

Proposed Rules

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. 03–016–2]

Cut Flowers From Countries With Chrysanthemum White Rust

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; reopening of a comment period.

SUMMARY: We are reopening the comment period for our proposed rule that would amend the cut flowers regulations to establish specific requirements for the importation of cut flowers that are hosts of chrysanthemum white rust (CWR) from countries where the disease is known to occur. We also proposed to amend the nursery stock regulations to update lists of countries where CWR is known to occur. This action will allow interested persons additional time to prepare and submit comments.

DATES: We will consider all comments that we receive on Docket No. 03–016–1 on or before October 21, 2005.

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

- **EDOCKET:** Go to <http://www.epa.gov/feddoCKET> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the “View Open APHIS Dockets” link to locate Docket No. 03–016–1.

- **Postal Mail/Commercial Delivery:** Please send four copies of your comment (an original and three copies) to Docket No. 03–016–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–016–1.

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov> and follow the instructions for locating Docket No. 03–016–1 and submitting comments.

Reading Room: You may read any comments that we receive on Docket No. 03–016–1 in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Ms. Sharon Porsche, Import Specialist, Commodity Import Analysis and Operation, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 734–5281.

SUPPLEMENTARY INFORMATION: On July 7, 2005, we published in the **Federal Register** (70 FR 39194–39199, Docket No. 03–016–1) a proposal to amend the cut flowers regulations to establish specific requirements for the importation of cut flowers that are hosts of chrysanthemum white rust (CWR) from countries where the disease is known to occur. We also proposed to amend the nursery stock regulations to update lists of countries where CWR is known to occur.

Comments on the proposed rule were required to be received on or before September 6, 2005. We are reopening the comment period on Docket No. 03–016–1 until October 21, 2005, an additional 45 days from the original close of the comment period. This action will allow interested persons additional time to prepare and submit comments. We will also consider all comments received between September 7, 2005 (the day after the close of the original comment period) and the date of this notice.

Done in Washington, DC, this 13th day of September 2005.

W. Ron DeHaven,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–18604 Filed 9–19–05; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN 3150–AH77

List of Approved Spent Fuel Storage Casks: Standardized NUHOMS®–32PT, –24PHB, and –24PTH Revision 8

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations revising the Transnuclear, Inc., Standardized NUHOMS® System listing within the “List of approved spent fuel storage casks” to include Amendment No. 8 to Certificate of Compliance Number (CoC No.) 1004. Amendment No. 8 to the Standardized NUHOMS® System CoC would add a new spent fuel storage and transfer system, designated the NUHOMS®–24PTH System, and modify the NUHOMS®–32PT and –24PHB dry shielded canister designs.

DATES: Comments on the proposed rule must be received on or before October 20, 2005.

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number (RIN 3150–AH77) in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including personal information such as social security numbers and birth dates in your submission.

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

E-mail comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your

comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking Web site at <http://ruleforum.llnl.gov>. Address questions about our rulemaking Web site to Carol Gallagher (301) 415-5905; e-mail cag@nrc.gov. Comments can also be submitted via the Federal eRulemaking Portal <http://www.regulations.gov>.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays (telephone (301) 415-1966).

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

Publicly available documents related to this rulemaking may be viewed electronically on the public computers at the NRC's Public Document Room (PDR), O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can be viewed and downloaded electronically via the NRC rulemaking Web site at <http://ruleforum.llnl.gov>.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/NRC/ADAMS/index.html>. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr@nrc.gov. An electronic copy of the proposed CoC, Technical Specifications (TS), and preliminary safety evaluation report (SER) can be found under ADAMS Package Accession No. ML051610554.

FOR FURTHER INFORMATION CONTACT: Jayne M. McCausland, telephone (301) 415-6219, e-mail, jmm2@nrc.gov of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule published in the final rules section of this **Federal Register**.

Procedural Background

On May 25, 2005, a direct final rule (70 FR 29931) and companion proposed rule (70 FR 30015) were published in the **Federal Register**, to revise the cask

system listing for the Transnuclear, Inc. (TN) Standardized NUHOMS® System, by adding Amendment No. 8 to the list of approved spent fuel storage casks in 10 CFR 72.214. After the rules were published, staff became aware of needed changes in the TS associated with the CoC, and on July 15, 2005, the NRC withdrew the direct final rule (70 FR 40879) and the proposed rule (70 FR 40924). This rule includes the original Amendment No. 8 changes, revised TS 1.2.17c and 1.2.18, Table 1-11, and additional changes, as discussed in the direct final rule. These additional changes were originally to be addressed as a subsequent amendment. However, the withdrawal of the May 25, 2005, package allowed the staff to combine this information into Amendment 8. This results in a more effective and efficient use of resources.

This rule is limited to the changes contained in Amendment No. 8 to CoC No. 1004 and does not include other aspects of the Standardized NUHOMS® System cask 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 direct final rule will become effective on December 5, 2005. However, if the NRC receives significant adverse comments by October 20, 2005, then the NRC will publish a document that withdraws the direct final rule and will subsequently address the comments received in a final rule. 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, in a substantive response:

(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 CoC or TS.

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Criminal penalties, Manpower training programs, 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; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR part 72.

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

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

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97-425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100-203, 101 Stat. 1330-232, 1330-236 (42 U.S.C. 10162(b), 10168(c),(d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97-425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

2. In § 72.214, Certificate of Compliance 1004 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * *

Certificate Number: 1004.

Initial Certificate Effective Date:

January 23, 1995.

Amendment Number 1 Effective Date:

April 27, 2000.

Amendment Number 2 Effective Date:

September 5, 2000.

Amendment Number 3 Effective Date:

September 12, 2001.

Amendment Number 4 Effective Date:

February 12, 2002.

Amendment Number 5 Effective Date:

January 7, 2004.

Amendment Number 6 Effective Date:

December 22, 2003.

Amendment Number 7 Effective Date:

March 2, 2004.

Amendment Number 8 Effective Date:

December 5, 2005.

SAR Submitted by: Transnuclear, Inc.

SAR Title: Final Safety Analysis

Report for the Standardized NUHOMS® Horizontal Modular Storage System for Irradiated Nuclear Fuel.

Docket Number: 72-1004.

Certificate Expiration Date: January 23, 2015.

Model Number: NUHOMS®-24P, -52B, -61BT, -32PT, -24PHB, and -24PTH.

* * * *

Dated at Rockville, Maryland, this 1st day of September, 2005.

For the Nuclear Regulatory Commission.

Luis A. Reyes,*Executive Director for Operations.*

[FR Doc. 05-18663 Filed 9-19-05; 8:45 am]

BILLING CODE 7590-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 210, 211, and 212**

[Docket No. 2004N-0439]

Current Good Manufacturing Practice for Positron Emission Tomography Drugs**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing proposed regulations on current good manufacturing practice (CGMP) for positron emission tomography (PET) drug products. The regulations are intended to ensure that PET drug products meet the requirements of the Federal Food, Drug, and Cosmetic Act

(the act) regarding safety, identity, strength, quality, and purity. We are proposing to establish CGMP requirements for approved PET drug products. For investigational and research PET drugs, the proposed rule states that the requirement to follow CGMP may be met by producing PET drugs in accordance with the United States Pharmacopeia (USP) general chapter on compounding PET radiopharmaceuticals. We are proposing to establish these CGMP requirements for all PET drugs under the provisions of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance entitled "PET Drug Products—Current Good Manufacturing Practice (CGMP)."

DATES: Submit written or electronic comments by December 19, 2005. Submit written comments on the information collection requirements by October 20, 2005. See section VII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: You may submit comments, identified by Docket No. 2004N-0439, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the Electronic Submissions portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). or Regulatory Information

Number (RIN) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Brenda Uratani, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301-827-8941.

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