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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: Direct final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending 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 will 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: The final rule is effective December 5, 2005, unless significant adverse comments are received by October 20, 2005. 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. If the rule is withdrawn, timely notice will be published in the **Federal Register**.

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 located 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 Accession No. ML051610554.

CoC No. 1004, the revised TS, the underlying SER for Amendment No. 8,

and the Environmental Assessment (EA), are available for inspection at the NRC PDR, 11555 Rockville Pike, Rockville, MD. Single copies of these documents may be obtained from Jayne M. McCausland, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6219, e-mail jmm2@nrc.gov.

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:

Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended (NWPAA), requires that "[t]he Secretary [of the Department of Energy (DOE)] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission." Section 133 of the NWPAA states, in part, that "[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 218(a) for use at the site of any civilian nuclear power reactor."

To implement this mandate, the NRC approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule in 10 CFR part 72 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" containing procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on December 22, 1994 (59 FR 65898), that approved the Standardized NUHOMS® System (NUHOMS®-24P and -52B) cask designs and added them to the list of NRC-approved cask designs in

§ 72.214 as CoC No. 1004. Amendments 3, 5, and 6, respectively, added the -61BT, -32PT, and -24PHB designs to the Standardized NUHOMS® System.

Discussion

On September 19, 2003, and as supplemented on January 22, April 21, May 28, July 6, August 16, September 17, September 23, October 8, October 11, October 26, November 29, 2004, and January 14, March 15, June 10, and July 20, 2005, the certificate holder, Transnuclear, Inc. (TN), submitted an application to the NRC to amend CoC No. 1004 to add a new spent fuel storage and transfer system, designated the NUHOMS®-24PTH System, and to modify the NUHOMS®-32PT and -24PHB dry shielded canister (DSC) designs. The NUHOMS®-24PTH System consists of new or modified components: (1) The -24PTH DSC; (2) a new -24PTH DSC basket design; (3) a modified horizontal storage module (HSM), designated the HSM-H; and (4) a modified transfer cask (TC), designated the OS 197FC TC. The NUHOMS®-24PTH System is designed to store fuel with maximum average burnup of up to 62 gigawatts-day/metric ton of uranium (GWd/MTU); maximum average initial enrichment of 5.0 weight percent; minimum cooling time of 3.0 years; and maximum heat load of 40.8 kilowatts (kW) per DSC. TS 1.2.18 and Table 1-11 are augmented to restrict the -24PTH DSC basket heat loading patterns to those analyzed in the Safety Analysis Report (SAR), and TS 1.2.17c is revised to delete the use of air for blowdown of the -24PTH DSC before drying operations. The changes to the -32PT and -24PHB systems include: (1) Revising the -32PT DSC Fuel Specification and Fuel Qualification Tables to include low enrichment and reconstituted fuel; (2) revising the -32PT DSC Fuel Specification Tables to show minimum boron loading concentration; (3) expanding the authorized contents for the -24PHB DSC; (4) revising the TC/DSC handling and lifting height specifications in TS 1.2.10 and 1.2.13; and (5) clarifying DSC surface contamination actions in TS 1.2.12. No other changes to the Standardized NUHOMS® System cask design were requested in this application. The NRC staff performed a detailed safety evaluation of the proposed CoC amendment request and found that an acceptable safety margin is maintained. In addition, the NRC staff has determined that there continues to be reasonable assurance that public health and safety and the environment will be adequately protected.

This direct final rule revises the Standardized NUHOMS® System cask design listing in § 72.214 by adding Amendment No. 8 to CoC No. 1004. The amendment consists of changes to the TS as described above. The particular TS which are changed are identified in the NRC staff's SER for Amendment No. 8.

The amended Standardized NUHOMS® System, when used in accordance with the conditions specified in the CoC, the TS, and NRC regulations, will meet the requirements of part 72; thus, adequate protection of public health and safety will continue to be ensured.

Discussion of Amendments by Section

Section 72.214 List of Approved Spent Fuel Storage Casks

Certificate No. 1004 is revised by adding the effective date of Amendment Number 8.

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 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 direct final rule includes the original Amendment No. 8 changes, the revised TS 1.2.17c and 1.2.18, Table 1-11, and additional changes, as discussed above. 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 No. 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 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 December 5, 2005. However, if the NRC receives significant adverse comments by October 20, 2005, then the NRC will

publish a document that withdraws this action and will address the comments received in response to the proposed amendments published elsewhere in this issue of the **Federal Register**. 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.

These comments will be addressed in a subsequent final rule. The NRC will not initiate a second comment period on this action.

Voluntary Consensus Standards

The National Technology Transfer 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 revises the Standardized NUHOMS® System cask design listed in § 72.214 (List of NRC-approved spent fuel storage cask designs). This action does not constitute the establishment of a standard that establishes generally applicable requirements.

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 are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended (AEA), or the provisions of Title 10 of the Code of Federal Regulations. Although an Agreement State may not adopt program elements reserved to 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.

Plain Language

The Presidential Memorandum dated June 1, 1998, entitled "Plain Language in Government Writing," directed that the Government's writing be in plain language. The NRC requests comments on this direct final rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the heading **ADDRESSES** above.

Finding of No Significant Environmental Impact: Availability

Under the National Environmental Policy Act of 1969, as amended, and the NRC regulations in subpart A of 10 CFR part 51, the NRC has determined that this rule is not a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The rule amends the CoC for the Standardized NUHOMS[®] System 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. The amendment adds a new spent fuel storage and transfer system, designated the NUHOMS[®]-24PTH System, and modifies the NUHOMS[®]-32PT and -24PHB DSC designs. The NUHOMS[®]-24PTH System consists of new or modified components: (1) The -24PTH DSC; (2) a new -24PTH DSC basket design; (3) a modified horizontal storage module, designated the HSM-H; and (4) a modified transfer cask, designated the OS 197FC TC. The NUHOMS[®]-24PTH System is designed to store fuel with maximum average burnup of up to 62 GWd/MTU; maximum average initial enrichment of 5.0 weight percent; minimum cooling time of 3.0 years; and maximum heat load of 40.8 kW per DSC. TS 1.2.18 and Table 1-11 are augmented to restrict the -24PTH DSC basket heat loading patterns to those analyzed in the SAR, and TS 1.2.17c is revised to delete the use of air for blowdown of the -24PTH DSC before drying operations. The changes to the

-32PT and -24PHB systems include: (1) Revising the -32PT DSC Fuel Specification and Fuel Qualification Tables to include low enrichment and reconstituted fuel; (2) revising the -32PT DSC Fuel Specification Tables to show minimum boron loading concentration; (3) expanding the authorized contents for the -24PHB DSC; (4) revising the TC/DSC handling and lifting height specifications in TS 1.2.10 and 1.2.13; and (5) clarifying DSC surface contamination actions in TS 1.2.12. The EA and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. Single copies of the EA and finding of no significant impact are available from Jayne M. McCausland, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6219, e-mail jmm2@nrc.gov.

Paperwork Reduction Act Statement

This direct final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, Approval Number 3150-0132.

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 OMB control number.

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, 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 § 72.214. On December 22, 1994 (59 FR 65898), the NRC issued an amendment to part 72 that approved the Standardized NUHOMS[®] System (NUHOMS[®]-24P and -52B) by adding it to the list of NRC-approved cask designs in § 72.214. Amendments 3, 5, and 6, respectively, added the -61BT, -32PT, and -24PHB designs to the Standardized NUHOMS[®] System. On

September 19, 2003, and as supplemented on January 22, April 21, May 28, July 6, August 16, September 17, September 23, October 8, October 11, October 26, November 29, 2004, and January 14, March 15, June 10, and July 20, 2005, the certificate holder, TN, submitted an application to the NRC to amend CoC No. 1004 to add a new spent fuel storage and transfer system, designated the NUHOMS[®]-24PTH System, and to modify the NUHOMS[®]-32PT and -24PHB DSC designs. The NUHOMS[®]-24PTH System consists of new or modified components: (1) The -24PTH DSC; (2) a new -24PTH DSC basket design; (3) a modified horizontal storage module, designated the HSM-H; and (4) a modified transfer cask, designated the OS 197FC TC. The NUHOMS[®]-24PTH System is designed to store fuel with maximum average burnup of up to 62 GWd/MTU; maximum average initial enrichment of 5.0 weight percent; minimum cooling time of 3.0 years; and maximum heat load of 40.8 kW per DSC. TS 1.2.18 and Table 1-11 are augmented to restrict the -24PTH DSC basket heat loading patterns to those analyzed in the SAR, and TS 1.2.17c is revised to delete the use of air for blowdown of the -24PTH DSC prior to drying operations. The changes to the -32PT and -24PHB systems include: (1) Revising the -32PT DSC Fuel Specification and Fuel Qualification Tables to include low enrichment and reconstituted fuel; (2) revising the -32PT DSC Fuel Specification Tables to show minimum boron loading concentration; (3) expanding the authorized contents for the -24PHB DSC; (4) revising the TC/DSC handling and lifting height specifications in TS 1.2.10 and 1.2.13; and (5) clarifying DSC surface contamination actions in TS 1.2.12.

The alternative to this action is to withhold approval of this amended cask system design and issue an exemption to each general license. This alternative would cost both the NRC and the utilities more time and money because each utility would have to pursue an exemption.

Approval of the direct final rule will eliminate this problem and is consistent with previous NRC actions. Further, the direct final rule will have no adverse effect on public health and safety. This direct final rule has no significant identifiable impact or benefit on other Government agencies. Based on this discussion of the benefits and impacts of the alternatives, 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 thus, this action is recommended.

Regulatory Flexibility Certification

In accordance with 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 the licensing and operation of nuclear power plants, independent spent fuel storage facilities, and TN. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR part 121.

Backfit Analysis

The NRC has determined that the backfit rule (10 CFR 50.109 or 10 CFR 72.62) does not apply to this direct final rule because this amendment does not involve any provisions that would impose backfits as defined. Therefore, a backfit analysis is not required.

Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

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. 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: 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 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. 05–18662 Filed 9–19–05; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 2005N–0338]

Medical Devices; Dental Devices; Classification of Oral Rinse to Reduce the Adhesion of Dental Plaque

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the oral rinse to reduce the adhesion of dental plaque device into class II (special controls). The special control that will apply to the device is the guidance document entitled "Class II Special Controls Guidance Document: Oral Rinse to Reduce the Adhesion of Dental Plaque." 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. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document that is the special control for this device.

DATES: This rule is effective October 20, 2005. The reclassification was effective March 28, 2005.

FOR FURTHER INFORMATION CONTACT: Robert Betz, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, ext. 125.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the 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 (the amendments), 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