

mail, postage prepaid on counsel for defendants Interstate Bakeries Corporation and Continental Baking Company, respectively: Terry Grimm, Winston & Strawn, 35 West Wacker Drive, Chicago, IL 60604; and Donald Hibner, Sheppard, Mullin, Richter & Hampton, 48th Floor, 333 South Hope Street, Los Angeles, CA 90071-1448.

Dated: July 21, 1995.

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NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Notice of Pending Submittal to the Office of Management and Budget (OMB) for Review

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to OMB, and solicitation of public comment.

SUMMARY: NRC is preparing a submittal to OMB for review and continued approval of information collection requirements currently approved by OMB under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

1. *Title of the information collection:* 10 CFR 35.32 and 35.33, "Quality Management Program and Misadministrations".

2. *Current OMB approval number:* 3150-0171.

3. *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.

4. *Who will be required to report:* 10 CFR Part 35 licensees and equivalent Agreement State licensees who use byproduct material in limited diagnostic and therapeutic ranges.

5. *An estimate of the annual number of respondents:* 10 CFR 35.32: 6300 licensees, 10 CFR 35.33: 75 licensees.

6. *An estimate of the total number of hours needed to complete the*

requirements or request: Approximately 41,821 hours (Reporting: 35,035 hrs/yr, and Recordkeeping: 6,786 hrs/yr). The Commission is currently reviewing the compatibility requirements for the Agreement States. Relief from certain of these requirements would significantly reduce the burden associated with 10 CFR 35.32. If relief is granted to the Agreement States, the staff will submit a modification of the burden estimate that reflects the changes.

7. *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.

Specific comments requested within 60 days:

1. Is the proposed renewal of the collection of information necessary for NRC to properly perform its functions, including whether the information will have practical utility?

2. Is the estimate of burden 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 collection of information be minimized, including the use of automated collection techniques?

Members of the public may obtain, free of charge, a copy of the DRAFT OMB clearance submittal. This information can be obtained by Internet: SLM2@nrc.gov or by calling Sally L. Merchant at (301) 415-7874. The NRC anticipates that the OMB clearance submittal will be available for inspection in the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, DC, on August 18, 1995.

Comments and questions should be directed to the NRC Clearance Officer, Brenda Jo. Shelton, U.S. Nuclear Regulatory Commission, T-6 F 33, Washington, D.C., 20555-0001, (301) 415-7233.

Dated at Rockville, Maryland, this 2nd day of August 1995.

For the U.S. Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

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Joint Nuclear Regulatory Commission/ Environmental Protection Agency Guidance on the Storage of Mixed Radioactive and Hazardous Waste

AGENCY: Nuclear Regulatory Commission.

ACTION: Publication of joint guidance and request for public comment.

SUMMARY: The Nuclear Regulatory Commission and Environmental Protection Agency (EPA) are jointly publishing herein a draft guidance document on the storage of mixed radioactive and hazardous waste (mixed waste). The Agencies are developing this guidance to assist mixed waste generators forced to store their mixed waste, pending the development of adequate treatment and disposal capacity for commercially generated mixed waste. The guidance points out areas of flexibility within NRC and EPA regulations that relate to the storage of mixed waste. Further, the guidance is consistent with the general approach EPA is undertaking as it reviews its current regulatory program. The Agencies are soliciting comments from members of the regulated community, the States, and the public. Interested individuals may provide the Agencies with their comments on the proposed guidance by forwarding their written comments to NRC at the address listed in the ADDRESSES section.