DEC 0 8 1993

13-02752-03
30-1609

Indiana University Medical
Center
Radiation Safety Office, CL 159
ATTN: Mack Richard, M.S.
541 Clinical Drive
Indianapolis, IN 46202-5111

Dear Mr. Richard:

This is in reference to your application dated February 12, 1992 and letters dated October 14, 1992, June 15, 1993 and August 27, 1993, requesting certain exemptions from 10 CFR Part 20.

Your requests for exemption of 10 CFR 20.1301(a)(1) and 20.1301(a)(2) as they pertain to your brachytherapy and radiopharmaceutical therapy programs are still being reviewed for technical merit. You will be notified at the conclusion of our review.

In accordance with Section 2.103, Part 2, Title 10, Code of Federal Regulations, some of your requests are hereby denied for reasons set forth below.

1. 10 CFR 20.2106: Recordkeeping requirements for personnel monitoring

   The old NRC Form 5 is not an appropriate document to record all the information required in the revised Part 20, such as total effective dose equivalent, committed effective dose equivalent, and so on. Accordingly, we are denying your request for exemption to 10 CFR 20.2106.

   Therefore, you must use the new form or equivalent to implement the revised Part 20. An equivalent form would be one that contains at least all of the information on the revised NRC Form 5.

2. 10 CFR 20.2104(d): Recordkeeping requirements for exposure history

   The old NRC Form 4 is not an appropriate document to record all the information required in the revised Part 20, such as internal dose. Accordingly, we are denying your request for exemption to 10 CFR 20.2104(d).

   Therefore, you must use the new form or equivalent to implement the revised Part 20. An equivalent form would be one that contains at least all of the information on the revised NRC Form 4.

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ML 3P1 DF
395384
F

3. 10 CFR 20.2104(f): Personnel monitoring record retention

Your request for exemption to 10 CFR 20.2104(f) does not give reasons for requesting the exemption, propose an alternative, or discuss the burden of the recordkeeping retention requirements. Therefore, we are denying your request for exemption to 10 CFR 20.2104(f).

As provided in Section 2.103 of 10 CFR Part 2, you have the right to request a hearing concerning these denials. If you wish to request a hearing, it must be submitted within 20 days from the date of this letter to the Secretary of the Commission, ATTN: Chief, Docketing and Service Branch, U.S. Nuclear Regulatory Commission, Washington D.C. 20555, with a copy of the Assistant General Counsel for Hearings, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

The request should reference this letter and Docket Number 030-01609.

Sincerely,

John B. Martin
Regional Administrator

Enclosure: 10 CFR Part 2

RIII	RIII	RIII	NMSS	RIII
Gattone/jaw	Madera	Caniano	Glenn	Axelson
11-22-93		11/23/93	11/24/93	11/22/93
RIII	RIII	RIII	RIII	
Pawlik	Berson	Miller	Martin	
	12/2	12/6/93	12/6/93	

3. 10 CFR 20.2104(f): Personnel monitoring record retention

Your request for exemption to 10 CFR 20.2104(f) does not give reasons for requesting the exemption, propose an alternative, or discuss the burden of the recordkeeping retention requirements. Therefore, we are denying your request for exemption to 10 CFR 20.2104(f).

As provided in Section 2.103 of 10 CFR Part 2, you have the right to request a hearing concerning these denials. If you wish to request a hearing, it must be submitted within 20 days from the date of this letter to the Secretary of the Commission, ATTN: Chief, Docketing and Service Branch, U.S. Nuclear Regulatory Commission, Washington D.C. 20555, with a copy of the Assistant General Counsel for Hearings, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

The request should reference this letter and Docket Number 030-01609.

Sincerely,

John B. Martin
Regional Administrator

Enclosure: 10 CFR Part 2

RIII	RIII	RIII	NMSS	RIII
Gattone/law	Madera	Caniano	Miller	Axelson
11-23 93			11/24/93	
RIII	RIII	RIII	RIII	
Pawlik	Berson	Miller	Martin	

CONVERSATION RECORD

TIME | DATE 11-24-93

O VISIT O CONFERENCE × TELEPHONE

O INCOMING
× OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT: Mack Richard
ORGANIZATION (OFFICE, DEPT.ETC.): IN University
TELEPHONE NO.: 317-274-4797

SUBJECT
C/N 95384
Lic. # 13-02752-03

SUMMARY
Per Roy Caniano's request, I discussed the contents of the eminent denial letter regarding exemptions to 10 CFR 20 prior to mail out.

The licensee understood the contents of the letter.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION: Bob Gattone
11-24-93

SIGNATURE: Robert G. Gattone Jr.

DATE

ACTION TAKEN

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

93-25

NOV 04 1993

MEMORANDUM FOR: Roy J. Caniano, Chief
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards, RIII

FROM: Frederick C. Combs, Chief
Operations Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: RESPONSE TO TECHNICAL ASSISTANCE REQUEST FROM INDIANA UNIVERSITY, INDIANAPOLIS, INDIANA (CONTROL NO. 95384)

This memorandum responds, in part, to your technical assistance request (TAR) dated September 7, 1993 (see Enclosure 1), regarding an Indiana University request for exemption from various sections of the revised 10 CFR Part 20. We are withholding decision at this time regarding the licensee's request for exemption from 10 CFR 20.1301, while we coordinate with the Office of the General Counsel. We will provide you with a response to Items 1 - 4 of the TAR once that issue is resolved. This memorandum responds to Items 5 - 7 of the TAR.

In Item 5 of the TAR, the licensee notes in their license renewal application that they do not intend to follow the requirements of § 20.2106 because their personnel monitoring vendor has not begun using the revised versions of NRC Forms 4 and 5 and transcription by hand would "be overly burdensome." The licensee's request for exemption should be denied. The old NRC Form 5 (§ 20.2106 only addresses Form 5) is not an appropriate document to record all the information required in the revised Part 20, such as total effective dose equivalent, committed effective dose equivalent, and so on. The licensee must use the new form or equivalent to implement the revised Part 20. An equivalent form would be one that contains at least all of the information on the NRC Form 5.

In Item 6 of the TAR, the licensee notes in their license renewal application that they do not intend to follow the requirements of § 20.2104(d) for the same reasons stated above. The licensee must use the revised NRC Form 4 or equivalent to meet the requirements of § 20.2104(d), because the old NRC Form 4 is not an appropriate document to record all the information, especially information on internal dose, that is required in the revised Part 20. An equivalent form would be one that contains at least all of the information on the NRC Form 4. The licensee's request for exemption from § 20.2104(d) should be denied.

In Item 7 of the TAR, the licensee notes in their license renewal application that they do not intend to follow the requirements of § 20.2104(f). However, the licensee does not give reasons for requesting the exemption, propose an alternative, or discuss the burden of the recordkeeping requirements. We agree with your recommendation to deny the licensee's request.

NOV 08 1993

A copy of Regulatory Guide 8.7, Revision 1, "Instructions for Recording and Reporting Occupational Radiation Exposure Data," is enclosed for you to provide to the licensee (see Enclosure 2). This regulatory guide provides information that may be helpful to the licensee regarding the new NRC Forms 4 and 5.

If you have any questions regarding this TAR, please contact Scott Moore at (301) 504-2514.

Frederick C. Combs, Chief
Operations Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosure: As stated

93-25

REQUEST FOR TECHNICAL ASSISTANCE

DATE: 9-7-93

TO: John E. Glenn, Chief, Medical, Academic, and Commercial Use Safety Branch, NMSS

FROM: Roy J. Caniano, Chief, Nuclear Materials Safety Branch, Region III

Jean 9/10/93

LICENSEE: Indiana University LICENSE NO. 13-02752-02

_____ X Control No. 98334 _____ (enclosed)

_____ X Letter dated October 14, 1993 _____ (enclosed)

_____ Suggested change in licensing procedure (enclosed)

_____ Other (see remarks)

Problem/Issue: Licensee requests multiple exemptions to revised 10 CFR Part 20 as follows:

1. 20.1301(a)(1)

Requests that the dose to individual members of the public from the brachytherapy program will not exceed 0.3 rem in a year (excluding pregnant women and minors).

2. 20.1301(a)(2)

Requests that the dose in any unrestricted area from implanted brachytherapy sources does not exceed 0.005 rem in any one hour (excluding pregnant women and minors).

3. 20.1301(a)(1)

Requests that the dose to individual members of the public from the radiopharmaceutical therapy patients not exceed 0.3 rem in a year (excluding pregnant women and minors).

4. 20.1301(a)(2)

Requests that the dose in any unrestricted area from radiopharmaceutical therapy patients does not exceed 0.005 rem in any one hour (excluding pregnant women and minors).

5. 20.2106

Requests exemption to recordkeeping requirements for individual monitoring results.

6. 20.2104(d)

Enclosure 1

Requests exemption to recording exposure history to include all of the information required by NRC Form 4.

3. 20.2104(f)

Requests exemption to retaining records as required by NRC Form 4 until the Commission terminates the pertinent license and retain records used in preparing the NRC Form 4 for 3 years after the record is made.

Action Req (req'd): Review the requests and provide guidance regarding approval/denial.

Recommended Alternative:

4. Recommend approval based on the following:

- o projection of low incidence of dose/dose rates in excess of regulatory limits
- o cost/benefit analysis performed
- o provisions to ensure dose does not exceed 0.3 rem/yr.
- o calculations based on conservative factors (e.g., doorway occupancy factor of 25%)
- o commitment to comply with regulations when minors or pregnant women are involved
- o prior to recent renewal, licensee was exempt from 10 CFR 20.105(a) for areas adjacent to therapy rooms

5. Recommend consideration if licensee indicates:

- o the specific portions of 10 CFR 20.2106 he requests exemption from (e.g., 20.2106(a)(2), etc.); and
- o for each portion, discuss how the proposed alternative satisfies the intent of the regulation.

6. Recommend consideration if licensee indicates the specific portions of NRC Form 4 he requests exemption of and, for each portion, discuss how the proposed alternative satisfies the intent of the requirement.

7. Recommend denial because the licensee does not discuss how this regulation puts an undue burden upon them.

Remarks: Application dated February 10, 1992.

Regional Reviewer: Bob Gattone

Reviewer Code: 53

Reviewer Phone No. 708-790-5545 _____

A question was raised regarding the effective half-life of 28 hours ^{131}I utilized in our calculations. This half-life is based upon our experience with patients undergoing treatment for thyroid carcinoma. Due to the fact that these patients have had a thyroidectomy, they have little remaining thyroid tissue. Thus, the biological rate of release for ^{131}I is much more rapid than an individual with a normally functioning thyroid gland. The value cited in ICRP 30 (7.6 days) is for a normal individual, not a patient.

VII. Based upon the aforementioned information, the expected duration of operations in excess of the 10 CFR 20.1301(a) limits would be only a few days each year. In the event that we would find that such limits are being exceeded > 30% of the time (our definition of "frequent"), additional shielding will be obtained or administrative restrictions implemented to assure such deviations above the limits are both infrequent and in keeping with the ALARA philosophy.

Response to Item 3 of July 16, 1993 NRC Letter

The rationale for not implementing the recordkeeping requirements of 10 CFR 20.2106 and 10 CFR 20.2104(d) and (f) were explained in item 14 of our response (dated October 14, 1992) to the original NRC deficiency letter dated August 11, 1992. That rationale was specifically discussed with Mr. Kevin Null and Mr. Mike McCann during their site visit for our NRC license renewal. At that time, Mr. McCann specifically instructed us to include our rationale for not following the aforementioned recordkeeping requirements and it was his opinion that such action was indeed appropriate.

Page 5 of licensee's letter dated 8/27/93 to Robert Gattone, RIII

13.C. Review added Attachment 11-2 and revised item IV.C.3. on page 11-3.

13.D.(1) The effluent release is based upon the revised 10 CFR 20, Appendix B, Table 2, Col. 1 values. It is our understanding that these values already include safety factors for ALARA.

13.D.(2) The release value for ^{3}H (and ^{3}H equivalent values) is based upon the revised 10 CFR 20 as mentioned above.

13.D.(3) As was discussed during the October 16, 17 site visit, the procedure specified in the initial application for computing the sum of the ratios value is equivalent to that specified in 10 CFR 20.

13.D.(4) Review added item VI.C.7. on page 11-5.

13.D.(5)a. Review revised item VI.F.1.a. on page 11-6.

13.D.(5)b. Review revised item VI.F.4. on page 11-7.

14. It is our intent to follow the revised 10 CFR 20 with some notable exceptions. First of all, the requirements of 10 CFR 20.2106 and 10 CFR 20.2104(d) and (f) require that records of individual monitoring results be maintained on revised versions of NRC Forms 4 and 5. Currently, personnel monitoring reports generated by our personnel monitoring vendor are designed to follow the current 10 CFR 20. Although the revised NRC Forms 4 and 5 have been published, our personnel monitoring vendor has not yet adopted the new format. It would be overly burdensome for us to transcribe the information from the old NRC Forms 4 and 5 to the new versions of same. We discussed this matter with a representative of our personnel monitoring vendor. He indicated that the new format which will be equivalent to the new NRC 4 and NRC 5 forms should be available in the latter part of 1993. Therefore, we will begin maintaining records on the new NRC Form 4 and 5 when our personnel monitoring vendor has adopted that format.

Note 1: A typographical error was noted in Item 10N - Program for Maintaining Radiation Exposures As Low As Reasonably Achievable (ALARA). Please remove page 10N-1 from the initial application and replace it with the revised page 10N-1.

Note 2: An attached revised TABLE OF CONTENTS which reflects sections or attachments which have been changed or added should replace the original TABLE OF CONTENTS in the initial application.

Page 3 of licensee's letter dated 10/14/92 to Kevin Null, RIII

U.S. NUCLEAR REGULATORY COMMISSION

Revision 1
June 1992

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.7

(Draft was issued as DG-8007)

INSTRUCTIONS FOR RECORDING AND REPORTING OCCUPATIONAL RADIATION EXPOSURE DATA

A. INTRODUCTION

Section 20.1502 of 10 CFR Part 20, "Standards for Protection Against Radiation," requires licensees to provide radiation monitoring for all occupationally exposed individuals who might receive a dose in excess of 10 percent of the limits in 10 CFR 20.1201, 20.1207, or 20.1208. In 10 CFR 20.2106, licensees are required to maintain records of the radiation exposures of all individuals for whom personnel monitoring is required (pursuant to 10 CFR 20.1502). According to 10 CFR 20.2104, the dose in the current monitoring year must be determined for all persons who must be monitored, and this information must be recorded on NRC Form 4 or equivalent. In addition, 10 CFR 20.2104 requires that, prior to allowing an individual to participate in a planned special exposure, records of all prior exposures must be acquired. Records of prior dose must be maintained on NRC Form 4 or its equivalent. Further, 10 CFR 20.2206 requires certain licensees to submit an annual report to NRC of the results of individual monitoring.

This guide describes an acceptable program for the preparation, retention, and reporting of records of occupational radiation exposures. It includes copies of NRC Forms 4 and 5 and detailed instructions on completing them.

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Part 20, which provides the regulatory basis for this guide. The information collection requirements in 10 CFR Part 20 have been cleared under OMB Clearance No. 3150-0014. The existing requirements for NRC Forms 4 and 5 were approved by the Office of Management under approval numbers 3150-0005 and 3150-0006.[1] The amended information collection requirements reflected in this guide and contained on the revised NRC Forms 4 and 5 will not become effective until after they are approved by the Office of Management and Budget. Notice of OMB approval will be published in the *Federal Register*.

B. DISCUSSION

This guide is structured to reflect the process a licensee would go through in deciding whether or not monitoring for occupational exposure to radiation is required under the revised 10 CFR Part 20. The guide describes acceptable methods for determination of prior exposures, records of monitoring provided, and reporting that are needed to comply with 10 CFR Part 20. NRC Forms 4 and 5 are provided. A format for electronically reporting exposure data to NRC is provided in Appendix A.

In order to avoid confusion with the acronym for effective dose equivalent (EDE), the abbreviation LDE is used to represent the eye (lens) dose equivalent, as defined in 10 CFR Part 20. The term total organ dose equivalent (TODE) has been added, and it means the sum of the deep dose equivalent and the

committed dose equivalent to the organ receiving the highest dose as described in 10 CFR 20.2106(a)(6).

C. REGULATORY POSITION

1. DETERMINATION OF MONITORING REQUIREMENTS

According to 10 CFR 20.1502, if an adult is likely to receive in 1 year a dose greater than 10 percent of any applicable limit, monitoring is required. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas. Further guidance on evaluating the need to provide monitoring is provided in Regulatory Guide 8.34, "Monitoring Criteria and Methods To Calculate Occupational Doses."

1.1 If Monitoring Is Not Required

If this prospective evaluation shows that the individual is not likely to exceed 10 percent of any applicable limit, there are no recordkeeping or reporting requirements in regard to the individual's exposure. For individuals who received exposure at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. Only dose that could be received at the facility performing the evaluation need be considered when determining the need for monitoring and, therefore, the recordkeeping and reporting requirements. If it is determined that monitoring is not required and a subsequent evaluation shows that the 10 percent threshold has or will be exceeded, the dose received when monitoring was not provided should be estimated, recorded, and reported. These estimates can be based on any combination of work location radiation monitoring or survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received.

If monitoring is not required to demonstrate compliance with all limits but is required relative to one or more specific limits, the licensee should enter "NR" in the blocks on NRC Forms 4 and 5 to indicate the areas for which monitoring was not required (e.g., extremity or skin doses). Where monitoring was provided but not measurable, the licensee should enter "ND" for "Not Detectable."

1.2 If Monitoring Is Required

If the prospective evaluation shows that the individual is likely to exceed 10 percent of an applicable limit, monitoring is required (10 CFR 20.1502). Recording and reporting of the results of monitoring performed, regardless of the actual dose received, is required by 10 CFR 20.2106(a) and 20.2206(b) respectively.

1.3 Documentation of Prior Exposures

For those individuals for whom monitoring is required, determination of current year exposure at other facilities is required by 10 CFR 20.2104. To document the determination of current year exposure, the individual to be monitored must provide an NRC Form 4 signed by the individual or a written statement that includes the names of all facilities that provided monitoring for occupational exposure to radiation during the current year and an estimate of the dose received. Although not required by the regulations, it is considered good health physics practice to verify the information provided by the individual. Verification may be documented with:

- An NRC Form 5 for each listed monitoring period, or
- Electronic, telephone, or facsimile transfer of dose data provided by licensees listed on the written statement, or
- An NRC Form 4 countersigned by a licensee or current employer.

In addition, 10 CFR 20.2104(a)(2) requires that licensees attempt to obtain the records of lifetime cumulative occupational radiation dose. To demonstrate compliance with this requirement, the individual to be monitored may provide a written estimate of the cumulative lifetime dose or an up-to-date NRC Form 4 signed by the individual. This information need not be verified so long as the individual does not participate in a planned special exposure.

NRC Forms 4 and 5 and termination letters or reports, which report the results of monitoring prior to implementation of the revised 10 CFR Part 20, may be used without recalculating dose according to the requirements of the revised 10 CFR Part 20. For the purpose of assessing prior dose, whole body dose in rem as reported on the old (1981 or earlier) NRC Forms 4 and 5 can be considered equivalent to total effective dose equivalent (TEDE).

1.4 Records of Prior Exposure for Persons Participating in Planned Special Exposures

If there are any periods of exposure during the life of the monitored individual that have not been determined and documented, participation in a planned special exposure is not permitted. Acceptable documentation of prior exposure is similar to that required for documenting current-year exposure. Alternatively, the licensee may request in writing that a report of the monitored individual's exposure history be provided by the NRC. To request an exposure history, the licensee may send a request signed by the monitored individual to:

REIRS Project Manager
Office of Nuclear Regulatory Research
U. S. Nuclear Regulatory Commission
Washington, DC 20555

The request should contain the social security number (or other unique identifying number) of the

monitored individual authorizing release of the information and the name and address of the person or licensee to whom the report should be sent. The REIRS database contains only reports submitted by the seven classes of licensees required by 10 CFR Part 20 to report occupational exposures. Any missing monitoring periods should be obtained directly from licensees.

1.5 Individuals with No Social Security Number

Doses to individuals who do not have a social security number, such as citizens of foreign countries, should be reported using another unique identification number. It is important to record the type of identification used in the data block labeled "ID type" that follows the "Identification Number" data block on NRC Form 4 and 5. The appropriate code listed below should be inserted in the blank labeled ID Type.

ID TYPE	CODE
U. S. Social Security Number	SSN
Passport Number	PPN
Canadian Social Insurance Number	CSI
Work Permit Number	WPN
INDEX Identification Number	IND
Other	OTH

The use of licensee-generated identification numbers should be avoided whenever possible.

2. RECORDS OF MONITORING RESULTS FOR INDIVIDUALS FOR WHOM MONITORING IS REQUIRED

The preparation of NRC Form 5 with the information clearly and legibly shown, or the collection of all the information requested by NRC Form 5 using paper or electronic media (see Appendix A), is required by 10 CFR 20.2106. Such a record must be maintained for each individual for whom personnel monitoring is required by 10 CFR 20.1502. In addition, certain classes of licensees report the results of this monitoring to NRC pursuant to 10 CFR 20.2206 either by submitting copies of NRC Form 5 or by transmitting the required information to NRC through electronic media. This report is filed annually. Instructions and additional information pertinent to each item are contained on Form 5.

2.1 Multiple Badges

Further guidance on interpreting the results of multiple dosimetric devices placed at different locations within a single dose category is provided in Regulatory Guide 8.34, "Monitoring Criteria and Methods To Calculate Occupational Doses."

2.2 Dose Calculations for CDE and TODE to the Maximally Exposed Organ

Licensees are required by 10 CFR 20.2106(a)(6) to record the total organ dose equivalent (TODE), which is the sum of the deep dose equivalent (DDE) and the committed dose equivalent (CDE) to the organ receiving the highest dose. Organ doses need not be calculated if the committed effective dose equivalent (CEDE) does not exceed 1 rem and there are no overexposures in any dose category within the monitoring year, including doses previously reported by other licensees. In this case, the licensee may record "NC" for "Not Calculated" in items 16 and 18 on NRC Forms 4 and 5. If during the course of the year the dose to date for the year exceeds 1 rem CEDE or the individual receives an overexposure in another dose category, the CDE to the maximally exposed organ must be calculated, recorded, and reported. When CDE and TODE to the maximally exposed organ must be calculated, the licensee should refer to Regulatory Guide 8.34, "Monitoring Criteria and Methods To Calculate Occupational Doses."

2.3 Dose to the Embryo/Fetus

A declared pregnant worker is a worker who has voluntarily informed her employer in writing of her pregnancy and the estimated month and year of conception. The embryo/fetus' dose for the entire gestation period must be recorded (10 CFR 20.2106(e)), but need not be included on NRC Forms 4 and 5. Multiple records are not required in the case of twins, triplets, etc. Any dose measured to demonstrate compliance with 10 CFR 20.1208 must be recorded.

Licensees should be sensitive to the issue of personal privacy with regard to embryo/fetus dose. If requested by the monitored woman, a letter report may be provided to subsequent licensees to document prior embryo/fetus dose. Further guidance on assessing dose to the embryo/fetus is provided in Regulatory Guide 8.36, "Radiation Dose to the Embryo/Fetus."

2.4 Transmittal of Reports to the NRC

Certain licensees are required by 10 CFR 20.2206(c) to submit reports of monitoring for the previous year to NRC on or before April 30. These reports should be sent to:

REIRS Project Manager
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, DC 20555

According to 10 CFR 20.2206(b), "...The licensee shall use Form NRC 5 or electronic media containing all the information required by Form NRC 5."

2.5 Electronic Reporting of Exposure Data

Licensees are encouraged to record and report these data electronically. The format for reporting radiation exposure data in an electronic, machine-readable format is provided in Appendix A of this guide.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plan for using this regulatory guide.

Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the methods described in this guide will be used in the evaluation of applications for new licenses, license renewals, and license amendments and for evaluating compliance with 10 CFR 20.1001–20.2401.

PAGE ____ OF ____

NRC FORM 4 (6-92) 10 CFR PART 20

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB NO. 3150-0005
EXPIRES:

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: MINUTES. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0005), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

CUMULATIVE OCCUPATIONAL EXPOSURE HISTORY

1. NAME (LAST, FIRST, MIDDLE INITIAL)	2. IDENTIFICATION NUMBER	3. ID TYPE	4. SEX: MALE ☐ FEMALE ☐	5. DATE OF BIRTH

6. MONITORING PERIOD	7. LICENSEE NAME	8. LICENSE NUMBER	9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐

11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

6. MONITORING PERIOD	7. LICENSEE NAME	8. LICENSE NUMBER	9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐

11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

6. MONITORING PERIOD	7. LICENSEE NAME	8. LICENSE NUMBER	9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐

11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

6. MONITORING PERIOD	7. LICENSEE NAME	8. LICENSE NUMBER	9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐

11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

6. MONITORING PERIOD	7. LICENSEE NAME	8. LICENSE NUMBER	9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐

11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

6. MONITORING PERIOD	7. LICENSEE NAME	8. LICENSE NUMBER	9. RECORD ☐ ESTIMATE ☐ NO RECORD ☐	10. ROUTINE ☐ PSE ☐

11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE	18. TODE

19. SIGNATURE OF MONITORED INDIVIDUAL	20. DATE SIGNED	21. CERTIFYING ORGANIZATION	22. SIGNATURE OF DESIGNEE	23. DATE SIGNED

8.7-5

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF NRC FORM 4

(All doses should be stated in rems)

1. Type or print the full name of the monitored individual in the order of last name (include "Jr," "Sr," "III," etc.), first name, middle initial (if applicable).

2. Enter the individual's identification number, including punctuation. This number should be the 9-digit social security number if at all possible. If the individual has no social security number, enter the number from another official identification such as a passport or work permit.

3. Enter the code for the type of identification used as shown below:

CODE	ID TYPE
SSN	U.S. Social Security Number
PPN	Passport Number
CSI	Canadian Social Insurance Number
WPN	Work Permit Number
IND	INDEX Identification Number
OTH	Other

4. Check the box that denotes the sex of the individual being monitored.

5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.

6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY - MM/DD/YY.

7. Enter the name of the licensee or facility not licensed by NRC that provided monitoring.

8. Enter the NRC license number or numbers.

9. Place an "X" in Record, Estimate, or No Record. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee intends to assign the record dose on the basis of TLD results that are not yet available.

10. Place an "X" in either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represents the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee should sum them and report the total of all PSEs.

11. Enter the deep dose equivalent (DDE) to the whole body.

12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.

13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE_WB).

14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE_ME).

15. Enter the committed effective dose equivalent (CEDE).

16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ.

17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.

18. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.

19. Signature of the monitored individual. The signature of the monitored individual on this form indicates that the information contained on the form is complete and correct to the best of his or her knowledge.

20. Enter the date this form was signed by the monitored individual.

21. [OPTIONAL] Enter the name of the licensee or facility not licensed by NRC, providing monitoring for exposure to radiation (such as a DOE facility) or the employer if the individual is not employed by the licensee and the employer chooses to maintain exposure records for its employees.

22. [OPTIONAL] Signature of the person designated to represent the licensee or employer entered in item 21. The licensee or employer who chooses to countersign the form should have on file documentation of all the information on the NRC Form 4 being signed.

23. [OPTIONAL] Enter the date this form was signed by the designated representative.

PRIVACY ACT STATEMENT

Pursuant TO 5 U.S.C. 552a(e)(3), enacted into law by Section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the U.S. Nuclear Regulatory Commission on NRC Form 4. This information is maintained in a system of records designated as NRC 27 and described at 55 Federal Register 33984 (August 20, 1990), or the most recent Federal Register publication of the Nuclear Regulatory Commission's "Republication of Systems of Records Notices" that is available at the NRC Public Document Room, Gelman Building, Lower Level, 2120 L Street NW, Washington, D.C.

1. **AUTHORITY:** Sections 53, 63, 65, 81, 103, 104, 161(b), and 161(o) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201(b), and 2201(o)). The authority for soliciting the social security number is 10 CFR Part 20.

2. **PRINCIPAL PURPOSE(S):** The information is used by the NRC in its evaluation of the risk of radiation exposure associated with the licensed activity and in exercising its statutory responsibility to monitor and regulate the safety and health practices of its licensees. The data permits a meaningful comparison of both current and long term exposure experience among types of licensees and among licensees within each type. Data on your exposure to radiation is available to you upon your request.

3. **ROUTINE USE(S):** The information may be used to provide data to other Federal and State agencies involved in monitoring and/or evaluating radiation exposure received by individuals employed as radiation workers on a permanent or temporary basis and exposure received by monitored visitors. The information may also be disclosed to an appropriate Federal, State, or local agency in the event the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** It is voluntary that you furnish the requested information, including social security number, however, the licensee must complete NRC Form 5 on each individual for whom personnel monitoring is required under 10 CFR 20.2106. Failure to do so may subject the licensee to enforcement action in accordance with 10 CFR 20.2401. The social security number is used to assure that NRC has an accurate identifier not subject to the coincidence of similar names or birthdates among the large number of persons on whom data is maintained.

5. **SYSTEM MANAGER(S) AND ADDRESS:**
REIRS Project Manager
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, DC 20555

NRC FORM 5
(6-92)
10 CFR PART 20

U.S. NUCLEAR REGULATORY COMMISSION

OCCUPATIONAL EXPOSURE RECORD FOR A MONITORING PERIOD

APPROVED BY OMB NO. 3150-0006
EXPIRES:

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: ____ MINUTES. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0006), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

1. NAME (LAST, FIRST, MIDDLE INITIAL)	2. IDENTIFICATION NUMBER	3. ID TYPE	4. SEX ☐ MALE ☐ FEMALE	5. DATE OF BIRTH

6. MONITORING PERIOD	7. LICENSEE NAME	8. LICENSE NUMBER(S)	9A	9B
			☐ RECORD	☐ ROUTINE
			☐ ESTIMATE	☐ PSE

INTAKES

10A. RADIONUCLIDE	10B. CLASS	10C. MODE	10D. INTAKE IN μCi

DOSES (in rem)

DEEP DOSE EQUIVALENT	(DDE)	11.
EYE DOSE EQUIVALENT TO THE LENS OF THE EYE	(LDE)	12.
SHALLOW DOSE EQUIVALENT, WHOLE BODY	(SDE,WB)	13.
SHALLOW DOSE EQUIVALENT, MAX EXTREMITY	(SDE,ME)	14.
COMMITTED EFFECTIVE DOSE EQUIVALENT	(CEDE)	15.
COMMITTED DOSE EQUIVALENT, MAXIMALLY EXPOSED ORGAN	(CDE)	16.
TOTAL EFFECTIVE DOSE EQUIVALENT *(BLOCKS 11 + 15)*	*(TEDE)*	17.
TOTAL ORGAN DOSE EQUIVALENT, MAX ORGAN *(BLOCKS 11 + 16)*	*(TODE)*	18.

19. COMMENTS

20. SIGNATURE – LICENSEE	21. DATE PREPARED

INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE COMPLETION OF NRC FORM 5

(All doses should be stated in rems)

1. Type or print the full name of the monitored individual in the order of last name (include "Jr," "Sr," "III," etc.), first name, middle initial (if applicable).

2. Enter the individual's identification number, including punctuation. This number should be the 9-digit social security number if at all possible. If the individual has no social security number, enter the number from another official identification such as a passport or work permit.

3. Enter the code for the type of identification used as shown below:

CODE	ID TYPE
SSN	U.S. Social Security Number
PPN	Passport Number
CSI	Canadian Social Insurance Number
WPN	Work Permit Number
IND	INDEX Identification Number
OTH	Other

4. Check the box that denotes the sex of the individual being monitored.

5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.

6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY - MM/DD/YY.

7. Enter the name of the licensee.

8. Enter the NRC license number or numbers.

9A. Place an "X" in Record or Estimate. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee intends to assign the record dose on the basis of TLD results that are not yet available.

9B. Place an "X" in either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represents the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee should sum them and report the total of all PSEs.

10A. Enter the symbol for each radionuclide that resulted in an internal exposure recorded for the individual, using the format "Xx-#," for instance, Cs-137 or Tc-99m.

10B. Enter the lung clearance class as listed in Appendix B to 10 CFR Part 20.1001-2401 (D, W, Y, V, or O for other) for all intakes by inhalation.

10C. Enter the mode of intake. For inhalation, enter "H." For absorption through the skin, enter "B." For oral ingestion, enter "G." For injection, enter "J."

10D. Enter the intake of each radionuclide in μCi.

11. Enter the deep dose equivalent (DDE) to the whole body.

12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.

13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE,WB).

14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE,ME).

15. Enter the committed effective dose equivalent (CEDE) or "NR" for "Not Required" or "NC" for "Not Calculated".

16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ or "NR" for "Not Required" or "NC" for "Not Calculated".

17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.

18. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.

19. Signature of the person designated to represent the licensee.

20. Enter the date this form was prepared.

21. COMMENTS.
In the space provided, enter additional information that might be needed to determine compliance with limits. An example might be to enter the note that the SDE,ME was the result of exposure from a discrete hot particle. Another possibility would be to indicate that an overexposed report has been sent to NRC in reference to the exposure report.

PRIVACY ACT STATEMENT

Pursuant TO 5 U.S.C. 552a(e)(3), enacted into law by Section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the U.S. Nuclear Regulatory Commission on NRC Form 5. This information is maintained in a system of records designated as NRC-27 and described at 55 Federal Register 33984 (August 20, 1990), or the most recent Federal Register publication of the Nuclear Regulatory Commission's "Republication of Systems of Records Notices" that is available at the NRC Public Document Room, Gelman Building, Lower Level, 2120 L Street NW, Washington, D.C.

1. **AUTHORITY:** Sections 53, 63, 65, 81, 103, 104, 161(b), and 161(o) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201(b), and 2201(o)). The authority for soliciting the social security number is 10 CFR Part 20.

2. **PRINCIPAL PURPOSE(S):** The information is used by the NRC in its evaluation of the risk of radiation exposure associated with the licensed activity and in exercising its statutory responsibility to monitor and regulate the safety and health practices of its licensees. The data permits a meaningful comparison of both current and long-term exposure experience among types of licensees and among licensees within each type. Data on your exposure to radiation is available to you upon your request.

3. **ROUTINE USE(S):** The information may be used to provide data to other Federal and State agencies involved in monitoring and/or evaluating radiation exposure received by individuals employed as radiation workers on a permanent or temporary basis and exposure received by monitored visitors. The information may also be disclosed to an appropriate Federal, State, or local agency in the event the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding.

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5. **SYSTEM MANAGER(S) AND ADDRESS:**
REIRS Project Manager
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, DC 20555

APPENDIX A
FORMAT FOR ELECTRONIC TRANSMISSION OF EXPOSURE DATA

Introduction

The following outlines a means by which licensees may satisfy the requirements of 10 CFR 20.2206, "Reports of Individual Monitoring," in an electronic format by submitting magnetic disks, cartridges, or tape with formatted radiation exposure data.

Media Requirements

The following data storage media are compatible with the Radiation Exposure Information Reporting System (REIRS). The electronic media listed below are preferred by NRC for these submissions and are presented in the order of preference. However, licensees are encouraged to submit data on whatever system is compatible with their existing systems. Other forms of data submission may also be acceptable. NRC will provide additional guidance to licensees upon request to the REIRS Project Manager.

PC Diskettes

3½" or 5¼"
Double sided, high or double density
Standard IBM-DOS format
ASCII character format

Magnetic Tape

8 mm tape cartridges
Data quality
ASCII or EBCDIC format

Transmittal Letters

With the submission of each disk, tape, or cartridge, the licensee should also submit a transmittal letter containing information that will minimize processing time and help resolve possible discrepancies. Each letter should contain the following information as a minimum:

- File name — Descriptive name of the file or files contained on the disk.
- Date Created — Date each file was created.
- Operating system — Operating system and version used to format the disk.
- Contact — Name and telephone number of the person knowledgeable about each file.
- Other instructions — Comments or explanation regarding the submission, the actual date, the data format, or the other important information.
- Signature and date — Dated signature of the licensee's authorized representative responsible for the data.

Expected Data

One routine Form 5 is expected for each monitored individual at the facility for the monitoring year. There may also be a Form 5 for a planned special exposure for some individuals. Because there should be few repetitions of employee information, the employee information is included in the Form 5. The primary license number is also included in each Form 5 to ensure that the records are assigned to the proper facility.

File Structure

The file structure consists of a Header Record, which provides information about the source of the data file, followed by Form 5 dose records and supporting Form 5 intake records. Each record contains only ASCII or EBCDIC printable characters and is terminated with a Carriage Return (CR) and a Line Feed (LF). All empty space in a field is padded with spaces. Text strings are expected to be left justified in a field and numbers are expected to be right justified in a field.

Header Record

The following record type occurs only once at the top of each data file to identify the source of the data.

Field	Width	Start Col.	End Col.	Description
Primary_License	13	1	13	Primary NRC license number.
Preparation_Date	8	15	22	Date the record was written to the data file formatted as 'YYYYMMDD.'
Licensee_Name	72	24	95	Name of NRC licensee.
Contact	72	97	168	Name of person to contact for further information about this data file.
Phone_Number	14	170	183	Contact's phone number.
Other_License_1	13	185	197	Other related NRC license numbers.
Other_License_2	13	199	211	Other related NRC license numbers.
Other_License_3	13	213	225	Other related NRC license numbers.
Other_License_4	13	227	239	Other related NRC license numbers.
Other_License_5	13	241	253	Other related NRC license numbers.
Other_License_6	13	255	267	Other related NRC license numbers.
Other_License_7	13	269	281	Other related NRC license numbers.
Other_License_8	13	283	295	Other related NRC license numbers.
Other_License_9	13	297	309	Other related NRC license numbers.
Other_License_10	13	311	323	Other related NRC license numbers.

Form 5 Dose Record

The following record type occurs once for each Form 5 being reported. It is followed by zero or more Form 5 Intake Records.

Field	Width	Start Col.	End Col.	Description
Employee_ID	12	1	12	SSN, PPN, CSI, WPN, IND, or OTH. IDs should have no punctuation.
ID_Type	3	14	16	'SSN,' 'PPN,' 'CSI,' 'WPN,' 'IND,' or 'OTH'
Primary_License	13	18	30	Primary NRC license number.
Preparation_Date	8	32	39	Date the record was written to the data file formatted as 'YYYYMMDD.'
Record_Type	1	41	41	'D' = DOSE
First_Name	25	43	67	Employee's full first name (no nicknames).
Middle_Initial	1	69	69	Employee's middle initial.
Last_Name	25	71	95	Employee's last name. Titles such as "Jr" should be separated from the last name by a space. No punctuation should be used in the title.
Sex	1	97	97	Employee's sex. 'M' = Male and 'F' = Female
Birth_Date	8	99	106	Employee's date of birth ('YYYYMMDD').
Monitoring_Start	8	108	115	Date monitoring began ('YYYYMMDD'). This is typically January 1 of the monitoring year for everyone except new hires.
Monitoring_End	8	117	124	Date monitoring ended ('YYYYMMDD'). This is typically December 31 of the monitoring year for everyone except terminations.
Report_Type	1	126	126	'R' = Record, or 'E' = Estimate
Exposure_Type	1	128	128	'R' = Routine, or 'P' = PSE

Field	Width	Start Col.	End Col.	Description
DDE	8	130	137	Deep dose equivalent in rems. This can be formatted as '999.999.'
LDE	8	139	146	Eye dose equivalent to the lens of the eye in rems. This can be formatted as '999.999.'
SDE_WB	8	148	155	Shallow dose equivalent, whole body in rems. This can be formatted as '999.999.'
SDE_ME	8	157	164	Shallow dose equivalent, max extremity in rems. This can be formatted as '999.999.'
CEDE	8	166	173	Committed effective dose equivalent in rems. This can be formatted as '999.999.'
CDE	8	175	182	Committed dose equivalent. This can be formatted as '999.999.'
TEDE	8	184	191	Total effective dose equivalent. This can be formatted as '999.999.'
TODE	8	193	200	Total organ dose equivalent, maximally exposed. This can be formatted as '999.999.'

Form 5 Intake Record

The following record should be provided for each intake on the Form 5 being reported.

Field	Width	Start Col.	End Col.	Description
Employee_ID	12	1	12	IDs should have no punctuation.
ID_Type	3	14	16	'SSN,' 'PPN,' 'CSI,' 'WPN,' 'IDL,' 'IND,' or 'OTH.'
Primary_License	13	18	30	Primary NRC license number.
Preparation_Date	8	32	39	This is the date from the parent **Form 5 Dose Record** formatted as 'YYYYMMDD.'
Record_Type	1	41	41	'I' = Intake
Radionuclide	9	43	51	Radionuclide abbreviation with the hyphen.
Class	1	53	53	'D,' 'Y,' 'W,' 'V,' or 'O' for other.
Mode	1	55	55	'H' = Inhalation, 'B' = Absorption, 'J' = Injection, 'G' = Ingestion
Intake	10	57	66	The amount of μCi for the radionuclide. This can be expressed in scientific notation using the format '+9.999E+99' or as a decimal number of less than 9 digits.

Form 5 Comment Record

The following record type occurs only when comments are necessary to explain special exposure calculations or overexposures.

Field	Width	Start Col.	End Col.	Description
Employee_ID	12	1	12	IDs should have no punctuation.
ID_Type	3	14	16	'SSN,' 'PPN,' 'CSI,' 'WPN,' 'IDL,' 'IND,' or 'OTH.'
Primary_License	13	18	30	Primary NRC license number.
Preparation_Date	8	32	39	This is the date from the parent **Form 5 Dose Record** formatted as 'YYYYMMDD.'
Record_Type	1	41	41	'C' = Comment
Comment	240	43	282	Explanatory comment when needed.

REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this regulatory guide. The regulatory analysis prepared for 10 CFR Part 20, "Standards for Protection Against Radiation" (56 FR 23360), provides the regulatory basis for this guide and examines the costs and benefits of the rule as implemented by the guide. A copy of the "Regulatory Analysis for the Revision of 10 CFR Part 20" (PNL–6712, November 1988), is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW., Washington, DC, as an enclosure to Part 20.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

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RADIATION
SAFETY OFFICE

August 27, 1993

Robert G. Gattone, Jr.
Nuclear Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III Office
799 Roosevelt Road
Glen Ellyn, IL 60137-5927

Re: Control Number 95384

Dear Mr. Gattone:

Attached please find our responses to your letter dated July 16, 1993. As evidenced by our extensive response, we consider this an issue of great importance.

Should you have any questions, please do not hesitate to contact this office. Thank you for your consideration in this matter.

Sincerely,

Mack L. Richard

Mack L. Richard, M.S.
Radiation Safety Officer

Attachments: 1

Clinical Building 159
541 Clinical Drive
Indianapolis, Indiana
46202-5111

317-274-4797
Fax: 317-274-2332

IU School of Medicine
IU Medical Center &
Associated Facilities

JUSTIFICATION FOR EXCEEDING LIMITS
SPECIFIED IN 10 CFR 20.1301(a)

Response to Item 1 of July 16, 1993 NRC Letter

I. We have performed an extensive review of direct radiation surveys in and around hospital rooms where our brachytherapy patients are located. Based upon that review, the following information has been obtained:

A. Over the past 1.5 years, approximately 18% of the surveys indicate that the instantaneous exposure rate at one foot outside the patient room door exceeded 2 mR/hr. Of those measurements, the highest was 4.5 mR/hr and the average was 3.1 mR/hr.

B. Over the same time period, only 3% of the surveys indicate that the instantaneous exposure rate at one foot from the barrier in an adjacent patient room exceeded 2 mR/hr. One of those was 3.2 mR/hr and the other was 3.7 mR/hr.

C. While the calculated integrated exposure (based upon treatment time) in the room doorways exceeded 100 mR, utilizing an "occupancy factor" of 0.25 (assumes someone present in the doorway 25% of the time), the actual integrated exposure in every case would be less than 100 mrem.

D. The additional person-rem associated with these exposures above the limits equate to approximately 0.28 person-rem/yr.

II. It is our opinion that exceeding the limits specified in 10 CFR 20.1301(a) in doorways and adjacent rooms around brachytherapy patients is justifiable based upon the information provided in section 10H,III,B of our license renewal application and the following additional information:

A. The requirements of 10 CFR 20.1301(a) are directly based upon the recommendations found in NCRP Report No. 91, section 17. That section of the report states, "For continuous (or frequent) exposure, it is recommended that the annual effective dose equivalent not exceed 1 mSv (0.1 rem)." The key words in this statement are "continuous (or frequent)." Based upon the information listed above, the instances where our exposure rates may exceed the aforementioned limits are neither continuous nor frequent.

B. The NCRP report further states, ". . . a maximum annual effective dose equivalent limit of 5 mSv (0.5 rem) is recommended to provide for infrequent annual exposures." As stated in our original license renewal application, we propose to limit the integrated exposure to no more than 300 mrem.

C. In the U.S. Nuclear Regulatory Commission safety goals policy (Federal Register 51:30033; 1986), the NRC's "rule of thumb" for radiation exposure avoidance is $1000/person-rem. We have considered adding additional shielding to patient rooms and found that the least expensive option would be to purchase a portable wall shield at a cost of $2485. When considering this, it would take almost 9 years before we would reach the exposure avoidance dollar value corresponding to $1000/person-rem ($2485/$1000 per person-rem ÷ 0.28 person-rem/yr = 8.875 years). Thus the cost of exposure avoidance in this case seems excessive.

D. We had considered the possibility of restricting the area around the doorways by posting a portable "radiation area" sign at some point outside the doorway where the exposure rate is < 2 mR/hr. While this would allow us to meet the regulation, it could present a hazard regarding access to the patient room in the event of an emergency (e.g. fire or cardiac arrest). Furthermore, as stated previously, individuals do not generally occupy the doorway area more than 25% of the time. This being the case, while the instantaneous exposure rate might exceed 2 mR/hr, the actual exposure that individuals might receive is expected to be 25% of the instantaneous exposure. We propose an upper limit of 5 mR/hr which would correspond to an individual exposure of 1.25 mR in any one hour.

E. For adjacent patient rooms, we did consider the possibility of vacating said rooms when the exposure rate exceeds 2 mR/hr. Once again this is possible; however, it is questionable as to whether such action is warranted given the small amount of exposure involved and the previously mentioned NCRP recommendations.

F. Based upon information received from our hospital administration, the average daily cost for a hospital patient is approximately $1500/day. If an adjacent room which generally houses two patients had to be vacated, the cost to the hospital would be $3000/day. Based upon our current information, we would expect no more than 5 situations per year where rooms would need to be vacated; however, assuming the average brachytherapy treatment time is 2 days, the annual cost for exposure avoidance would be $30,000 (5 pt/yr x 2 day/pt x $3000/day). Utilizing the cost avoidance dollar value of $1000/person-rem, the maximum annual amount to be spent for exposure avoidance should be the aforementioned value multiplied by the predicted annual collective dose equivalent. This equates to $280.00 ($1000/person-rem x 0.28 person-rem/yr). The annual cost ($30,000) is far greater than the appropriate cost avoidance value ($280). Furthermore, if no additional patient rooms were available, we would be faced with a situation where treatment might have to be denied which is not in the best interest of the patient.

G. Under our previous NRC license, we had specific permission pursuant to 10 CFR 20.105(a) to exceed the limits specified in 10 CFR 20.105(b)(1), thereby allowing an instantaneous exposure rate in unrestricted areas of 5 mrem/hr around patient rooms. There seems to be no justifiable reason for not continuing this permission under 10 CFR 20.1301(c).

Response to Item 2 of July 16, 1993 NRC Letter

III. We have also performed a review of the direct radiation surveys for our hospitalized ^{131}I therapy patients. Based upon that review the following information has been obtained:

A. The 2 mR/hr limit was exceeded in less than 20% of the ^{131}I patient treatments. In all cases, this exposure rate was noted in an adjacent patient room. The highest exposure rate was 3.3 mR/hr and the average exposure rate above the limit was 2.3 mR/hr.

B. Due to the rapid biological elimination of ^{131}I in these patients (Effective $T_{\frac{1}{2}}$ = 28 hours), the calculated integrated exposure to an individual in the adjacent area was less than 100 mR in all cases.

C. Calculation of the "excess integrated exposure" (i.e. the integrated exposure above 2 mR/hr) indicated that the total person-rem over a six month period would be approximately 0.082 person-rem. Thus, the annual collective dose would be approximately 0.165 person-rem.

IV. It is our opinion that exceeding the limits specified in 10 CFR 20.1301(a) in doorways and adjacent rooms around ^{131}I patients is justifiable based upon the information provided in section 10I,II,B of our license renewal application and the following additional information:

A. The requirements of 10 CFR 20.1301(a) are directly based upon the recommendations found in NCRP Report No. 91, section 17. That section of the report states, "For continuous (or frequent) exposure, it is recommended that the annual effective dose equivalent not exceed 1 mSv (0.1 rem)." The key words in this statement are "continuous (or frequent)." Based upon the information listed above, the instances where our exposure rates may exceed the aforementioned limits are neither continuous nor frequent. Furthermore, while the integrated exposure to individuals exposed to our proposed 5 mR/hr limit could be greater than 100 mrem (see license renewal application section 10I,II,B,2), the "excess" integrated exposure (i.e. that part of the integrated exposure contributed by the exposure rate above 2 mR/hr) would be less than 100 mrem.

B. In the U.S. Nuclear Regulatory Commission safety goals policy (Federal Register 51:30033; 1986), the NRC's "rule of thumb" for radiation exposure avoidance is $1000/person-rem. We have considered adding additional shielding to patient rooms and found that the least expensive option would be to purchase a portable wall shield at a cost of $2485. When considering this, it would take approximately 15 years before we would reach the exposure avoidance dollar value of $1000/person-rem ($2485/$1000 per person-rem ÷ 0.164 person-rem/yr = 15.15 years). Thus the cost of exposure avoidance in this case seems excessive.

C. We had considered the possibility of restricting the area around the doorways by posting a portable "radiation area" sign at some point outside the doorway where the exposure rate is < 2 mR/hr. While this would allow us to meet the regulation, it could present a hazard regarding access to the patient room in the event of an emergency (e.g. fire or cardiac arrest). Furthermore, as stated previously, individuals do not generally occupy the doorway area more than 25% of the time. This being the case, while the instantaneous exposure rate might exceed 2 mR/hr, the actual exposure that individuals might receive is expected to be 25% of the instantaneous exposure. We propose an upper limit of 5 mR/hr which would correspond to an individual exposure of 1.25 mR in any one hour.

D. For adjacent patient rooms, we did consider the possibility of vacating said rooms when the exposure rate exceeds 2 mR/hr. Once again this is possible; however, it is questionable as to whether such

action is warranted given the small amount of exposure involved and the previously mentioned NCRP recommendations.

E. As previously mentioned, the average daily cost for a hospital patient is approximately $1500/day. If an adjacent room which generally houses two patients had to be vacated, the cost to the hospital would be $3000/day. Based upon our current information, we would expect no more than 10 situations per year where rooms would need to be vacated; however, assuming the average brachytherapy treatment time is 2 days, the annual cost for exposure avoidance would be $60,000 (10 pt/yr x 2 day/pt x $3000/day). Utilizing the cost avoidance dollar value of $1000/person-rem, the maximum annual amount to be spent for exposure avoidance should be the aforementioned value multiplied by the predicted annual collective dose equivalent. This equates to $165.00 ($1000/person-rem x 0.165 person-rem/yr). The annual cost ($60,000) is far greater than the appropriate cost avoidance value ($165). Furthermore, if no additional patient rooms were available, we would be faced with a situation where treatment might have to be denied which is not in the best interest of the patient.

F. Under our previous NRC license, we had specific permission pursuant to 10 CFR 20.105(a) to exceed the limits specified in 10 CFR 20.105(b)(1), thereby allowing an instantaneous exposure rate in unrestricted areas of 5 mrem/hr around patient rooms. There seems to be no justifiable reason for not continuing this permission under 10 CFR 20.1301(c).

V. A number of precautions will be implemented to maintain exposures to individuals in the doorways and adjacent rooms around both brachytherapy and ^{131}I patients as low as reasonably achievable (ALARA).

A. To minimize the exposure in doorways, the treated patients' beds will be moved as far away from the doorway as practicable.

B. We do possess one portable bedside shield for brachytherapy patients. When the exposure rate is greater than 2 mR/hr in an adjacent controlled area, we will attempt to position said shield in such a way as to minimize the exposure in either the doorway or adjacent room. If two or more patients are being treated concurrently and the exposure rates in adjacent areas exceed 2 mR/hr for more than one patient, the portable shield will be utilized to reduce the highest adjacent area radiation exposure level.

C. As mentioned in the NRC license renewal application, the exposure limits specified in 10 CFR 1301(a) will be strictly followed in adjacent rooms housing either pregnant patients or pediatric patients.

D. As mentioned in the NRC license renewal application, the instantaneous exposure rate will not be allowed to exceed 5 mR/hr. For areas adjacent to brachytherapy patients, the calculated integrated exposure (i.e. the exposure rate x treatment time) will not be allowed to exceed 300 mR. As illustrated in the NRC license renewal application, the calculated integrated exposure would not exceed 200 mR during a routine ^{131}I treatment.

VI. A question was raised regarding the effective half-life of 28 hours for ^{131}I utilized in our calculations. This half-life is based upon our experience with patients undergoing treatment for thyroid carcinoma. Due to the fact that these patients have had a thyroidectomy, they have little remaining thyroid tissue. Thus, the biological rate of release for ^{131}I is much more rapid than an individual with a normally functioning thyroid gland. The value cited in ICRP 30 (7.6 days) is for a normal individual, not a patient.

VII. Based upon the aforementioned information, the expected duration of operations in excess of the 10 CFR 20.1301(a) limits would be only a few days each year. In the event that we would find that such limits are being exceeded > 30% of the time (our definition of "frequent"), additional shielding will be obtained or administrative restrictions implemented to assure such deviations above the limits are both infrequent and in keeping with the ALARA philosophy.

Response to Item 3 of July 16, 1993 NRC Letter

The rationale for not implementing the recordkeeping requirements of 10 CFR 20.2106 and 10 CFR 20.2104(d) and (f) were explained in item 14 of our response (dated October 14, 1992) to the original NRC deficiency letter dated August 11, 1992. That rationale was specifically discussed with Mr. Kevin Null and Mr. Mike McCann during their site visit for our NRC license renewal. At that time, Mr. McCann specifically instructed us to include our rationale for not following the aforementioned recordkeeping requirements and it was his opinion that such action was indeed appropriate.

JUL 16 1993

Indiana University Medical Center
Radiation Safety Office, CL 159
ATTN: Mack L. Richard, M.S.
Radiation Safety Officer
541 Clinical Drive
Indianapolis, IN 46202-5111

Dear Mr. Richard:

We have reviewed your letter dated June 15, 1993 requesting amendment to NRC License Number 13-02752-03 and find that we will need additional information as follows:

1. Radiation Safety Program Precautions and Procedures for Brachytherapy

In order for us to properly evaluate your request for exemptions to:

- 10 CFR 20.1301(a)(1) (allowing the total effective dose equivalent to individual members of the public from your brachytherapy program to exceed 0.1 rem in a year); and

- 10 CFR 20.1301(a)(2) (allowing the dose in any unrestricted areas from brachytherapy sources to exceed 0.002 rem in any one hour)

you need to submit the information requested in 10 CFR 20.1301 (c)(1).

Therefore, demonstrate the need for and the expected duration of operations in excess of the limits outlined above.

2. Radiation Safety Program Procedures for Radiopharmaceutical Therapy Patients Requiring Hospitalization

In order for us to properly evaluate your request for exemptions to:

- 10 CFR 20.1301(a)(1) (allowing the total effective dose equivalent to individual members of the public from your iodine-131 radiopharmaceutical therapy program to exceed 0.1 rem in a year); and

- 10 CFR 20.1301(a)(2) (allowing the dose in any unrestricted areas from iodine-131 radiopharmaceutical sources to exceed 0.002 rem in any one hour)

you need to submit the following information:

a. Pursuant to 10 CFR 20.1301 (c)(1), demonstrate the need for and the expected duration of operations in excess of the limits outlined above.

F

b. Your iodine-131 effective half-life (28 hours) is much different than that reported in ICRP-30 (7.6 days). Therefore, discuss the methodology you used to determine biological half-life and effective half-life.

3. 10 CFR Part 20

On January 1, 1994, all NRC licensees will be required to comply with revised 10 CFR 20. Until that date, licensees have the option of implementing all of revised 10 CFR 20 or withholding compliance with revised 10 CFR 20. Implementation is all or none (i.e., partial implementation of revised 10 CFR 20 is prohibited).

Based on your correspondence, it appears you chose early implementation of revised 10 CFR 20. However, you indicate a partial implementation by excluding 10 CFR 20.2106 and 20.2104(d) and (f). Therefore, it is necessary for you to confirm implementation of the entire revised 10 CFR 20, or state your intention of withholding implementation of revised 10 CFR 20 until January 1, 1994.

The enclosed Regulatory Guides 8.34 and 8.7 may provide guidance that may assist you in complying with 10 CFR 20.2103 and 20.2104(d) and (f).

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 95384.

Upon failure to file an answer within the specified time, we will consider that you have abandoned your request and will void this action. This is without prejudice to resubmission of the application.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708)790 [illegible].

Sincerely,

Original Signed By
Robert G. Gattone, Jr.
Nuclear Materials Licensing Section

Enclosures:
1. 10 CFR Part 20
2. Regulatory Guide 8.34
3. Regulatory Guide 8.7

RIII
Gattone/rg
7/15/93

RIII
Frazier
7/15/93

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02110
STATUS CODE: 0
FEE CATEGORY: 7B EX 3E
EXP. DATE: 19971130
FEE COMMENTS: 170.11(A)(4) CAL EX
DECOM FIN ASSUR REQD: Y

LICENSE FEE TRANSMITTAL

53

A. REGION III

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: INDIANA UNIVERSITY
RECEIVED DATE: 930621
DOCKET NO: 3001609
CONTROL NO.: 395384
LICENSE NO.: 13-02752-03
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 0
CHECK NO.: ---

3. COMMENTS
add'l info to
CN 93038

SIGNED P. Antosh
DATE 7-8-93

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED) ✓

1. FEE CATEGORY AND AMOUNT: 7B EX 3E FEE NOT REQUIRED
Addl Info 393038

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ✓
RENEWAL ---
LICENSE ---

3. OTHER ---

SIGNED Rita Messina
DATE 7/23/93

RECEIVED
JUL 16 1993
REGION III

ROUTING AND TRANSMITTAL SLIP

Date 7-1-93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Debbie		
2.		
3.		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

Please control in as additional information to CIN 93038 and return pending file to me ASAP.

Indiana University Lic. # 13-02752-03

Thanks

P.S. - Action to be assigned to me — 53

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
Bob	Phone No.

5041-102

☆ U.S. G.P.O. 1991 281-781/40016

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

CONTROL NO. 395384

INDIANA UNIVERSITY
MEDICAL CENTER

RADIATION SAFETY OFFICE
Clinical Building 159
541 Clinical Drive
Indianapolis, IN 46202-5111
(317) 274-4797

June 15, 1993

Mr. Michael McCann
Materials Licensing Section
U.S.N.R.C. - Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Mike:

Per our telephone conversation of this morning, we hereby request that a member of your staff review sections 10H and 10I (specific pages 10H-2 and 10I-2) of our NRC license renewal application (NRC license #13-02752-03) regarding acceptable exposure limits in areas adjacent to rooms where brachytherapy and radiopharmaceutical patients are located. As I mentioned to you this morning, we recently discovered that the provisions of these two sections may have been overlooked during the renewal process due to the fact that there is no specific reference in our NRC license regarding NRC authorization to deviate from the requirements of 10 CFR 20.1301(a).

Should you have any questions or require further information, please do not hesitate to contact me. Thank you for your attention in this matter.

Sincerely,

Mack L. Richard

Mack L. Richard, M.S.
Radiation Safety Officer