

doses to an embryo/fetus or nursing child, or leaking sources are reportable on occurrence. An organization desiring to become a certifying entity must tender an application upon intent.

**5. Who will be required or asked to report:** Physicians and medical institutions holding an NRC license authorizing the administration of byproduct material or radiation therefrom to humans for medical use.

**6. An estimate of the number of responses:** 93,966 (26,850 NRC licensees, 67,116 Agreement State licensees). In addition, 4 new organizations are expected to apply to become certifying entities and 35 will be required to submit modified procedures.

**7. The estimated number of annual respondents:** 1,902 NRC licensees and 4,755 Agreement State licensees.

**8. An estimate of the total number of hours needed annually to complete the requirement or request:** Part 35: 877,807 hours (251,192 hours for NRC licensees, 626,381 hours for Agreement State licensees, and 234 hours for certifying organizations) (an average of 132 hours per licensee). In addition, there is a one-time burden of 2,956 hours for certifying organizations to submit new or modified procedures. NRC Form 313: 68 additional hours (48 hours for NRC licensees and 20 hours for Agreement State licensees).

**9. An indication of whether Section 3507(d), Pub. L. 104-13 applies:**  
Applicable

**10. Abstract:** 10 CFR Part 35, "Medical Use of Byproduct Material," is being restructured into a risk-informed performance-based regulation. The proposed rule contains mandatory requirements that apply to NRC licensees authorized to administer byproduct material or radiation therefrom to humans for medical use. In addition, requirements are being added for organizations desiring to be recognized by NRC as certifying organizations.

The information in the required reports and records is used by the NRC to ensure that public health and safety is protected, and that the possession and use of byproduct material is in compliance with the license and regulatory requirements.

Submit, by September 16, 1998, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the burden estimate accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

**4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?**

A copy of the submittal may be viewed free of charge at the NRC Public Document Room, 2120 L Street, NW (lower level), Washington, DC. The proposed rule indicated in "The title of the information collection" is or has been published in the **Federal Register** within several days of the publication date of this **Federal Register** Notice. Instructions for accessing the electronic OMB clearance package for the rulemaking have been appended to the electronic rulemaking. Members of the public may access the electronic OMB clearance package by following the directions for electronic access provided in the preamble to the titled rulemaking.

Comments and questions should be directed to the OMB reviewer by September 16, 1998:

Erik Godwin, Office of Information and Regulatory Affairs (3150-0010, and -0120), NEOB-10202, Office of Management and Budget, Washington DC 20503

Comments can also be submitted by telephone at (202) 395-3084.

The NRC Clearance Officer is Brenda Jo. Shelton, 301-415-7233.

Dated at Rockville, Maryland, this 11th day of August 1998.

For the Nuclear Regulatory Commission.

**Beth St. Mary,**

*Acting NRC Clearance Officer, Office of the Chief Information Officer.*

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BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** U. S. Nuclear Regulatory Commission (NRC).

**ACTION:** Notice of the OMB review of information collection and solicitation of public comment.

**SUMMARY:** The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

- 1. Type of submission:** Revision.
- 2. The title of the information collection:**

10 CFR 35.32 and 35.33 "Quality Management Program and Misadministrations"

- 3. The form number if applicable:** Not Applicable.

- 4. How often the collection is required:**

For quality management program (QMP):

**Reporting:** New applicants for medical use licenses, who plan to use byproduct material in limited diagnostic and therapy quantities under Part 35, must develop a written QMP and submit a copy of it to NRC. When a new modality involving therapeutic quantities of byproduct material is added to an existing license, current licensees must submit QMP modifications.

This ICR burden estimate is inflated by the one-time cost for the development and submission of QMPs for approximately 2000 Agreement States licensees in the ten Agreement States who have not adopted the rule and are not required to.

**Recordkeeping:** Records of written directives, administered dose or dosage, annual review, and recordable events, for 3 years.

For Misadministrations:

**Reporting:** Whenever a misadministration occurs.

**Recordkeeping:** Records of misadministrations for 5 years.

**5. Who will be required or asked to report:** NRC Part 35 licensees who use byproduct material in limited diagnostic and therapeutic ranges and similar type of licensees regulated by Agreement States.

**6. An estimate of the number of responses:** 3,194.

**7. The estimated number of annual respondents:** 6300 (for both reporting and recordkeeping).

**8. An estimate of the total number of hours needed annually to complete the requirement or request:** 34,743 hours for applicable licensees (Reporting: 24,400 Hrs/yr, and Recordkeeping: 10,343 Hrs/yr, or an average of 5.5 hrs per licensee).

**9. An indication of whether Section 3507(d), Pub. L. 104-13 applies:** Not Applicable.

**10. Abstract:** In the medical use of byproduct material, there have been instances where byproduct material was not administered as intended or was administered to a wrong individual, which resulted in unnecessary exposures or inadequate diagnostic or therapeutic procedures. The most frequent causes of these incidents were:

insufficient supervision, deficient procedures, failure to follow procedures, and inattention to detail. In an effort to reduce the frequency of such events, the NRC requires licensees to implement a quality management program (§ 35.32) to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician.

Collection of this information enables the NRC to ascertain whether misadministrations are investigated by the licensee and that corrective action is taken. Additionally, NRC has a responsibility to inform the medical community of generic issues identified in the NRC review of misadministrations.

On May 6, 1998, an invitation to comment on the information collection requirements for 10 CFR 35.32 and 35.33 was published in the **Federal Register** (63 FR 25098). NRC received two responses. The NRC is evaluating the reporting and recordkeeping requirements associated with this clearance as part of NRC's efforts to revise 10 CFR Part 35, "Medical Use of Byproduct Material," in its entirety. The proposed rule is expected to be published for comment in August 1998. The comments received in response to the May 1998 **Federal Register** notice will be considered during development of the final rule.

A copy of the final supporting statement may be viewed free of charge at the NRC Public Document Room, 2120 L Street, NW (lower level), Washington, DC. OMB clearance requests are available at the NRC worldwide web site (<http://www.nrc.gov>) under the FedWorld collection link on the home page tool bar. The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer by September 16, 1998: Erik Godwin, Office of Information and Regulatory Affairs (3150-0171), NEOB-10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395-3084.

The NRC Clearance Officer is Brenda Jo. Shelton, 301-415-7233.

Dated at Rockville, Maryland, this 5th day of August 1998.

For the Nuclear Regulatory Commission.

**Brenda Jo. Shelton,**

*NRC Clearance Officer, Office of the Chief Information Officer.*

[FR Doc. 98-22086 Filed 8-14-98; 8:45 am]

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## NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-413 and 50-414]

### Duke Energy Corporation; Notice of Consideration of Issuance of Amendments To Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of amendments to Facility Operating License Nos. NPF-35 and NPF-52, issued to Duke Energy Corporation (the licensee), for operation of the Catawba Nuclear Station, Units 1 and 2, located in York County, South Carolina.

The proposed amendments would revise the Technical Specifications (TS), deleting Surveillance Requirement 4.8.1.1.2.i.2. This requires the performance, every 10 years, of a pressure test of those portions of the diesel fuel oil system designed to Section III, subsection ND of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (ASME Code) at a test pressure equal to 110 percent of the system design pressure. This requirement is in conflict with a relief granted by the staff on February 13, 1995, authorizing the licensee to implement the alternative rules of ASME Section XI, Code Case N-498-1. Code Case N-498-1 permits the use of VT-2 visual examination in conjunction with a system pressure test on Class 3 systems in lieu of hydrostatic testing. The deletion of TS 4.8.1.1.2.i.2 would remove such conflict.

The licensee requested approval on an exigent basis pursuant to its request for enforcement discretion. The staff verbally granted the enforcement discretion on August 6, 1998, and affirmed it by a subsequent notice of enforcement discretion (NOED) letter dated August 7, 1998. The NOED stated that the enforcement discretion is in effect until the issuance of amendments to revise TS 4.8.1.1.2.i.2. The staff intends to issue such amendments within 4 weeks of the NOED letter. This issuance schedule would not be accommodated by the normal 30-day notice to the public.

Before issuance of the proposed license amendments, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

Pursuant to 10 CFR 50.91(a)(6) for amendments to be granted under exigent circumstances, the NRC staff

must determine that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

#### First Standard

Implementation of this amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated. Approval of this amendment will have no significant effect on accident probabilities or consequences. The diesel generator fuel oil system is not an accident initiating system; therefore, there will be no impact on any accident probabilities by the approval of this amendment. Each unit's diesel generator fuel oil system is currently fully capable of meeting its design basis accident mitigating function. Therefore, there will be no impact on any accident consequences.

#### Second Standard

Implementation of this amendment would not create the possibility of a new or different kind of accident from any accident previously evaluated. No new accident causal mechanisms are created as a result of NRC approval of this amendment request. No changes are being made to the plant which will introduce any new accident causal mechanisms. This amendment request does not impact any plant systems that are accident initiators, since the diesel generator fuel oil system is an accident mitigating system.

#### Third Standard

Implementation of this amendment would not involve a significant reduction in a margin of safety. Margin of safety is related to the confidence in the ability of the fission product barriers to perform their design functions during and following an accident situation. These barriers include the fuel cladding, the reactor coolant system, and the containment system. The performance of these fission product barriers will not be impacted by implementation of this proposed amendment. The diesel generator fuel oil system for each unit is already capable of performing as designed. No safety margins will be impacted.

Based upon the preceding analysis, Duke Energy [Corporation] has concluded that the proposed amendment does not involve a significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three