Diane Flack

August 7, 1998

SUMMARY OF INFORMATION COLLECTION REQUEST

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

Current Burden/Responses: Part 35: 1,371,096 hours (1,336,353 Part 35 hours plus 34,743 QM hours)

6,681,204 responses (6,678,285 Part 35 responses plus 2,919 QM responses)

Form 313: 73,041 hours/11,844 responses

Proposed Burden/Responses: Part 35: 878,792 hours/93,966 responses

Form 313: 73,109 hours/93,971 responses

Burden Attributable to Third-Party Collections: Part 35: 620 hours

Frequency of Response: On Occasion, every 5 years

Number of Respondents: 6,696

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: Branch Chief
Medical, Academic and Commercial Use Safety 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 June 17, 1998. 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

NRC FORM 408
(11-97)
NRCMD 3.54

U.S. NUCLEAR REGULATORY COMMISSION

ASSESSMENT OF PROPOSED INFORMATION COLLECTION

TO: INFORMATION MANAGEMENT COORDINATOR	TITLE OF INFORMATION COLLECTION REQUIREMENT
Frank Cardile, NMSS	Complete revision to 10 CFR Part 35, Medical Use of Byproduct Material

THE FOLLOWING FACTORS WERE CONSIDERED IN EVALUATING THE PROPOSED INFORMATION COLLECTION REQUIREMENT. *(If the response is not so, check "No" and explain under "Remarks.")*	YES	NO
1. The requirement is needed. *(It is the best means to achieve a necessary regulatory objective.)*	X	
2. The requirement has practical utility, i.e., the NRC has the capability to use the information in a timely and useful fashion.	X	
3. The schedule for imposing the requirement is reasonable.	X	
4. The requirement selected is the least burdensome method of achieving a necessary regulatory objective.	X	
5. The requirement does not duplicate or overlap requirements imposed by the NRC.	X	
6. The requirement does not duplicate or overlap requirements imposed by other Government agencies.	X	
7. The method used to estimate the burden is adequate.	X	
8. The burden estimates are reasonable when compared with similar requirements previously submitted.	X	
9. The methods proposed for collecting or keeping the information are consistent with sound records management practices.	X	
10. The records retention period is sufficiently definitive and reasonable.	X	
11. The requirement adequately identifies the records to be maintained and the information to be reported.	X	
12. NRC administrative support requirements are sufficient to manage the information collection.	X	
13. The information collection will not cause NRC to exceed its Information Collection Budget.	X	

REMARKS *(If an explanation to items 1 through 13 above, reference the remark to the item number)*

OCIO REVIEWER - (Assigned Analyst) Beth C. St. Mary Reports and Information Management Staff/RMB/OCIO	SIGNATURE	DATE 08/07/98
OCIO APPROVAL - (Branch Level) Brenda Jo. Shelton NRC Clearance Officer/OCIO	SIGNATURE	DATE 08/10/98

NRC FORM 620
(10-95)

U.S. NUCLEAR REGULATORY COMMISSION

PROGRAM OFFICIAL CERTIFICATION FOR PROPOSED COLLECTION OF INFORMATION

TITLE OF COLLECTION

10 CFR PART 35 - MEDICAL USE OF BYPRODUCT MATERIAL

I certify that the proposed collection of information --
(Program Official should answer the following questions and certify responses by signing below.

	YES	NO	N/A
1. Reduces to the extent practicable the burden, including with respect to small entities, using techniques such as; (1) establishing differing timetables or reporting requirements to account for available resources, (2) clarifying, consolidating, or simplifying reporting requirements, and (3) exempting entities from all or part of the information collection requirement.	√		
2. Is written using plain, coherent, and unambiguous terminology and is understandable to respondents.	√		
3. Will be implemented in ways consistent and compatible, to the maximum extent practicable, with respondents' existing reporting and recordkeeping practices.	√		
4. Has been developed by an office that has planned and allocated resources for the efficient and effective management and use of the information, including processing the information in a manner to enhance, where appropriate, the information's utility to agencies and the public.	√		
5. Uses effective, efficient, and appropriate statistical survey methodology.			√
6. To the maximum extent practicable, uses information technology to reduce burden and improve data quality, agency efficiency and responsiveness to the public.	√		
7. Is necessary for NRC to properly perform its functions, and that the information has practical utility.	√		
8. Is not unnecessarily duplicative of information otherwise reasonably accessible to the agency.	√		
9. Indicates for each recordkeeping requirement the record retention.	√		
10. Informs potential respondents why the information is being collected; its necessity to the agency's performance; provides an estimate of and request for comment on the burden; indicates whether responses are mandatory, voluntary, or required to obtain a benefit (citing authority); confidentiality (citing authority); and the fact that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.	√		

Program Office Official Catherine Haney Date 8-10-98
(Signature)

Catherine Haney, Section Leader
Rulemaking and Guidance Branch
Division of Industrial and Medical Nuclear Safety
(Type or print name)