

proposed action will result in a process that is equivalent to the existing identification verification process.

#### *Alternative Use of Resources*

This action does not involve the use of any resources not previously considered in the Final Environmental Statement for the Byron Station, Units 1 and 2.

#### *Agencies and Persons Consulted*

In accordance with its state policy, on December 20, 1995, the staff consulted with the Illinois State official, Mr. Frank Niziolek, Head, Reactor Safety Section; Division of Engineering; Illinois Department of Nuclear Safety, regarding the environmental impact of the proposed action. The State official had no comments.

#### *Finding of No Significant Impact*

Based upon the foregoing environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed exemption.

For further details with respect to this action, see the licensee's letter dated November 6, 1995, which is available for public inspection at the Commission's Public Document Room, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Byron Public Library, 109 N. Franklin, P.O. Box 434, Byron, Illinois.

Dated at Rockville, Maryland, this 22nd day of December 1995.

For the Nuclear Regulatory Commission.  
Robert A. Capra,

*Director, Project Directorate III-2, Division of Reactor Projects—III/IV Office of Nuclear Reactor Regulation.*

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#### **Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget (OMB) Review**

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

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

**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).

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: One time submittal of a quality management program (QMP) for each existing and new licensee, when the QMP is modified, or when new modalities (uses) are added to an existing license. Misadministrations are reported as they occur. Records of written directives, administered dose or dosage, an annual review of the QMP, and recordable events must be maintained in auditable form for 3 years and misadministrations for 5 years.
5. Who will be required or asked to report: 10 CFR Part 35 licensees and equivalent Agreement State licensees who use byproduct material in limited diagnostic and therapeutic ranges.
6. An estimate of the number of responses: 3825.
7. The estimated number of annual respondents: 6388.
8. An estimate of the total number of hours needed annually to complete the requirement or request: Approximately 51,778 hours (reporting: 38,706 hrs/yr and recordkeeping: 13,072 hrs/yr).
9. An indication of whether Section 3507(d), Pub. L. 104-13 applies: applicable.
10. Abstract: In the medical use of byproduct material, there have been instances where byproduct material was not administered as intended or administered to a wrong individual which resulted in unnecessary exposures or inadequate or incorrect diagnostic or therapeutic procedures. The most frequent causes of these incidents were: insufficient supervision, deficient procedures, failure to follow procedures, and inattention to detail. To reduce the frequency of such events, the NRC requires licensees to implement a quality management program (10 CFR 35.32) to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician.

Records and reports to NRC are required for certain errors in the administration of limited diagnostic and

therapeutic quantities of byproduct material by medical use licensees. Section 35.33 clarifies these requirements to avoid confusion over whether certain events should be reported to NRC and to help ensure that the licensee is in compliance with the requirements. NRC has a responsibility to inform the medical community of generic issues identified in the NRC review of misadministrations.

NRC has revised the definition for "misadministration" in 10 CFR 35.2, "Definitions." The revision considerably reduces the number of "errors" that must be reported to the NRC or an Agreement State.

Collection of this information will enable the NRC to ascertain whether misadministrations are investigated by the licensee and that corrective action is taken.

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. Members of the public who are in the Washington, DC, area can access the submittal via modem on the Public Document Room Bulletin Board (NRC's Advanced Copy Document Library) NRC subsystem at FedWorld, 703-321-3339. Members of the public who are located outside of the Washington, DC, area can dial FedWorld, 1-800-303-9672, or use the FedWorld Internet address: fedworld.gov (Telnet). The document will be available on the bulletin board for 30 days after the signature date of this notice. If assistance is needed in accessing the document, please contact the FedWorld help desk at 703-487-4608.

Comments and questions should be directed to the OMB reviewer by January 29, 1996: Troy Hillier, 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 27th day of December 1995.

For the Nuclear Regulatory Commission.  
Gerald F. Cranford,

*Designated Senior Official for Information Resources Management.*

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