APHIS. In the absence of data establishing the need for annual booster vaccinations, labeling must bear the following statement: “The need for annual booster vaccination has not been established for this product; consultation with a veterinarian is recommended.”

(j) All but very small final container labels for feline panleukopenia vaccines shall contain the following recommendations for use:

(1) Killed virus vaccines. Vaccinate healthy cats with one dose, except that if the animal is less than 12 weeks of age, a second dose should be given at 12 to 16 weeks of age.

(2) Modified live virus vaccines. Vaccinate healthy cats with one dose, except that if the animal is less than 12 weeks of age, a second dose should be given at 12 to 16 weeks of age.

(m) All labels for autogenous biologics must specify the name of the microorganism(s) or antigen(s) that they contain, and shall bear the following statement: “Potency and efficacy of autogenous biologics have not been established. This product is prepared for use only by or under the direction of a veterinarian or approved specialist.”

(o) All labels for conditionally licensed products shall bear the following statement: “This product license is conditional; efficacy and potency have not been fully demonstrated.”

PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

9. The authority citation for part 114 continues to read as follows:


10. Section 114.11 is revised to read as follows:

§ 114.11 Storage and handling.

Biological products at licensed establishments must be protected at all times against improper storage and handling. Completed product must be kept under refrigeration at 35 to 46 °F (2 to 8 °C), unless the inherent nature of the product makes storage at different temperatures advisable, in which case, the proper storage temperature must be specified in the filed Outline of Production. All biological products to be shipped or delivered must be securely packed.

Done in Washington, DC this 7th day of January 2011.

John Ferrell,

Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2011–648 Filed 1–12–11; 8:45 am]
BILLING CODE 4310–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN 3150–AI89

[NRC–2011–0002]

List of Approved Spent Fuel Storage Casks: NUHOMS® HD System Revision 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is proposing to amend its spent fuel storage cask regulations by revising the Transnuclear, Inc. (TN) NUHOMS® HD System listing within the “List of Approved Spent Fuel Storage Casks” to include Amendment No. 1 to Certificate of Compliance (CoC) Number 1030. Amendment No. 1 would revise the definitions for Damaged Fuel Assembly and Transfer Operations; add definitions for Fuel Class and Reconstituted Fuel Assembly; add Combustion Engineering 16x16 class fuel assemblies as authorized contents; reduce the minimum off-normal ambient temperature from −20 °F to −21 °F; expand the authorized contents of the NUHOMS® HD System to include pressurized water reactor fuel assemblies with control components; reduce the minimum initial enrichment of fuel assemblies from 1.5 weight percent uranium-235 to 0.2 weight percent uranium-235; clarify the requirements of reconstituted fuel assemblies; add requirements to qualify metal matrix composite neutron absorbers with integral aluminum cladding; clarify the requirements for neutron absorber tests; delete use of nitrogen for draining the water from the dry shielded canister (DSC), and allow only helium as a cover gas during DSC cavity water removal operations; and make corresponding changes to the technical specifications (TS).

DATES: Comments on the proposed rule must be received on or before February 14, 2011.

ADDRESSES: Please include Docket ID NRC–2011–0002 in the subject line of your comments. For instructions on submitting comments and accessing documents related to this action, see Section I, “Submitting Comments and Accessing Information” in the SUPPLEMENTARY INFORMATION section of this document. You may submit comments by any one of the following methods.


Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff. E-mail comments to: Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301–415–1677.

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

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

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal Rulemaking Web site, http://www.regulations.gov. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this document using the following methods:

NRC’s Public Document Room (PDR): The public may examine and have
NRC is publishing this proposed rule concurrently as a direct final rule in the Rules and Regulations section of this Federal Register. Adequate protection of public health and safety continues to be ensured. The direct final rule will become effective on March 29, 2011. However, if the NRC receives significant adverse comments on the direct final rule by February 14, 2011, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments received in response to the proposed revisions in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

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

1. The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:
   a. The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis;
   b. The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record;
   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 TS.

For additional procedural information, see the direct Final Rule published in the Rules and Regulations section of this Federal Register.

Procedural Background

On May 6 and 7, 2010, respectively, a direct final rule (75 FR 24786) and companion proposed rule (75 FR 25120) were published in the Federal Register to revise the cask system listing for the TN NUHOMS® HD System by adding Amendment No. 1 to the list of approved spent fuel storage casks in Title 10 of the Code of Federal Regulations (10 CFR 72.214). After the rules were published, the applicant identified that a certain TS for Boral characterization (TS 4.3.1, “Neutron Absorber Tests”) was not written precisely and in a manner that could be readily and demonstrably implemented. On July 16, 2010, the NRC withdrew the direct final rule (75 FR 41369) and the companion proposed rule (75 FR 41404). The applicant submitted revised language for TS 4.3.1 (and Final Safety Analysis Report (FSAR) sections incorporated into the TS by reference) on July 26 and August 24, 2010, which NRC staff reviewed and found to be acceptable. This proposed rule includes the original Amendment No. 1 changes and the revised TS 4.3.1 and FSAR sections incorporated into the TS by reference.

This rule is limited to the changes contained in Amendment No. 1 to CoC No. 1090 and does not include other aspects of the NUHOMS® HD System design. Because NRC considers this action noncontroversial and routine, the
DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

14 CFR Part 39
RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 170 and ERJ 190 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

It has been reported during operational checks that some failures of the Escape Slide 4A4030–4 installed on the forward passenger and service door have occurred which prevented the door from opening.

This condition could delay an emergency evacuation and increase the chance of injury to passengers and flight crew.

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by February 28, 2011.

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

• Federal eRulemaking Portal: Go to http://www.regulations.gov. Follow the instructions for submitting comments.
• Fax: (202) 493–2251.
• Mail: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
• Hand Delivery: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

We will post all comments we receive, without change, to http://www.regulations.gov, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The Agência Nacional de Aviação Civil (ANAC), which is the aviation authority for Brazil, has issued Brazilian Airworthiness Directive 2009–11–01, dated November 30, 2009, applicable to Model ERJ 170 airplanes; and Airworthiness Directive 2009–08–02, dated August 18, 2009, applicable to Model ERJ 190 airplanes; (referred to after this as “the MCAI”), to correct an unsafe condition for the specified products.

MCAI 2009–11–01 states:

It has been reported during operational checks that some failures of the Escape Slide P/N [part number] 4A4030–2 and P/N 4A4030–4 installed on the forward passenger and service door have occurred which prevented the door from opening.

Since this condition could delay an emergency evacuation and increase the chance of injury to passengers and flight crew, a corrective action is required.

MCAI 2009–08–02 states:

It has been reported during operational checks some failures in the deployment of the Escape Slide P/N 104003–1 installed in the forward passenger and service door, preventing the door opening.

Since this condition could impede an emergency evacuation and increase the chance of injury to passengers and flight crew, a corrective action is required.

The required actions include modifying the escape slides of the forward passenger and service doors, and doing boroscope inspections for damage of the aspirator body and inlet cross valve. Corrective actions include replacing the aspirator body. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Goodrich Interiors has issued Service Bulletin 4A4030–25A379, dated August 10, 2009, for Model ERJ 170 airplanes; and Service Bulletin 104003–25A380, Revision 2, dated July 7, 2009, for Model ERJ 190 airplanes. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA’s Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our