

# Rules and Regulations

Federal Register

Vol. 80, No. 222

Wednesday, November 18, 2015

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-2015-0186]

RIN 3150-AJ65

#### List of Approved Spent Fuel Storage Casks: NAC International, Inc., MAGNASTOR® Cask System; Certificate of Compliance No. 1031, Amendment Nos. 0-3, 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 NAC International, Inc. (NAC), MAGNASTOR® Cask System listing within the “List of approved spent fuel storage casks” to include Revision 1 to Amendment Nos. 0 (the initial Certificate), 1, 2, and 3 to Certificate of Compliance (CoC) No. 1031. Revision 1 to Amendment Nos. 0-3 to CoC No. 1031 makes changes to the Technical Specifications (TSs), including correcting a typographical error in two actual boron loadings in TS 4.1.1(a), and revising the decay times in Tables B2-4 (for Amendment Nos. 0 and 1) and B2-5 (for Amendment Nos. 2 and 3) in Appendix B of the TSs for minimum additional decay time required for spent fuel assemblies that contain nonfuel hardware.

**DATES:** The direct final rule is effective February 1, 2016, unless significant adverse comments are received by December 18, 2015. If the direct final rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the **Federal Register**.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 is able to ensure consideration only for

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-2015-0186. 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:** Solomon Sahle, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-3781; email: [Solomon.Sahle@nrc.gov](mailto:Solomon.Sahle@nrc.gov).

#### 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 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 Documents

## I. Obtaining Information and Submitting Comments

### A. Obtaining Information

Please refer to Docket ID NRC-2015-0186 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-2015-0186.
- 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-2015-0186 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. Procedural Background

This rule is limited to the changes contained in Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 and does not include other aspects of the MAGNASTOR® 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 that 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 February 1, 2016. However, if the NRC receives significant adverse comments on this direct final rule by December 18, 2015, the NRC will publish a document that withdraws this action, and will subsequently address the comments received in a final rule as a response to the companion proposed rule published in the Proposed Rule section of this issue of the **Federal Register**. Absent significant modifications to the proposed revisions requiring 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 TSs.

For detailed instructions on submitting 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 “[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 within 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 issued a final rule on November 21, 2008 (73 FR 70587), that approved the NAC MAGNASTOR® Cask System design to add Amendment No. 0 to the list of NRC-approved cask designs in 10 CFR 72.214 as CoC No. 1031. Subsequently on June 15, 2010 (75 FR 33678), the NRC issued a final rule adding Amendment No. 1 to CoC No. 1031 to the list of NRC-approved cask designs in 10 CFR 72.214. Similar final rules were issued on November 14, 2011 (76 FR 70331), and June 25, 2013 (78 FR 37927), to add Amendment Nos. 2 and 3 to CoC No. 1031, respectively, to the list of NRC-approved cask designs in 10 CFR 72.214.

By letter dated June 5, 2014 (ADAMS Accession No. ML14160A856), NAC submitted a technical deficiency report for the calculation error associated with the additional cooling time required for

fuel assemblies that contain nonfuel hardware—one issue sought to be addressed by this revision. In its letter, NAC stated that Duke Energy Carolinas, LLC (Duke Energy), hold the only two general licenses (Catawba Nuclear Station and McGuire Nuclear Station) that are loading and storing casks using Amendment No. 2 to CoC No. 1031; and that ZionSolutions is the only general licensee currently loading and storing casks using Amendment No. 3 to CoC No. 1031. According to NAC, no casks manufactured under CoC No. 1031, Amendment Nos. 0 and 1, have been purchased by a general licensee. Subsequently, NAC contacted the licensees loading and storing casks Amendment Nos. 2 and 3 to CoC No. 1031 to notify them of the errors and to determine whether any loaded casks did not meet or planned loading would not meet the correct additional cool times.

In its revision request dated January 14, 2015, NAC provided letters from both Duke Energy and ZionSolutions discussing the actions Duke Energy and ZionSolutions took after being notified of the errors. Duke Energy established administrative controls to ensure that all loaded storage casks will meet the proposed cooling time limits in Table B2–5, which are more conservative than the additional cooling time limits in Table B2–5 of the TSs for Amendment No. 2. Duke Energy evaluated the five already-loaded storage systems to ensure compliance with NAC’s proposed Table B2–5 (correct additional cooling times for spent fuel assemblies that contain control components). Duke Energy determined that all five already-loaded systems meet NAC’s proposed Table B2–5. Additionally, Duke Energy stated that the five storage casks loaded since Duke Energy implemented administrative controls to ensure compliance with NAC’s proposed Table B2–5 also meet both the TSs and NAC’s proposed Table B2–5. Duke Energy documented these results within the Duke Energy corrective action program.

ZionSolutions initiated a condition report to review the loading records of the 20 already-loaded storage systems and those storage systems that ZionSolutions planned to continue loading using this amendment. ZionSolutions also established administrative controls to ensure that all loaded storage casks will meet the proposed cooling time limits in NAC’s proposed Table B2–5, which are more conservative than the additional cooling time limits in Table B2–5 of the TSs for Amendment No. 3.

#### IV. Discussion of Changes

By application dated June 20, 2014 (ADAMS Accession No. ML14174B095), as supplemented January 14, 2015 (ADAMS Accession No. ML15016A047), NAC submitted an application for revision to Amendment Nos. 0 (the initial certificate), 1, 2, and 3 to CoC No. 1031, MAGNASTOR® Cask System. Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 makes changes to the TSs, including correcting a typographical error in two actual boron loadings in TS 4.1.1(a), and revising the decay times in Tables B2–4 (for Amendment Nos. 0 and 1) and B2–5 (for Amendment Nos. 2 and 3) in Appendix B of the TSs for minimum additional decay time required for spent fuel assemblies that contain nonfuel hardware.

As documented in the Safety Evaluation Reports (SERs) (ADAMS Accession Nos. ML15180A092, ML15180A141, ML15180A220, and ML15180A281), for Revision 1 to Amendment Nos. 0–3 to CoC No. 1031, the NRC staff performed detailed safety evaluations of the proposed CoC revision request. There are no significant changes to cask design requirements in the proposed CoC revision. 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 insignificant. This amendment does not reflect a significant change in design or fabrication of the cask. In addition, any resulting occupational exposure or offsite dose rates from the implementation of Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 would remain well within the 10 CFR part 20 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 supporting the July 18, 1990, final rule. There will be no significant change in the types or significant revisions in the amounts of any effluent released, no significant increase in the individual or cumulative radiation exposure, and no significant increase in the potential for or consequences from radiological accidents.

This direct final rule revises the MAGNASTOR® Cask System listing in 10 CFR 72.214 by adding Revision 1 to Amendment Nos. 0–3 to CoC No. 1031. The amendment 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 MAGNASTOR® cask design, when used under the conditions specified in the CoC, the TS, 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 MAGNASTOR® Cask Systems that meet the criteria of Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 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 that are 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 MAGNASTOR® Cask System design listed in 10 CFR 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 direct final rule is classified as Compatibility Category “NRC.” Compatibility is not required for Category “NRC” regulations. The NRC program elements in this category are those that 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 via a mechanism that is consistent with the particular State's administrative procedure laws, but 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, 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 MAGNASTOR® Cask System listing within the “List of approved spent fuel storage casks” to include Revision 1 to Amendment Nos. 0–3 to CoC No. 1031. Under the National Environmental Policy Act 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 is not required. The NRC has made a finding of no significant impact on the basis of this environmental assessment.

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

This direct final rule amends the CoC for the MAGNASTOR® Cask System design within the list of approved spent fuel storage casks that power reactor licensees can use to store spent fuel at reactor sites under a general license. Specifically, Revision 1 to Amendment Nos. 0–3 to CoC No. 1031, corrects a typographical error in two actual boron loadings in TS 4.1.1(a), and revises the decay times in Tables B2–4 (for Amendment Nos. 0 and 1) and B2–5 (for Amendment Nos. 2 and 3) in Appendix B of the TSs for minimum additional decay time required for spent fuel assemblies that contain nonfuel hardware.

##### 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 environmental assessment for the 1990 final rule. The environmental assessment for this amendment tiers off of the environmental assessment for the July 18, 1990, final rule. Tiering on past environmental assessments is a standard process under the National Environmental Policy Act.

The NAC MAGNASTOR® Cask System is 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 (ISFSI), 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 containment, shielding, and criticality control. If there is no loss of confinement, shielding, or criticality control, the environmental impacts would be insignificant. This amendment 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 amendment. In addition, because there are no significant design or process changes, any resulting occupational exposure or offsite dose rates from the implementation of Revision 1 to Amendments Nos. 0–3 to CoC No. 1031 would remain well within the 10 CFR part 20 limits. Therefore, the proposed CoC revision will not result in any radiological or non-radiological environmental impacts that significantly differ from the environmental impacts evaluated in the environmental assessment supporting the July 18, 1990, final rule. There will be no significant change in the types or significant revisions in the amounts of any effluent released, no significant increase in the individual or cumulative radiation exposure, and no significant increase in the potential for or consequences from radiological accidents. The NRC staff documented its safety findings in the SERs for these revisions.

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

The alternative to this action is to deny approval of Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 and end the direct final rule. Consequently, any 10 CFR part 72 general licensee that seeks to load spent nuclear fuel into MAGNASTOR® Cask Systems in accordance with the changes described in proposed Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 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, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee. Therefore, the environmental impacts would be the same or less than the action.

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

Approval of Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 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 environmental assessment.

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

The environmental impacts of the action have been reviewed under the requirements in 10 CFR part 51. Based on the foregoing environmental assessment, the NRC concludes that this direct final rule entitled, “List of Approved Spent Fuel Storage Casks: NAC International, Inc., MAGNASTOR® Cask System; Certificate of Compliance No. 1031, Amendment Nos. 0–3, Revision 1,” will not have a significant effect on the human environment. Therefore, the NRC has determined that an environmental impact statement is not necessary for this direct final rule.

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

This direct final rule does not contain any information collection requirements and, therefore, is 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 NAC. These entities do not fall within the scope of 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 contained in 10 CFR 72.214. The NRC issued a final rule on November 21, 2008 (73 FR 70587), that approved the NAC MAGNASTOR® Cask System design to add Amendment No. 0 to the list of NRC-approved cask designs in 10 CFR 72.214 as CoC No. 1031. Subsequently on June 15, 2010 (75 FR 33678), the NRC issued a final rule adding Amendment No. 1 to CoC No. 1031 to the list of NRC-approved cask designs in 10 CFR 72.214. Similar final rules were issued on November 14, 2011 (76FR 70331), and June 25, 2013 (78 FR 37927), to add Amendment Nos. 2 and 3 to CoC No. 1031, respectively, to the list of NRC-approved cask designs in 10 CFR 72.214.

On June 20, 2014, as supplemented January 14, 2015, NAC submitted an application to revise the MAGNASTOR® Cask Systems as described in Section IV, “Discussion of Changes,” of this document.

The alternative to this action is to withhold approval of Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 and to require any 10 CFR part 72 general licensee seeking to load spent nuclear fuel into the MAGNASTOR® Cask System under the changes described in Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 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 this direct final rule is consistent with previous NRC actions. Further, as documented in the SERs and the environmental assessment, 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**

The NRC has determined that the backfit rule (10 CFR 72.62) does not apply to this direct final rule. Therefore, a backfit analysis is not required. This direct final rule revises Amendment Nos. 0–3 for CoC No. 1031 for the MAGNASTOR® Cask System, as currently listed in 10 CFR 72.214, “List of approved spent fuel storage casks.” Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 corrects a typographical error in two actual boron loadings in TS 4.1.1(a), and revises the decay times in Tables B2–4 (for Amendment Nos. 0 and 1) and B2–5 (for Amendment Nos. 2 and 3) in Appendix B of the TSs for minimum additional decay time required for spent fuel assemblies that contain nonfuel hardware.

Although NAC has manufactured casks under existing CoC No. 1031, Amendment Nos. 0–3, that are being revised by this final rule, NAC, as the vendor, is not subject to backfitting protection under 10 CFR 72.62. Moreover, NAC requested these changes and has requested to apply it to the existing casks manufactured under Amendment Nos. 0–3. Therefore, even if the vendor were deemed to be an entity protected from backfitting, this request represents a voluntary change and is not backfitting for the vendor.

Under 10 CFR 72.62, general licensees are entities that are protected from backfitting. However, according to NAC, no general licensees have purchased the systems under CoC No. 1031, Amendment Nos. 0 and 1, which are, in part, the subject of this revision.

Therefore, the changes in CoC No. 1031, Amendment Nos. 0 and 1, which are approved in this direct final rule do not fall within the definition of backfitting under 10 CFR 72.62 or 10 CFR 50.109(a)(1), or otherwise represent an inconsistency with the issue finality provisions applicable to combined licenses in 10 CFR part 52 for general licensees.

According to NAC, casks under CoC No. 1031, Amendment Nos. 2 and 3, have been provided to two general licensees (Duke Energy Carolinas, LLC, loaded under CoC No. 1031, Amendment No. 2; and Zion Solutions loaded under CoC No. 1031, Amendment No. 3). 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 delivered under CoC No. 1031, Amendment Nos. 2 and 3, now must be evaluated under 10 CFR 72.212 consistent with Revision 1 to Amendment Nos. 2 and 3 to CoC No. 1031, this change in the evaluation method and criteria constitutes a change in a procedure required to operate an ISFSI and, therefore, would constitute backfitting under 10 CFR 72.62(a)(2).

However, in this instance, NAC has provided documentation from the general licensees voluntarily indicating their lack of objection to Revision 1 to, Amendment Nos. 2 and 3 to CoC No. 1031. Specifically, in this instance, both licensees indicated their intention to upgrade their existing CoC No. 1031, Amendment Nos. 2 and 3, storage fleet to Amendment Nos. 4 or 5 of CoC No. 1031. These later amendments to CoC No. 1031 are consistent with the corrections being made in this revision. Therefore, although the general licensees are entities protected from

backfitting, this request represents a voluntary change and is not backfitting. In order to provide general licensees adequate time to implement the revised CoC in the event that they have not upgraded to Amendment Nos. 4 or 5 by the time these revisions become effective, the revised CoC also incorporates a condition that provides general licensees 180 days from the effective date of Revision 1, for each revised certificate, to implement the changes authorized by this revision and to perform the required evaluation.

In addition, the changes in Revision 1 to CoC No. 1031, Amendment Nos. 0–3 to CoC No. 1031, do not apply to casks which were manufactured to other amendments of CoC No. 1031, and, therefore, have no effect on current ISFSI licensees using casks which were manufactured to other amendments of CoC No. 1031. For these reasons, NRC approval of Revision 1 to, Amendment Nos. 0–3 to CoC No. 1031, does not constitute backfitting for users of the MAGNASTOR® Cask System which were manufactured to other amendments of CoC No. 1031, under 10 CFR 72.62, 10 CFR 50.109(a)(1), or the issue finality provisions applicable to combined licenses in 10 CFR part 52.

Accordingly, no backfit analysis or additional documentation addressing the issue finality criteria in 10 CFR part 52 has been prepared by the staff.

**XIII. Congressional Review Act**

This action is not a major rule as defined in the Congressional Review Act (5 U.S.C. 801–808).

**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 No. 1031, Amendment No. 0, Revision 1 .....	ML15180A230.
Proposed CoC No. 1031 Amendment No. 0, Revision 1, TS Appendix A .....	ML15180A238.
Proposed CoC No. 1031 Amendment No. 0, Revision 1, TS Appendix B .....	ML15180A270.
Proposed SER for CoC No. 1031 Amendment No. 0, Revision 1 .....	ML15180A281.
Proposed CoC No. 1031, Amendment No. 1, Revision 1 .....	ML15180A161.
Proposed CoC No. 1031 Amendment No. 1, Revision 1, TS Appendix A .....	ML15180A164.
Proposed CoC No. 1031 Amendment No. 1, Revision 1, TS Appendix B .....	ML15180A192.
Proposed SER for CoC No. 1031 Amendment No. 1, Revision 1 .....	ML15180A220.
Proposed CoC No. 1031, Amendment No. 2, Revision 1 .....	ML15180A114.
Proposed CoC No. 1031, Amendment No. 2, Revision 1, TS Appendix A .....	ML15180A119.
Proposed TS Amendment No. 2, Revision 1, TS Appendix B .....	ML15180A128.
Proposed SER for CoC No. 1031 Amendment No. 2, Revision 1 .....	ML15180A141.
Proposed CoC No. 1031, Amendment No. 3, Revision 1 .....	ML15180A033.
Proposed CoC No. 1031 Amendment No. 3, Revision 1, TS Appendix A .....	ML15180A077.
Proposed CoC No. 1031 Amendment No. 3, Revision 1, TS Appendix B .....	ML15180A087.
Proposed SER for CoC No. 1031 Amendment No. 3, Revision 1 .....	ML15180A092

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–2015–0186. 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–2015–0186); (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 is adopting 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 No. 1031 is revised to read as follows:

#### § 72.214 List of approved spent fuel storage casks.

\* \* \* \* \*

Certificate Number: 1031.

Initial Certificate Effective Date: February 4, 2009, superseded by Initial Certificate, Revision 1, on February 1, 2016.

Initial Certificate, Revision 1, Effective Date: February 1, 2016.

Amendment Number 1 Effective Date: August 30, 2010, superseded by Amendment Number 1, Revision 1, on February 1, 2016.

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

Amendment Number 2 Effective Date: January 30, 2012, superseded by Amendment Number 2, Revision 1, on February 1, 2016.

Amendment Number 2, Revision 1, Effective Date: February 1, 2016.

Amendment Number 3 Effective Date: July 25, 2013, superseded by Amendment Number 3, Revision 1, on February 1, 2016.

Amendment Number 3 Revision 1, Effective Date: February 1, 2016.

Amendment Number 4 Effective Date: April 14, 2015.

Amendment Number 5 Effective Date: June 29, 2015.

SAR Submitted by: NAC International, Inc.

SAR Title: Final Safety Analysis Report for the MAGNASTOR® System. Docket Number: 72–1031.

Certificate Expiration Date: February 4, 2029.

Model Number: MAGNASTOR®.

\* \* \* \* \*

Dated at Rockville, Maryland, this 5th day of November, 2015.

For the Nuclear Regulatory Commission.

Glenn M. Tracy,

Acting, Executive Director for Operations.

[FR Doc. 2015–29424 Filed 11–17–15; 8:45 am]

BILLING CODE 7590–01–P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

21 CFR Parts 1, 11, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA–2011–N–0920]

RIN 0910–AG36

#### Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Clarification of Compliance Date for Certain Food Establishments

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

**ACTION:** Final rule; clarification of compliance date for certain food establishments.

**SUMMARY:** The Food and Drug Administration (FDA or we) is clarifying the compliance date that we provided for certain food establishments subject to a final rule that published in the **Federal Register** of September 17, 2015. Among other things, that final rule amended our regulation for current good manufacturing practice in manufacturing, packing, or holding human food to modernize it, and to add requirements for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish and implement hazard analysis and risk-based preventive controls for human food. We are taking this action in response to requests for clarification of the compliance date for facilities that manufacture, process, pack, or hold grade “A” milk or milk products and that are regulated under the National Conference on Interstate Milk Shipments (NCIMS) system.

**DATES:** The compliance date under the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (published on September 17, 2015 at 80 FR 55908) for grade “A” milk and milk products covered by NCIMS under the PMO is September 17, 2018.

#### FOR FURTHER INFORMATION CONTACT:

Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2166.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of September 17, 2015 (80 FR 55908), we published a final rule entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” (the final human preventive controls rule). Among other things, the final human preventive controls rule amended our regulation for current good manufacturing practice in manufacturing, packing, or holding human food to modernize it, and to add requirements for domestic and foreign facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d) to establish and implement hazard analysis and risk-based preventive controls for human food. In the preamble to the final human preventive controls rule (80 FR 55908), we stated that the rule is effective November 16, 2015, and provided for compliance dates of 1 to 3 years in most cases.