

and must pay the Agency for such holiday work at an hourly rate of \$44.40.

Done at Washington, DC, on January 17, 2002.

Margaret O'K. Glavin,

Acting Administrator.

[FR Doc. 02-1751 Filed 1-23-02; 8:45 am]

BILLING CODE 3410-DM-P

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 72

RIN 3150-AG87

#### List of Approved Spent Fuel Storage Casks: FuelSolutions™ Cask System Revision; Confirmation of Effective Date

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Direct final rule; confirmation of effective date.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is confirming the effective date of January 28, 2002, for the direct final rule that appeared in the **Federal Register** of November 14, 2001 (66 FR 56982). This direct final rule amended the NRC's regulations by revising the BNFL Fuel Solutions (FuelSolutions™) cask system listing within the "List of Approved Spent Fuel Storage Casks" to include Amendment No. 2 to Certificate of Compliance (CoC) Number 1026. Amendment No. 2 modified the Technical Specifications (TS) to allow the W74 canister to be placed in the transfer cask instead of the spent fuel pool until the affected storage cask is repaired or replaced. The TS were also modified to clarify the description of the other non-fissile material permitted to be stored in the W74 canister and to revise the temperatures to correspond to the liner thermocouples. This document confirms the effective date.

**DATES:** The effective date of January 28, 2002, is confirmed for this direct final rule.

**ADDRESSES:** Documents related to this rulemaking, including comments received, may be examined at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. These same documents may also be viewed and downloaded electronically via the rulemaking website (<http://ruleforum.llnl.gov>). For information about the interactive rulemaking website, contact Ms. Carol Gallagher (301) 415-5905; e-mail [CAG@nrc.gov](mailto:CAG@nrc.gov).

#### FOR FURTHER INFORMATION CONTACT:

Merri Horn, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone (301) 415-8126 (e-mail: [mlh1@nrc.gov](mailto:mlh1@nrc.gov)).

**SUPPLEMENTARY INFORMATION:** On November 14, 2001 (66 FR 56982), the NRC published in the **Federal Register** a direct final rule amending its regulations in 10 CFR 72 to revise the BNFL Fuel Solutions (FuelSolutions™) cask system listing within the "List of Approved Spent Fuel Storage Casks" to include Amendment No. 2 to Certificate of Compliance (CoC) Number 1026. Amendment No. 2 modified the Technical Specifications (TS) to allow the W74 canister to be placed in the transfer cask instead of the spent fuel pool until the affected storage cask is repaired or replaced. The TS were also modified to clarify the description of the other non-fissile material permitted to be stored in the W74 canister and to revise the temperatures to correspond to the liner thermocouples. In the direct final rule, NRC stated that if no significant adverse comments were received, the direct final rule would become final on the date noted above. The NRC did not receive any comments that warranted withdrawal of the direct final rule. Therefore, this rule will become effective as scheduled.

Dated at Rockville, Maryland, this 17th day of January, 2002.

For the Nuclear Regulatory Commission.

Michael T. Lesar,

Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration.

[FR Doc. 02-1719 Filed 1-23-02; 8:45 am]

BILLING CODE 7590-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 876

[Docket No. 01P-0304]

#### Medical Devices; Gastroenterology-Urology Devices; Classification of the Ingestible Telemetric Gastrointestinal Capsule Imaging System

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the ingestible telemetric gastrointestinal capsule imaging system device into class II (special controls). The special

controls that will apply to this device are set forth below. The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997 (FDAMA). The agency is classifying this device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

**DATES:** This rule is effective February 25, 2002.

#### FOR FURTHER INFORMATION CONTACT:

Carolyn Neuland, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1220.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In accordance with section 513(f)(1) of 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 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 the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the FDA regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.