May 7, 2004

SUMMARY OF INFORMATION COLLECTION REQUEST

Title: 10 CFR Part 35, Medical Use of Byproduct Material

Current Burden/Responses: 890,095 hours/214,402 responses

Proposed Burden/Responses: 1,113,217 hours/242,030 responses (51,309 responses from NRC licensees + 1,759 recordkeepers and 184,686 responses from Agreement State licensees + 6,332 recordkeepers)

Frequency of Response: On occasion, every 10 years, one-time for certifying entities

Reasons for Changes in Burden/Responses:

Although the number of NRC medical use licensees has increased from 1,655 to 1,759 for the clearance renewal period, the NRC licensee burden has decreased by 12,049 hours, from 254,079 hours during the last clearance period to 242,030 hours, based primarily on a better estimate of the number of licensees subject to certain requirements.

There are currently a total of 17,109 Agreement State licensees and 4,818 NRC licensees. Therefore, there are approximately 3.6 Agreement State licensees to each NRC licensee (4818 X 3.6 = 17,345). During the last clearance period this ratio was 2.5 Agreement State licensees to each NRC licensee. Therefore, using this new ratio, the burden for the Agreement States has increased by 235,364 hours from 635,695 to 871,059 hours because of the increase in the number of licensees, although the burden per respondent/recordkeeper has, for the most part remained unchanged.

In addition to the burden changes because of the increase in the number of licensees, the burden for several sections has been re-estimated based on experience. The burden in § 35.2060 associated with direct measurement of dosages required in § 35.60 was significantly reduced (-29.9K hours) because most licensees receive unit doses from commercial nuclear pharmacies and few are required to make the direct measurements. The burden in § 35.2433 was also significantly reduced (-25.6K hours) due to a lower estimate in the number of decay calculations required by § 35.433. The burden estimate for § 35.2632 significantly increased (11.3K hours) because the number of licensees with remote afterloaders has increased and most remote afterloaders require more frequent calibrations. The slight decrease in NRC licensee burden for § 35.2643 reflects an increase in the number of licensees with remote afterloaders but a reduction of the average number of patients treated per licensee. However, as indicated above, because the revised Agreement State ratio significantly increases the number of Agreement State licensees, the total burden for this section results in a 30K burden hour increase.

Overall, the burden for Part 35 has increased by a total of 222,781 hours, from 890,095 to 1,113,217 hours, resulting in a burden increase of more than 25%. The number of responses has increased by 27,628, from 214,402 to 242,030 responses, primarily because of the increase in the number of licensees.

Level of Concurrence: Branch Chief,

Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

Recordkeeping Requirements in Accordance with the Retention Periods for Records Rule:

Recordkeeping retentions are in accordance with standard record retention periods.

Search of the Information Requirements Control Automated System (IRCAS):

IRCAS was searched. No duplication was found.

Abstract:

10 CFR Part 35, “Medical Use of Byproduct Material,” contains NRC’s requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. 10 CFR Part 35 contains mandatory requirements that apply to NRC licensees authorized to administer byproduct material or radiation therefrom to humans for medical use. 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.

cc: B. St. Mary