PDR

Standard Form 83
(Rev. September 1983)

Request for OMB Review

DESIGNATED ORIGINAL

Certified By

Important

Read instructions before completing form. Do not use the same SF 83 to request both an Executive Order 12291 review and approval under the Paperwork Reduction Act.

Answer all questions in Part I. If this request is for review under E.O. 12291, complete Part II and sign the regulatory certification. If this request is for approval under the Paperwork Reduction Act and 5 CFR 1320, skip Part II, complete Part III and sign the paperwork certification.

Send three copies of this form, the material to be reviewed, and for paperwork—three copies of the supporting statement, to:

Office of Information and Regulatory Affairs
Office of Management and Budget
Attention: Docket Library, Room 3201
Washington, DC 20503

PART I.—Complete This Part for All Requests.

1. Department/agency and Bureau/office originating request

U. S. Nuclear Regulatory Commission

2. Agency code

3 1 5 0

3. Name of person who can best answer questions regarding this request

Norman McElroy

Telephone number

(301) 492-3417

4. Title of information collection or rulemaking

Medical Quality Assurance Assessment

5. Legal authority for information collection or rule *(cite United States Code, Public Law, or Executive Order)*

42 USC 2201(c) or

6. Affected public *(check all that apply)*

1 ☐ Individuals or households
2 ☒ State or local governments
3 ☐ Farms
4 ☒ Businesses or other for-profit
5 ☒ Federal agencies or employees
6 ☒ Non-profit institutions
7 ☒ Small businesses or organizations

PART II.—Complete This Part Only if the Request is for OMB Review Under Executive Order 12291

7. Regulation Identifier Number (RIN)

___ ___ ___ ___ ___ ___ ___ ___ ___ ___, or ☐ None assigned

8. Type of submission *(check one in each category)*

Classification
1 ☐ Major
2 ☐ Nonmajor

Stage of development
1 ☐ Proposed or draft
2 ☐ Final or interim final, with prior proposal
3 ☐ Final or interim final, without prior proposal

Type of review requested
1 ☐ Standard
2 ☐ Pending
3 ☐ Emergency
4 ☐ Statutory or judicial deadline

9. CFR section affected

_____ CFR _____

10. Does this regulation contain reporting or recordkeeping requirements that require OMB approval under the Paperwork Reduction Act and 5 CFR 1320? ☐ Yes ☐ No

11. If a major rule, is there a regulatory impact analysis attached? 1 ☐ Yes 2 ☐ No

If "No," did OMB waive the analysis? 3 ☐ Yes 4 ☐ No

Certification for Regulatory Submissions

In submitting this request for OMB review, the authorized regulatory contact and the program official certify that the requirements of E.O. 12291 and any applicable policy directives have been complied with.

Signature of program official — Date

Signature of authorized regulatory contact — Date

12. *(OMB use only)*

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PDC

PART III.—Complete This Part Only if the Request is for Approval of a Collection of Information Under the Paperwork Reduction Act and 5 CFR 1320.

13. Abstract—Describe needs, uses and affected public in 50 words or less

Radioactive Materials, Radiation Safety, Nuclear Medicine"
The assessment will be conducted through use of a questionnaire that will be completed by NRC inspectors during inspections of medical licensees. The assessment will provide information to NRC on the quality assurance programs and procedures at licensees' medical institutions. Results will be used in NRC's quality assurance rulemaking.

14. Type of information collection *(check only one)*

Information collections not contained in rules

1 [X] Regular submission
2 [ ] Emergency submission *(certification attached)*

Information collections contained in rules

3 [ ] Existing regulation *(no change proposed)*
4 [ ] Notice of proposed rulemaking (NPRM)
5 [ ] Final, NPRM was previously published
6 Final or interim final without prior NPRM
A [ ] Regular submission
B [ ] Emergency submission *(certification attached)*

7. Enter date of expected or actual Federal Register publication at this stage of rulemaking *(month, day, year)* _____

15. Type of review requested *(check only one)*

1 [X] New collection
2 [ ] Revision of a currently approved collection
3 [ ] Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection
4 [ ] Reinstatement of a previously approved collection for which approval has expired
5 [ ] Existing collection in use without an OMB control number

16. Agency report form number(s) *(include standard/optional form number(s))*

Not applicable

17. Annual reporting or disclosure burden

1 Number of respondents	602
2 Number of responses per respondent	1
3 Total annual responses *(line 1 times line 2)*	602
4 Hours per response	2
5 Total hours *(line 3 times line 4)*	1204

18. Annual recordkeeping burden

1 Number of recordkeepers	
2 Annual hours per recordkeeper	
3 Total recordkeeping hours *(line 1 times line 2)*	
4 Recordkeeping retention period	years

19. Total annual burden

1 Requested *(line 17-5 plus line 18-3)*	1204
2 In current OMB inventory	0
3 Difference *(line 1 less line 2)*	+ 1204
Explanation of difference	
4 Program change	+ 1204
5 Adjustment	

20. Current *(most recent)* OMB control number or comment number

21. Requested expiration date

3 years from approval date

22. Purpose of information collection *(check as many as apply)*

1 [ ] Application for benefits
2 [X] Program evaluation
3 [ ] General purpose statistics
4 [ ] Regulatory or compliance
5 [X] Program planning or management
6 [ ] Research
7 [ ] Audit

23. Frequency of recordkeeping or reporting *(check all that apply)*

1 [ ] Recordkeeping

Reporting

2 [ ] On occasion
3 [ ] Weekly
4 [ ] Monthly
5 [ ] Quarterly
6 [ ] Semi-annually
7 [ ] Annually
8 [ ] Biennially
9 [X] Other *(describe)* One time

24. Respondents' obligation to comply *(check the strongest obligation that applies)*

1 [X] Voluntary
2 [ ] Required to obtain or retain a benefit
3 [ ] Mandatory

25. Are the respondents primarily educational agencies or institutions or is the primary purpose of the collection related to Federal education programs? [ ] Yes [X] No

26. Does the agency use sampling to select respondents or does the agency recommend or prescribe the use of sampling or statistical analysis by respondents? [ ] Yes [X] No

27. Regulatory authority for the information collection

10 CFR Part 35 ; or _____ FR _____ ; or, Other *(specify)* _____

Paperwork Certification

In submitting this request for OMB approval, the agency head, the senior official or an authorized representative, certifies that the requirements of 5 CFR 1320, the Privacy Act, statistical standards or directives, and any other applicable information policy directives have been complied with.

Signature of program official — Joyce Aménta — Date

Signature of agency head, the senior official or an authorized representative
Joyce A. Amenta
Designated Senior Official
for Information Resources Management — Date 3/16/89

SUPPORTING STATEMENT

FOR

MEDICAL QUALITY ASSURANCE ASSESSMENT

Description of the Information Collection

As part of an effort to modify the regulatory framework concerning medical quality assurance (QA), the NRC plans to conduct a one-time assessment of QA programs and procedures at all NRC medical licensees' facilities. This assessment, to be conducted through a questionnaire that will be completed during NRC inspections of medical licensees, provides specific information on the QA programs and procedures that are in use at licensees' medical institutions. The assessment will also provide information on the QA procedures in use, as well as a thorough description of the medical licensees' teletherapy, brachytherapy, and nuclear medicine programs.

NRC inspectors will complete the questionnaire during a regularly scheduled inspection, recording answers provided by the licensee. Then the regionally-based inspectors will send a copy of the finished questionnaire back to NRC Headquarters, where it will be analyzed. The information collected and results of the analysis are expected to assist the NRC in the following manner:

1) Results of the assessments will guide NRC's QA rulemaking effort by providing information about QA practices that may require regulatory modifications.

2) Answers provided in the assessment will apprise NRC of existing QA programs and procedures used by medical licensees and general practices commonly used among the medical community.

3) Licensee's responses to the questionnaire will be used to identify parameters that indicate the licensee's level of quality assurance and overall ability to control radioactive material in accordance with license conditions and NRC regulations.

Pilot Program on QA for Medical Use of Byproduct Material

This assessment is separate from another information collection being conducted by NRC involving medical quality assurance. That collection is also related to the proposed rulemaking to require medical licensees to implement quality assurance procedures. NRC plans to conduct a pilot program to determine whether the proposed QA procedures would interfere with the proper delivery of medical care. The pilot program would involve trial use of the proposed QA procedures by volunteer hospitals or clinics for a specified period of time and reports to NRC on the impacts from the trial use. There is no duplication between the information to be collected under the pilot program and the information to be collected under this Medical Quality Assurance Assessment. The information collection under the pilot program has been submitted to and approved by OMB under clearance number 3150-0145.

A. JUSTIFICATION

1. Need for the Collection of Information. On October 2, 1987, the NRC published a proposed rule on "Basic Quality Assurance in Radiation Therapy" in the Federal Register (52 FR 36942). In that document, the NRC proposed to amend its regulations in 10 CFR Part 35 concerning the medical use of byproduct material to require NRC medical licensees to implement certain quality assurance steps that would reduce the chance of therapy misadministrations. In the same issue of the Federal Register (October 2, 1987; 52 FR 36949), the NRC published an advance notice of proposed rulemaking concerning "Comprehensive Quality Assurance in Medical Use and a Standard of Care". The advance notice stated that the NRC was considering amendment to its regulations that apply to the use of byproduct

material for radiation therapy and diagnostic uses involving large radiation dosages. The document also noted that in addition to the current requirements for quality assurance, the contemplated amendments would require licensees that offer teletherapy or brachytherapy services to implement a comprehensive quality assurance program to reduce the chance of misadministration.

Since October 1987, the NRC's medical QA rulemaking process has progressed. Comments on both notices were received, and the NRC's Advisory Committee on the Medical Uses of Isotopes offered guidance to NRC staff on the appropriate direction of QA rulemaking. Substantial NRC staff resources are being expended on developing a set of medical QA regulations which are pertinent, timely, and sufficient to assure adequate protection of the public health and safety.

The QA rulemaking process is now at a stage where the NRC must gather information on existing QA programs and procedures in use by medical licensees. Such information is necessary to assure that the NRC's medical QA regulations address real concerns and problems at the licensee level. Before proposing effective regulations, the NRC must understand to what extent QA systems are in place among medical licensees, and, equally important, to what degree licensees lack QA programs. Furthermore, the NRC must know how effective those QA programs are in preventing misadministrations, as well as how QA programs, and their effectiveness, vary among different types of medical licensees (e.g., different sizes, missions, funding, staffing, etc.).

The NRC proposes to use the attached questionnaire (see Enclosure 1) to gather this information. The questionnaire is designed to elicit information that is easy to characterize, not subject to distortion by the licensee or inspector, and indicative of licensee support of the QA program.

Information-gathering activities will take place during regularly scheduled NRC inspections. Inspectors will devote part of the inspection time to completing the questionnaire with each medical licensee. An inspector will ask the licensee the questions given in Enclosure 1 and record the licensee's response. Licensees will be asked to verbally provide the information; the licensee will not be expected to complete the form in writing or to interpret any of the information. In some cases, the inspector may note the information during the existing inspection process. For instance, information on numbers and brands of nuclear medicine equipment may already be available as the inspector checks the licensee's facility; and information on misadministrations is obtained when the inspector reviews licensee records during the inspection. In these types of cases, the inspector will just consolidate already available information with the questionnaire. Since NRC inspections of medical licensees occur at this time, the information-gathering will not require new forms of interaction between the NRC and licensees. The use of the questionnaire during inspections will only lengthen the inspection time by an estimated two (2) hours per inspection.

The assessment serves as one action being taken by NRC in accordance with the NRC's policy statement published February 9, 1979 (44 FR 8242). That policy statement notes, in part, that:

a. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

b. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

c. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

The questionnaire only serves as an information-gathering tool for the inspector. Inspectors will use the questionnaire to gather information for the QA regulatory development study and to identify areas which may merit further inspection.

Once the questionnaires are complete, they will be filed at the NRC Regional Office, with a copy sent to NRC Headquarters. Personnel at NRC Headquarters will collect, process, code, and analyze the information reported on the questionnaires. The results will then be used to identify areas where medical QA rulemaking should be initiated, modified, or stopped.

The questionnaire is intended for one-time use with each medical licensee. The NRC has issued licenses for the use of byproduct material for medical purposes to various individuals and institutions throughout the United States and its Territories. Each licensee has an assigned NRC inspection frequency, based upon the type of license, and inspection frequencies range from annually for certain types of medical licensees to once every seven years for other licensees. Most medical licensees that possess radionuclides for human use are inspected at least once every four years. NRC proposes to use the questionnaire once with each medical licensee. The questionnaire will be completed at the licensee's next regularly scheduled inspection.

Finally, this information collection is necessary because medical QA issues and programs have evolved and changed rapidly over the past several years. Independent medical advisory and accreditation groups have placed increased emphasis on quality assurance in the medical community, and licensees' programs have presumably changed (or, in

some cases, have failed to change) to meet expected standards. These changes have occurred since the NRC began addressing medical QA issues in the early 1970's. The NRC needs up-to-date information on QA programs in use by medical licensees to assure that NRC rulemaking addresses current problems, not ones that occurred years ago.

2. Agency Use of Information. Refer to Enclosure 1. The following sub-headings follow the same format as the questionnaire.

Questionnaire Heading and Licensee Identification Data - Identifying data on the licensee, contact telephone number, and inspection information is needed for future identification, analysis, and follow-up, if necessary. The NRC needs to reference each set of responses with the particular institution being assessed. Licensee numbers and docket numbers are necessary for NRC filing systems. Licensee contact information is needed for follow-up, if incomplete or unusual responses are given at the time of the inspection.

Part I: GENERAL

A. Licensee Type - The NRC issues licenses to various types of medical entities -- hospitals, physicians, clinics, large institutions, small facilities, etc. These different organizations also provide a variety of services and are managed in different ways. Information on the facility, management, service, and bed size will provide a general characterization of the licensee and will tell NRC whether to be more alert for QA problems in certain types of licensees.

B. Quality Assurance Program - The NRC believes that QA programs are not standardized among its medical licensees. Thus, information on the QA program specific to radiation medicine is needed from each licensee. If a written policy statement is

available, NRC will collect it, analyze it, and compare it to misadministration occurrences and/or poor regulatory compliance by the licensee. The extent of licensee use of major medical organization guidelines is unknown, so this information gives NRC a measure of how licensees are using industry standards.

Specific information on the licensee's auditing procedures, time spent on radiation tasks, and qualifications of person performing radiation safety tasks gives NRC feedback on how the licensee's written QA policy is implemented. The facility's responses will indicate whether the radiation safety/QA program is integrated into the licensee's management or whether it is an additional duty within the licensee's organization.

Human factors is a developing field in radiation safety organizations. The NRC requests information on human factors analysis at medical licensees to gauge the extent and type of such analysis among the medical community.

C. Misadministrations - Responses concerning misadministrations, which are defined in 10 CFR 35.2, will allow the NRC to understand how licensees investigate events. NRC will use this to examine licensees' methods of misadministration investigation. Misadministrations -- characterized as a mistake in the administration of radiopharmaceuticals or radiation therapy -- represent a possible breakdown in radiation safety procedures. Licensees with functioning QA programs should identify, investigate, correct, and prevent, if appropriate, any misadministrations. A licensee's actions regarding misadministrations will inform the NRC about the licensee's QA program effectiveness.

Part II: TELETHERAPY
Part III: BRACHYTHERAPY
Part IV: NUCLEAR MEDICINE

(These three parts are constructed in parallel, with similar questions in each part. They are described together, below.)

A. Program - Each of the three parts (teletherapy, brachytherapy, and nuclear medicine) identifies whether the licensee provides a particular type of service. If that service is provided then the questionnaire continues on to the next question. If the service is not provided, the inspector will skip the part and continue on to the next part of the questionnaire.

The teletherapy part requests information on the licensee's x-ray teletherapy and electron teletherapy programs, in addition to the cobalt teletherapy program. Although x-ray teletherapy and electron teletherapy programs are not regulated by the NRC, many medical licensees use the same QA programs and procedures for these programs as they do for licensed activities. In addition, the NRC regulates total exposure of radiation workers who work with byproduct materials, so NRC is concerned with the total radiation environment at medical licensees' facilities. That environment includes possible exposure to non-licensed sources, too. Thus, information on licensee x-ray teletherapy and electron teletherapy issues also provides information on the licensed programs.

B. Equipment - NRC will examine responses to the equipment section to identify the equipment used by the licensee to provide radiation medicine services. Such a characterization of the equipment may provide an indicator of the licensee's fiscal support of a particular service and will also tell if the licensee is keeping up-to-date with current medical care

standards. Maintaining medical equipment standards and providing sufficient fiscal support are critical QA areas. Number, brands, ages, and characteristics of equipment are indicative of the licensee's devotion to providing quality medical care.

The equipment section in the brachytherapy part questions the licensee about radium, as well as other radionuclides. Radium is not a licensed byproduct material, so its use is not regulated by the NRC; but as explained earlier for teletherapy programs, licensees routinely apply the same QA procedures to both licensed and non-licensed programs with no distinction between the two. Also, NRC regulates total exposure of radiation workers using byproduct materials, even if those workers also use non-licensed materials. Therefore, information on radium QA is directly applicable to the licensed byproduct material QA program. Adverse conditions in one could demonstrate a problem in the other. So, QA issues are rarely separable between the licensed and non-licensed activities. The same rationale is used in questioning about linear accelerators in the teletherapy part.

C. Computer Hardware and Software - NRC is seeking responses from licensees concerning their computer treatment planning hardware and software because computers are now integrated into most medical licensees' radiation therapy programs. Furthermore, NRC knows of some cases in which incorrect use of computer software was a major cause of misadministrations; so use of computer hardware and software should be included in radiation medicine quality assurance programs. Information of this type collected by the NRC may lead to changes in regulations to insure that computer generated information is accurate, valid, and not inadvertently misused.

D. Staffing - The questionnaire asks for data concerning numbers of different types of medical staff members involved in the radiation medicine program, their certification, and whether the members are full time or part time workers.

The questionnaire also requests the number of procedures performed by the licensee (i.e., "load") during the previous year. This information, in conjunction with the staffing levels, will tell NRC whether regulations are needed on the number of responsibilities and tasks assigned to different types of workers.

The licensee's responses will help NRC to evaluate whether current training requirements and staffing levels are appropriate to provide adequate assurance of public health and safety. The questionnaire will also provide a comparison between the staffing levels at different institutions.

E. Clinical/Treatment Process for Patients - Each part of the questionnaire calls on the licensee to provide information concerning which of its employees performs specific steps in the clinical process for teletherapy, brachytherapy, and nuclear medicine. The steps are standard within the medical industry. Responses will provide specific information on the extent of voluntary licensee compliance with national standards of practice published by major medical organizations. Compliance with these organizations' standards presumably offers a greater assurance of quality care and minimizes chances for misadministrations.

F. Miscellaneous - Information collected on continuing education provides NRC with data on whether or not licensees are training and supporting training of their radiation safety and radiation medicine personnel. Licensee responses on management support of training, frequency, personnel attending, and topics presented will indicate to the NRC whether medical industry training is

sufficient or whether NRC should change training regulations or modify regulatory guidance.

The teletherapy part of the questionnaire also questions licensees on quality assurance practices that are often used in teletherapy programs, namely chart reviews and port films. Licensees' answers on these two items will provide information on specific QA steps that the NRC believes may be essential to early detection of mistakes. In the past, mistakes not detected by such means have evolved into reportable misadministrations.

3. Reduction of Burden Through Information Technology. There are no legal obstacles to reducing the burden associated with this information collection. However, because of the types of information sought and the one-time collection, the assessment does not lend itself readily to the use of automated information technology for transfer.

4. Effort to Identify Duplication. The Information Requirements Control Automated System (IRCAS) was searched to identify duplication. None was found.

5. Effort to Use Similar Information. Some information requested on the questionnaire is already collected or available during the existing inspection process. Information concerning facility characteristics, equipment, misadministrations, and training are examples of areas where the inspector can record information that may already be available. In those cases, the inspector will consolidate the collected information on the questionnaire, thereby minimizing the burden on the licensee. However, for a large part of the questionnaire, similar information is not available to the NRC.

6. Effort to Reduce Small Business Burden. The need to determine extent and effectiveness of QA programs and procedures at medical licensees' facilities is the same for large and small entities. However, small entities which do not have some of the programs in the questionnaire, such as teletherapy or brachytherapy, will not be asked to provide responses to those sections. It is not possible to reduce the burden on small entities by less frequent or less complete collection of information because information is needed on all kinds of and sizes of licensees.

7. Consequences of Less Frequent Collection. This information collection will be on a one-time-only basis. Less frequent collection (i.e., not at all) would impair the ability of the NRC to evaluate licensees' QA programs and to issue effective QA regulations.

8. Circumstances Which Justify Variation From OMB Guidelines. There is no variation from OMB guidelines.

9. Consultations Outside the NRC. The Advisory Committee on the Medical Uses of Isotopes provided guidance to NRC staff on the need to collect information on medical industry QA practices to help provide an informed basis for the QA rulemaking.

10. Confidentiality of Information. NRC provides no pledge of confidentiality for the collection of information, except for proprietary information. Responses and results obtained through the questionnaires, except for proprietary information, may be released to the public.

11. Justification for Sensitive Questions. None. The questionnaire does not contain any sensitive questions.

12. Estimate of Burden. See Enclosure 2.

13. Estimated Annualized Cost to the Federal Government. See Enclosure 3.

14. Publication for Statistical Use. None. Publication of the collected responses and analysis is not intended.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in the collection of this information. Each person or institution licensed for the medical use of byproduct material will provide responses to the questionnaire.

MEDICAL USE QUALITY ASSESSMENT

PLEASE FILE THIS COMPLETED FORM IN THE INSPECTION DOCKET FILE, AND FORWARD A COPY TO JAMES H. MYERS, MEDICAL AND ACADEMIC SECTION, NMSS MAIL STOP 6H3, HEADQUARTERS

Licensee: _____

Docket Numbers: _____

License Numbers: _____

Licensee Contact: _____

Licensee Contact Telephone Number: ( ) _____

Date of Inspection: _____

Inspector: _____

Region: ____

PART I: GENERAL

A. Licensee Type:

1. Facility:
   - a. _____ hospital
   - b. _____ clinic
   - c. _____ private practice
   - d. _____ other (specify) _____

2. Management:
   - a. _____ government
   - b. _____ not for profit
   - c. _____ for profit
   - d. _____ other (specify) _____

3. Service
   - a. _____ conventional care
   - b. _____ teaching and research
   - c. _____ specialty
   - d. _____ other (specify) _____

4. Number of beds: _____

B. Quality Assurance Program:

1. Does the licensee have a written policy statement (or statements) on quality assurance specific to radiation medicine?
_____ YES _____ NO (if NO, go to question C).

2. Attach copy of policy statement(s) if available. _____ ATTACHED
_____ NOT AVAILABLE

3. Does the policy statement reference the guidelines of major medical organizations such as the Joint Commission for Accreditation of Healthcare Organizations, American Board of Radiology, or others?
_____ YES _____ NO

If YES, list the organizations: a. _____
b. _____
c. _____

4. Does the policy statement call for periodic audits of the quality assurance program? _____ YES _____ NO

If YES: a. Are audits performed by individuals or organizations that are independent of the licensee? ____ YES ____ NO

b. How often are audits performed?
_____ audits/ _____ (month, quarter, year, etc.)

c. Lists dates and auditing organization for last four audits.
(1) _____
(2) _____
(3) _____
(4) _____

5. How many hours a week does the person (either the RSO or a designated technologist) who does the bulk of the radiation safety tasks spend on those tasks? _____ hours/week

6. Qualifications of the person who does the bulk of the radiation safety tasks:
a. Education: ____ OJT
____ AA/AS
____ BA/BS
____ Advanced Degree

b. Experience: ____ Years in field
____ Years at facility

c. Certification: ____ (ABR, ABHP, ARRT, JNMTCB, AOBR, etc. or NA)

7. Is the licensee's radiation safety program analyzed by a human factors specialist?

_____ YES _____ NO

If YES, list the departments:

If YES, give examples of procedures that are analyzed:

8. Inspectors' overall observations and comments about the licensee's quality assurance program:

C. Misadministrations:

1. Did the licensee have any misadministrations over the past twelve months?

_____ YES _____ NO

2. If any misadministrations have occurred, did the licensee perform an investigation?

_____ YES _____ NO _____ N/A

3. If an investigation was performed, is the report readily available?

_____ YES _____ NO _____ N/A

4. Is the information provided by the licensee consistent with the NRC's inspection file reports?

_____ YES _____ NO _____ N/A

Discuss as appropriate:

5. Did the licensee's Radiation Safety Committee attempt to identify the cause of the misadministration(s)?

_____ YES _____ NO _____ N/A

6. Did the licensee take corrective action to prevent further occurrences of misadministrations?

_____ YES _____ NO _____ N/A

7. Discuss corrective actions:

PART II: TELETHERAPY

A. Program:

1. Does the licensee have a cobalt teletherapy program?
   _____ YES _____ NO

2. Does the licensee have an X-RAY teletherapy program?
   _____ YES _____ NO

3. Does the licensee have an electron teletherapy program?
   _____ YES _____ NO

(If NO to all three above questions, go to PART III: BRACHYTHERAPY)

B. Capital Equipment

1. Number, brand, age and exposure rate (RHM) of cobalt units (the whole unit, not just the source):
   a. Number: _____
   b. Brand(s): _____
   c. Age(s): _____
   d. RHM: _____

   e. Not Applicable: _____

2. Number, brand, age, and photon and electron energies of linear accelerators:
   a. Number: _____
   b. Brand(s): _____
   c. Age(s): _____
   d. Photon and Electron Energies: _____

   e. Not Applicable: _____

3. Number, brand, and age of simulators:
   a. Number: _____
   b. Brand(s): _____
   c. Age(s): _____

   d. Not Applicable: _____

4. Number, brand, and age of the following dosimetry equipment:

Equipment	Number	Brand(s)	Age(s)	N/A
a. Primary standard chamber and electrometer:	_____	_____ _____	_____	_____
b. Secondary standard chamber and electrometer:	_____	_____	_____	_____

Equipment		Number	Brand(s)	Age(s)	N/A
c.	Isodose plotter:	____	_____	____	____
d.	Chamber constancy checker:	____	_____	____	____
e.	Other (e.g., Monitrex or custom-made device): _____	____	_____	____	____

C. Computer Hardware and Software:

1. Does the licensee use a computer (or computers) in teletherapy treatment planning?
   _____ YES _____ NO (If NO, go to D).

2. Number, brand, and age of teletherapy treatment planning computers:
   a. Number: _____
   b. Brand(s): _____
   c. Age(s): _____

3. Is the computer system:
   a. _____ Dedicated turnkey hardware/software package?
   b. _____ Standard desk top computer and off-the-shelf software?
   c. _____ Other (specify)

4. If computers are used for teletherapy treatment planning:
   a. What percentage of cobalt patients? ___% or ___ NA.
   b. What percentage of X-ray patients? ___% or ___ NA.
   c. What percentage of electron patients? ___% or ___ NA.

5. Does the licensee:
   a. Develop its own software? ____ YES, ____ NO
   b. Only use commercially available software? ____ YES, ____ NO
   c. Buy and extensively modify commercial software? ____ YES, ____ NO
   d. Name and manufacturer of commercial software used _____
      _____ _____ or ____ NA.

6. Does the licensee "lock-out" programs that are not to be used on the treatment planning computers?
   _____ YES _____ NO

7. How does the licensee maintain quality assurance of treatment unit data that is loaded into the treatment planning computers? (Describe QA of data, QA of loading process, and whether phantoms are used as a check on the system.)

8. How are computer calculations for individual patient doses checked? (describe)

D. Staffing	# Cer-* tified	# Not Certified	# In-Training	FT/PT**
1. Oncologists (MD):	_____	_____	_____	_____
2. Physicists (Phys):	_____	_____	_____	_____
3. Dosimetrists (Dos):	_____	_____	_____	_____
4. Technologists (Tech):	_____	_____	_____	_____
5. Consultant (C):	_____	_____	_____	_____

6. Others: Nurse(N) ____; Social Worker(SW) ____; Transporter(Tr) ___;

Lab Assistants(LA) ____; Technologist Assistants(TA) ____;

_____ ____; _____ ____

* Current certification by any national certifying body, such as ABR, ABHP, ARRT, JNMTCB, AOBR, etc.

** FT = Full Time, PT = Part Time

E. Load	Number of new patients last year	Not Applicable
1. Cobalt	_____	_____
2. X-ray	_____	_____
3. Electron	_____	_____

F. Treatment process for cobalt patients

Step*	Done by**	Reviewed by**
1. Clinical Evaluation	_____	_____
2. Therapeutic Decision-Making	_____	_____
3. Target Volume Localization		
Definition of tumor	_____	_____
Identification of sensitive organs and tissues	_____	_____
Measurement of patient	_____	_____
Construction of patient contours	_____	_____
Shaping of field	_____	_____
4. Treatment Planning		
Selection of treatment technique	_____	_____
Computation of dose distribution	_____	_____
Calculation of dose/time/volume relationship	_____	_____
5. Simulation of Treatment	_____	_____
6. Fabrication of Treatment Aids		
Construction of custom blocks, compensating filters	_____	_____
Selection of immobilization devices	_____	_____

* See "Radiation Oncology in Integrated Cancer Management," 1986.

** If step is not performed, write "NA." If step is performed, use the following abbreviations for the person performing the test, or write in the position if none of these applies:

MD = oncologist	C = consultant	Tr = transporter
Phys = physicist	N = nurse	LA = lab assistant
Dos = dosimetrist	SW = social worker	TA = tech. assistant
Tech = technologist		

7. Treatment

Initial verification of treatment set-up	_____	_____
Verification of accuracy of repeated treatments	_____	_____
Continual assessment of equipment performance	_____	_____
Periodic checks of dosimetry, record-keeping	_____	_____
8. Patient Evaluation During Treatment	_____	_____
9. Follow-up Evaluation	_____	_____
10. QA Physicial Measurements		
Weekly spot-checks	_____	_____
Annual calibration	_____	_____
Measurements on custom patient devices	_____	_____

* See "Radiation Oncology in Integrated Cancer Management," 1986.
** Use abbreviations from page E2-7. If step is not performed, write "NA."

G. Miscellaneous

1. Chart reviews

   a. How frequently are they scheduled? _____

   b. Who attends? _____

2. How often does the licensee take port films? _____

3. On-site continuing education

   a. Does the licensee support (time, tuition, travel) continuing education?
   on-site ____ YES, ____ NO,
   off-site ____ YES, ____ NO.

   b. How frequently is this provided? _____

   c. Who attends? _____

   d. What kinds of topics are presented? (Give examples)
   _____

4. On what percentage of patients is a physical measurement made to confirm the dose rate for that specific patient?

PART III: BRACHYTHERAPY

A. Does the licensee have a brachytherapy program? _____ YES, _____ NO. (If NO, go to PART IV: Nuclear Medicine).

B. Equipment

		Total Activity on Hand	# of Sources or Seeds on Hand	Not Applicable
1.	Cesium inventory:	_____ mCi	_____ sources	_____
2.	Radium inventory:	_____ mCi	_____ sources	_____
3.	Usual iridium inventory on hand:	_____ mCi	_____ seeds	_____
4.	Usual iodine seed inventory on hand:	_____ mCi	_____ seeds	_____
5.	High Dose Rate brachytherapy unit:	_____ mCi	_____ sources	_____
6.	Strontium eye applicator:	_____ mCi		
7.	Other (specify): _____			

C. Computer hardware and software (do not duplicate if same as for teletherapy)

1. Does the licensee use a computer (or computers) in brachytherapy treatment planning?
   _____ YES, _____ NO

2. Number, brand, and age of brachytherapy treatment planning computers:
   a. Number: _____
   b. Brand(s): _____
   c. Age(s): _____

3. Is the computer system:
   a. _____ The same as used for teletherapy?
   b. _____ Dedicated turnkey hardware/sofware package?
   c. _____ Standard desk top computer and off-the-shelf hardware?
   d. _____ Other (specify) _____

4. What portion of brachytherapy patients have their doses calculated on a computer system?

	Percentage	Not Applicable
cesium:	_____%	_____
radium:	_____%	_____
iridium:	_____%	_____
iodine:	_____%	_____

5. Does the licensee:
   a. Develop its own software? ____ YES, ____ NO.
   b. Only use commercially available software? ____ YES, ____ NO.
   c. Buy and extensively modify commercial software? ____ YES, ____ NO.

6. Does the licensee "lock-out" programs that are not to be used on the treatment planning computers? ____ YES, ____ NO.

7. How does the licensee maintain quality assurance of treatment unit data that is loaded into the treatment planning computers? (Describe both QA of data and QA of loading process.)

8. How are computer calculations for individual patient doses checked? (describe)

D. Staffing*	# Cer-tified**	# Not Certified	# In-Training	FT/PT***
1. Oncologists (MD):	_____	_____	_____	_____
2. Physicists (Phys):	_____	_____	_____	_____
3. Dosimetrists (Dos):	_____	_____	_____	_____
4. Technologists (Tech):	_____	_____	_____	_____
5. Consultant (C):	_____	_____	_____	_____

6. Others: Nurse(N) ____; Social Worker(SW) ____; Transporter(Tr) ____;
   Lab Assistants(LA) ____; Technologist Assistants(TA) ____;
   _____ ____; _____ _____ ____

* If you completed this information in Part I: Teletherapy, do not repeat.
** Current certification by any national certifying body, such as ABR, ABHP, ARRT, JNMTCB, AOBR, etc.
*** FT = Full Time, PT = Part Time

E. Load

		Number of patients treated last year	Not Applicable
1.	Cesium	_____	_____
2.	Radium	_____	_____
3.	Iridium	_____	_____
4.	Iodine	_____	_____
5.	High Dose Rate Unit	_____	_____
6.	Strontium	_____	_____
7.	Other (specify)	_____	_____

F. Treatment process for brachytherapy patients

Step*		Done by**	Reviewed by**
1.	Clinical Evaluation	_____	_____
2.	Therapeutic Decision-Making	_____	_____
3.	Target Volume Localization		
	Definition of tumor	_____	_____
	Identification of sensitive organs and tissues	_____	_____
4.	Treatment Planning		
	Selection of volume for implantation	_____	_____
	Appraisal of dosimetry	_____	_____
	Estimation of tolerance to procedure	_____	_____
	Check-off of equipment	_____	_____
	Arrangement for surgical suite and anesthesia	_____	_____

* See "Radiation Oncology in Integrated Cancer Management," 1986.
** Use abbreviations from page E2-7. If step is not performed, write "NA."

Step*	Done by**	Reviewed by**
5. Treatment		
Examination of anesthetized patient	_____	_____
Review of initial treatment plan	_____	_____
Implantation	_____	_____
6. Verification of implantation	_____	_____
7. Dosimetry		
Calculation from actual implantation	_____	_____
Establishment of time for removal	_____	_____
8. Patient Evaluation During Treatment	_____	_____
9. Removal of implant	_____	_____
10. Follow-up Evaluation	_____	_____

* See "Radiation Oncology in Integrated Cancer Management," 1986.
** Use abbreviations from page E2-7. If step is not performed, write "NA."

G. Miscellaneous

Continuing education (do not repeat information provided under Part I: Teletherapy)

1. Does the licensee support (time, tuition, travel) continuing education?

   on-site ____ YES, ____ NO,
   off-site ____ YES, ____ NO.

2. How frequently is this provided? _____

3. Who attends? _____

4. What kinds of topics are presented? (Give examples)

   _____

PART IV: NUCLEAR MEDICINE

A. Does the licensee have a nuclear medicine program?
_____ YES, _____ NO (If NO, the form is complete).

B. Capital Equipment

1. Number, brand, and age of cameras:
   Number: _____
   Brand(s): _____
   Age(s): _____

   Not Applicable: _____

2. Number, brand, and age of imaging manipulation computers:
   Number: _____
   Brand(s): _____
   Age(s): _____

   Not Applicable: _____

3. Number, brand, and age of dose calibrators:
   Number: _____
   Brand(s): _____
   Age(s): _____

   Not Applicable: _____

4. Number, brand, and age of survey instruments:
   Number: _____
   Brand(s): _____
   Age(s): _____

   Not Applicable: _____

C. Staffing

	# Certified*	# Not Certified	# In-Training	FT/PT**
1. Physicians (MD):	_____	_____	_____	_____
2. Physicists (Phys):	_____	_____	_____	_____
3. Technologists (Tech):	_____	_____	_____	_____
4. Technicians (Tcn):	_____	_____	_____	_____
5. Consultant (C):	_____	_____	_____	_____

6. Others: Nurse(N) ____; Social Worker(SW) ____; Transporter(Tr) ____;
Lab Assistants(LA) ____; Technologist Assistants(TA) ____;
Radiopharmacists (RadPh) _____; _____ ____;
_____ _____

* Current certification by any national certifying body, such as ABR, ABHP, ARRT, JNMTCB, AOBR, etc.

** FT = Full Time, PT = Part Time

D. Number of imaging procedures last year: _____

E. Clinical process for imaging patients

Step	Done by**	Reviewed by**
1a. Dosage Preparation (on-site)		
Generator elution	_____	_____
Moly test	_____	_____
Kit reconstitution	_____	_____
Tagging test	_____	_____
Dosage preparation	_____	_____

** If step is not performed, write "NA." If step is performed, use the following abbreviations for the person performing the test, or write in the position if none of these applies:

MD = physician	C = consultant	LA = lab assistant
Phys = physicist	N = nurse	TA = tech. assistant
Tech = technologist	SW = social worker	RadPh = radiopharmacist
Tcn = technician	Tr = transporter	

Step		Done by**	Reviewed by**
1b.	Dosage Ordering (nuclear pharmacy)		
	Prepare order list	_____	_____
	Place order	_____	_____
	Verify packing slip	_____	_____
2.	Referral review	_____	_____
3.	Scheduling	_____	_____
4.	Dosage administration	_____	_____
5.	Imaging and data collection		
	Simple static	_____	_____
	Simple dynamic	_____	_____
	Complex dynamic	_____	_____
6.	Computer processing of images	_____	_____
7.	Evaluation	_____	_____
8.	QA Physical Measurements		
	Dose calibrator	_____	_____
	Camera	_____	_____
	Film processor	_____	_____

** Use abbreviations from page E2-14. If step is not performed, write "NA."

F. Miscellaneous

Continuing education

1. Does the licensee support (time, tuition, travel) continuing education?

   on-site ___ YES, ___ NO,
   off-site ___ YES, ___ NO.

2. How frequently is this provided? _____

3. Who attends? _____

4. What kinds of topics are presented? (Give examples)

   _____

ENCLOSURE 2

ESTIMATE OF BURDEN

1. Time Burden

The estimated one-time burden for this information collection is approximately two (2) hours for each medical licensee. Table A (Enclosure 4 to the Supporting Statement) shows the types and numbers of licensees that will complete the questionnaire. A total of approximately 2408 licensees will be assessed over a period of about four years, with the number of assessments completed (industry-wide) decreasing in each succeeding year. The first year of questionnaire use will have the heaviest workload, with about 999 licensees taking part in the assessment. The average number of licensees assessed per year is 602 licensees/year (2408 licensees/4 years). Total average medical industry burden each year is approximately 1204 hours (602 licensees x 2 hours per licensee). Total industry burden over the life of the program is approximately 4816 hours (2408 licensees x 2 hours/licensee).

2. Cost Burden

Estimated one-time cost per respondent, based on an assumed $100/hour professional labor rate, is approximately $200. ($100 per hour x 2 hours). Total average industry cost each year is approximately $120,000 (602 licensees x $200 per licensee). Total industry cost over the life of the program is approximately $482,000 (2408 licensees x $200 per licensee; rounded to the nearest thousand).

3. Labor Rate Assumptions

The $100/hour labor rate used above is an assumption of the hourly cost of licensees' professional medical staff to provide responses to the questionnaire. In many instances, technicians or technologists may provide responses to the questionnaire, in which case the labor rate (and, therefore, licensees' costs) would be substantially lower. In other instances, professional staff such as doctors or administrators may provide responses, in which case the labor rate and associated costs might be higher. The $100/hour professonal labor rate is considered by NRC staff to be a conservative estimate.

4. Number of Medical Licensees

The number of respondents is based on the number of medical licensees as of January 1989. The number of medical licensees has remained fairly constant over time. Barring any unforeseen major regulatory or industry actions that might cause changes, the number of medical licensees is expected to remain stable over the period of questionnaire use. It is possible that within the next few years, certain States may enter into agreement with the NRC to regulate their own medical licensees. If such events do occur, the total number of respondents (and associated industry burden and cost) would decrease. However, as a conservative estimate, it is assumed in the above calculations that the number of medical licensees will remain stable and that January 1989's data is representative of the number of medical licensees over the next four years.

ENCLOSURE 3

ESTIMATED ANNUALIZED COST TO THE FEDERAL GOVERNMENT

The questionnaire will be used with a total of approximately 2408 medical licensees (see Enclosure 4 to the Supporting Statement, "Table A"). Since it is used on a one-time basis during the medical licensee's next regularly scheduled inspection, and since inspection frequencies vary among the different types of licensees, the 2408 medical licensees will be assessed over a period of approximately four years. The first year will have the highest number of assessments, about 999, with the actual number of assessments (and associated costs) decreasing during succeeding years of the project. To estimate the annualized cost to the Federal government, the average number of licensees to be assessed each year will be used in the following calulations (that is, the total number of licensees divided by four years). That average number of licensees assessed per year is about 602 licensees/year (2408 licensees divided by 4 years). All of the following cost estimates are rounded to the nearest thousand dollars.

I. Completing the Questionnaire

Estimated NRC time to complete questionnaire with the licensee — T_1 = 2 hours/licensee

Approximate average labor rate for NRC staff time — L_1 = \$60/hour

Average number of licensees to be assessed each year — N_1 = 602 licensees

So, estimated annualized cost to the Federal government to complete (but not analyze) the questionnaire is:

$Cost_1 = T_1 \times L_1 \times N_1$ = 2 hours/licensee x \$60/hour x 602 licensees

$Cost_1$ = \$72,000

II. Administrative Functions (Coding, copying, filing, follow-up, etc.)

Estimated NRC staff time for administrative functions — T_2 = 1 hour/questionnaire

Approximate average labor rate for NRC staff time — L_2 = \$60/hour

Average number of questionnaires to be assessed each year — N_2 = 602 questionnaires

So, estimated annualized cost to the Federal government to complete administrative functions associated with the questionnaire is:

$Cost_2 = T_2 \times L_2 \times N_2$ = 1 hour/quest. x \$60/hour x 602 questionnaires

$Cost_2$ = \$36,000

III. Analysis

Approximately 625 hours/year will be used for analysis of the licensees' responses to the questionnaire. At an approximate average labor rate for NRC professional time of $60/hour, the analysis will cost the Federal government:

$Cost_3$ = 625 hours/year x $60/hour

$Cost_3$ = $38,000

IV. Materials and Other Operating Expenses

Additional cost for materials, copy supplies, mailing, and other operational expenses is estimated to be approximately $1000/year.

$Cost_4$ = $1000

The total estimated annualized cost to the Federal government for the use of this questionnaire is incurred from the labor costs and from the cost of materials and other operating expenses. That total annualized cost for an average year is:

Total Annualized Cost = $Cost_1$ + $Cost_2$ + $Cost_3$ + $Cost_4$

= $72,000 + $36,000 + $38,000 + $1000

Total Annualized Cost = $147,000

Again, it should be recognized that this is the average annualized cost to the Federal government to use the questionnaire. Actual costs will differ over the four years of the program, with costs being greatest in the first year and decreasing substantially in successive years.

ENCLOSURE 4

TABLE A:

BREAKDOWN OF QUESTIONNAIRE RECIPIENTS

Program Code	Title	[1] # of Licenses	[2] Inspec. Priority	[3] # in 1st Year	# in 2nd Year	# in 3rd Year	# in 4th Year
02110	Medical Institution Broad	116	1	116	0	0	0
02120	Medical Institution Other - Group	1403	3	468	468	467	0
02121	Medical Institution Other - Nongroup	15	4	4	4	4	3
02200	Medical Private Practice - Group	270	4	68	68	67	67
02201	Medical Private Practice - Nongroup	209	4	53	52	52	52
02209	Grandfathered General Medical Use - 35.31	77	4	20	19	19	19
02210	Eye Applicators Strontium-90	51	4	13	13	13	12
02220	Mobile Nuclear Medicine Service	21	2	11	10	0	0
02300	Teletherapy	246	1	246	0	0	0
	TOTALS	2408		999	634	622	153

[1] Current as of January 23, 1989.

[2] Freqency of inspection is determined by inspection priority. The inspection priority is the interval, in years, between successive NRC inspections. For example, an inspection priority of 4 means one inspection every four years.

[3] The "# in 1st Year" is the number of licensees which will complete the one-time questionnaire assessment in the first year of its use.