10154).

Section 72.96(d) also issued under Nuclear Waste Policy Act sec. 145(g) (42 U.S.C. 10165(g)).

Subpart J also issued under Nuclear Waste Policy Act secs. 117(a), 141(h) (42 U.S.C. 10137(a), 10161(h)).

Subpart K also issued under sec. 218(a) (42 U.S.C. 10198).

■ 2. In § 72.214, Certificate of Compliance No. 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).

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

xxxx  
Amendment Number 9, Revision 1, Effective Date: March 21, 2016.

Safety Analysis Report (SAR)  
Submitted by: Holtec International.  
SAR 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 22nd day of December, 2015.

For the Nuclear Regulatory Commission.

**Glenn M. Tracy,**

*Acting, Executive Director for Operations.*

[FR Doc. 2015-33280 Filed 1-5-16; 8:45 am]

BILLING CODE 7590-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 884

[Docket No. FDA-2015-N-4408]

#### Medical Devices; Obstetrical and Gynecological Devices; Classification of the Intravaginal Culture System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the intravaginal culture system into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the intravaginal culture system's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

**DATES:** This order is effective January 6, 2015. The classification was applicable on November 2, 2015.

**FOR FURTHER INFORMATION CONTACT:** Jason Roberts, Center for Devices and

Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G218, Silver Spring, MD 20993-0002, 240-402-6400, [jason.roberts@fda.hhs.gov](mailto:jason.roberts@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with

the device or if FDA determines that the device submitted is not of "low-moderate risk" or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On February 23, 2015, INVO Bioscience, submitted a request for classification of the INVOcell™ Intravaginal Culture System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request for de novo classification in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on November 2, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 884.6165 (21 CFR 884.6165).

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an intravaginal culture system will need to comply with the special controls named in this final order. The device is assigned the generic name intravaginal culture system, and it is identified as a prescription device intended for preparing, holding, and transferring human gametes or embryos during intravaginal in vitro fertilization (IVF) or intravaginal culture procedures.

FDA has identified the following risks to health associated specifically with this type of device, as well as the measures required to mitigate these risks in table 1: