March 8, 2001

SUMMARY OF INFORMATION COLLECTION REQUEST

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

Current Burden/Responses: Part 35: 1,329,424 hours (1,294,681 Part 35 hours plus 34,743 QM hours)

6,679,448 responses (6,676,254 Part 35 responses plus 3,194 QM responses)

Form 313: 66,652 hours/9,007 responses

Proposed Burden/Responses: Part 35: 889,754 hours/214,402 responses
Form 313: 67,325 hours/9,015 responses

Frequency of Response: On Occasion, every 10 years

Number of Respondents: 5,793

Reasons for Changes in Burden/Responses:

10 CFR Part 35 has been totally revised to eliminate prescriptive requirements, including substantial components of the quality management rule requirements. Requirements for quality management programs have been eliminated. Prescriptive requires for radiation safety committees have been eliminated, and requirements for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program now are required only for licensees with multiple modalities or multiple users. Modified requirements for written directives are retained. Licensees will be able to revise their radiation protection program without Commission approval under specified circumstances. In addition, prescriptive general technical requirements also have been eliminated and provisions have been added for organizations to become certifying organizations.

Level of Concurrence: Section Chief
Rulemaking and Guidance 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: Records retentions are in accordance with standard retentions.

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

IRCAS was searched on February 1, 2001. No duplication was found.

Abstract:

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 Part is being completely revised as described above under "Reasons for Change in Burden/Responses." In addition, requirements are being added for organizations desiring to be recognized by NRC as certifying organizations.

cc: B. St. Mary