

Memorial Hospital

October 26, 1982 License No.13-12371-01 Refer to control No. 11841

Mike McCann, Materials License Section U.S. Nuclear Reg. Commission, Region III 799 Roosevelt Road Glen Ellyn, IL 60137

Dear Cr. McCann

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This is in reply to our phone conversaton and I will try by this letter to help clarify some items on the renewal application.

- Item 9 (Appendix C): The pied for a high energy survey meter is agreed with and we will order a Cutie Pie Survey Meter with a range up to 25R/hr (model 051-740, Atomic Products Corporation).
- 2. Item 6B (Cesium 137): After talking with you, I spoke with Dr. Joe Conley, the Radiation Therapist, about setting up a program to conform with Item 20 of the Regulatory Guide. However, he stated that he did not forsee the hospital buying any Cesium for a long time. Currently, Dr. Conley is in practice with Dr. Ben Alt and Dr. Ben Birkhead at St. Anthony's Hospital in Louisville, KY. They have Radium and Cesium sources stored there and use those whenever they have a case at Memorial Hospital. It is about 18 miles between these hospitals and Dr. Conley transports the sources in a lead containe* himself for each case. A copy of his nursing instructions is enclosed. Therefore, Item 6B and Group VI in Item 6A will remain not applicable for us and please delete our request for Cesium 137.
- 3. Item 19, Safe Handling of Therapeutic doses of liquid L-131: We do not have a fume hood in the Radiology Department. However, we have access to a hood in the Laboratory across the hall. We will follow the instructions on page 26 of our application and use the fume hood in the Laboratory for the initial opening of the liquid I-131 bottle. We will then recap the bottle and take it immediately to the patient's room and administer it to the patient.
- ALARA Program: We will follow the model program outlined in Appendix O of the Regulatory Guide to implement the ALARA program at Memorial Hospital.

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Page 2 October 26, 1982 Mike McCann

5. One new item not mentioned in our renewal application is to have one of our associates listed as a user. Dr. Steve Regan has joined us and his qualifications are as listed on the enclosed form NRC-313M, A and B, and he is licensed to practice medicine in Indiana. Would you please ammend our license so as to include him.

I believe that will cover the items in question but don't hesitate to call or write if you need further information.

Sincerely

William V. Johnson, M.D.

Radiologist

jkd/WVJ

enclosure

APPENDIX A

Dr Carley's

THERAPEUTIC USE OF SEALED SOURCES

- 1. All patients treated with brachytherapy sources will be placed in a private room with toilet, preferably an end room.
- The patient's room will be properly posted in accordance with 20.203 of 10 CFR Part 20, or Section 12, 902 KAR 100:020.
- 3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rates will be determined at the patient's bedside, 3 feet from the patient, 3 feet from the bed, at the entrance door, and in adjacent rooms.
- 4. Immediately after sources are implanted, the form, "Nursing Care For Patients Receiving Intracavitary Cesium Therapy" will be placed on the patient's chart.
- Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraph 20.105(b) of 10 CFR Part 20, or Section 7, 902 KAR 100:020.
- Nurses caring for brachytherapy patients should be assigned film budges.
- 7. At the conclusion of treatment, a survey will be performed to ensure that all sources have been removed from the patient and that no sources remain in the patient's room or any other area occupied by the patient. At the same time, all radiation signs will be removed.

APPENDIX B

MURSING INSTRUCTIONS FOR PATIENTS WITH INTRACAVITARY CESIUM

a. Special restrictions may be noted on the patient's chart. Murses should read these instructions before administering to the patient. Call the Radiation Safety Officer or his designee with any questions about the care of these patients in regard to radiation safety precautions.

Dr Couley's

- b. Nurses should spend only the minimum time necessary near a patient for routine nursing care. Do not exceed the time specified in Table 1, paragraph o.
- c. When a nurse receives an assignment to a therapy patient, a film or TLD badge should be obtained immediately from the Radiation Safety Officer or his designee. The badge shall be worn only by the nurse to whom it is issued and shall not be exchanged between nurses.
- Pregnant nurses shall not be assigned to the personal care of these patients.
- e. Never touch needles, capsules, or containers holding brachytherapy sources. If a source becomes dislodged, contact the Radiation Safety Officer or the radiotherapist immediately.
- Bed baths given by the nurse should not be given while the sources are in place.
- g. Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary unless orders to the contrary have been written.
- h. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered.
- All bed linens must be checked with a radiation survey meter before being removed from the patient's room to ensure that no dislodged sources are inadvertently removed.
- These patients must stay in bed unless orders to the contrary are written.
- k. Visitors will be limited to those over 18 years of age, unless other instructions are noted on the patient's chart'.
- Visitors should sit at least 6 feet from the patient and should not remain longer than the time specified on the form posted on the patient's door and/or on his chart (30 minutes per day).

- m. No nurse, visitor, or attendant who is pregnant shall be permitted in the room of a patient while brachytherapy sources are implanted in the patient. Female visitors should be asked whether they are pregnant.
- n. Emergency Procedures:

(1) If an implanted source becomes loose or separated from the patient, or

(2) If the patient requires emergency care, <u>immediately</u> call the radiotherapist or Radiation Safety Officer

Dr. Ben Birkhead: 587-1161 ext 1646 or (502) 897-7745

Dr. Joe Conley: 587-1161 ext 1646 or (812) 969-2455

dilligram equivant of Radium used	Maximum Daily Time*			ά
	2ft.	3ft.	4ft.	6ft.
100	thr.	yhr. 1	lhr.	2hr. 4
25 10	1 23	2 5	4 10	8 over 12

TABLE 1

"Taken from "Safe Hundling of Radioactive Isotopes in Medical Practice," E. H. Quimby, The Macmillan Co., New York (1960).

APPENDIX C

NURSING CARE FOR PATIENTS RECEIVING IMTRACAVITARY CESIUM THERAPY

- Every patient receiving Cesium-137 intracavitary treatment is to be restricted to bed in a private room with toilet.
- 2. Nurses should spend only the minimum amount of time near the patient required for ordinary nursing care and should wear a film badge. (See Max. Time in Table). SPECIAL RESTRICTIONS MAY BE NOTED BELOW. Private duty nurses remaining in the patient's room must be instructed by the doctor as to the distance to maintain except during actual nursing operations. Pregnant nurses shall not care for the patient.

In Conley's

- Patients are allowed visitors who are over 18 years old and not pregnant unless other instructions are given. They must, however, sit at least 6 feet away from the patient and may not remain longer than 30 minutes per day.
- 4. Instruments and containers used to handle Cesium sources do not become radioactive. Special instruments are used only to simplify handling and to maintain appropriate distances from the hands to the sources.
- No special precautions are needed for sputum, urine, vomitus, feces, dishes, instruments, or utensils. Hold bedding for protection survey.
- Surgical dressings and bandages should be changed only as directed by the radiotherapist** or the physician designated by him.
- Perineal care is not given during the treatment, but the perineal pad may be changed when necessary. If the pad is changed, be sure the radioactive sources or source containers are not disturbed or loosened.
- 8. IF THE CESIUM NEEDLES, CAPSULES, OR CONTAINERS BECOME LOOSE OR FALL OUT DO NOT TRY TO REPLACE THEM. CALL THE RADIOTHERAPIST OR RADIOLOGIST ON CALL.

SPECIAL INSTRUCTIONS:

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	50 25 10		2010°. 12 21-3	ishr. 1 2 5		1hr. 2 4 10		2hr. 4 8 over 12
44 [[Dr.	Ben Joe	Birkhead - Conley -	- 587-1161 ext. 1 - 587-1161 ext. 1	1646 1646	(502) 8 (812) 9	397-7745 369-2455	(home) (home)

APPENDIX D Dr Conly's

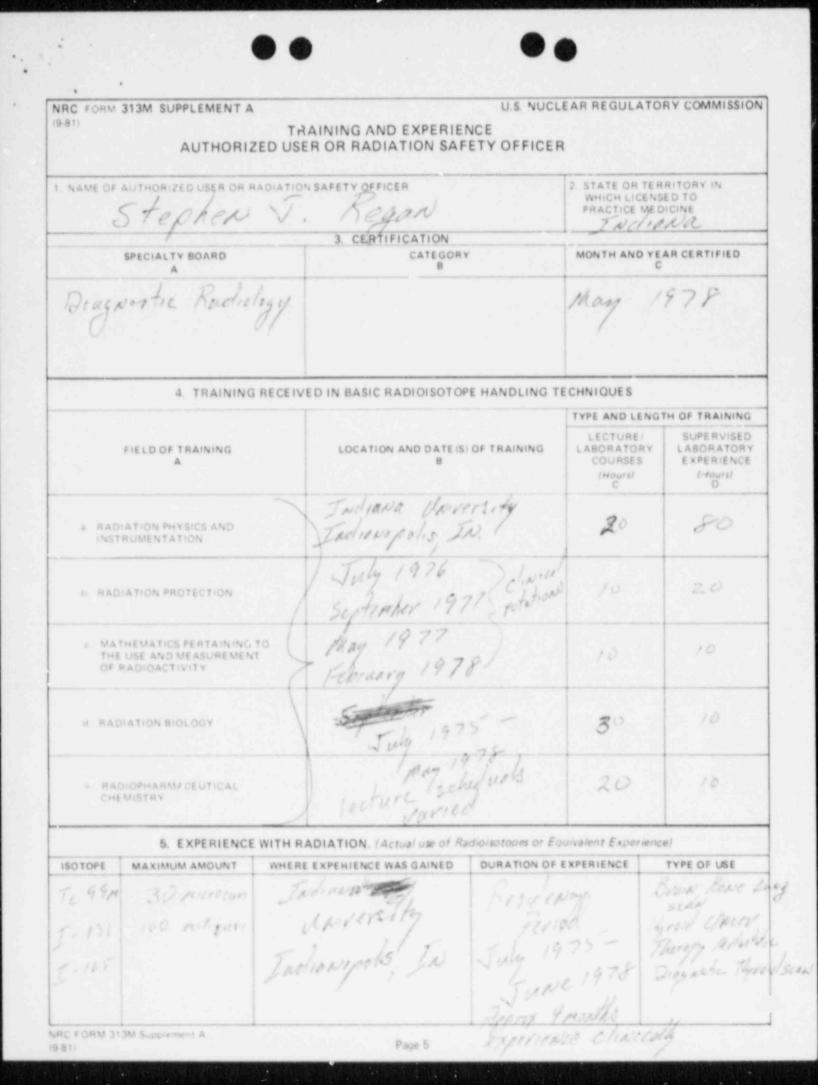
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RADIATION PROTECTION SURVEY

* * BRACHYTHERAPY * *

NAME:	DATE:
HOSPITAL:	ROOM NO. :
	NOUNT OF ACTIVITY:
DATE AND TIME OF INSERTION: OPERATING ROOM CLEARANCE SURVEY	by:mR/hr.
DATE AND TIME OF REMOVAL: PATIENT ROOM CLEARANCE SURVEY	by:mR/hr.
EXPOSURE RATES	with sources (mR/hr.)
3 ft. from patient	
6 ft. from patient	
Entrance Door	
Adjacent Room	
Adjacent Room	
Other	· · · · · · · · · · · · · · · · · · ·
Survey by:	Date and Time:
Instrument Used	Cal. Date
Survey by:	Date and Time:
Instrument Used	Cal. Date

and the state



U. S. NUCLEAR REGULATORY COMMISSION NRC FORM 313M SUPPLEMENT B (9.81) PRECEPTOR STATEMENT Supplement 8 must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. KEY TO COLUMN C APPLICANT PHYSICIAN'S NAME AND ADDRESS PERSONAL PARTICIPATION SHOULD CONSIST OF: 5 Covey Court FULL NAME 1 Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage. 2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data. 3-Adequate period of training to enable physician to manage radioactive ZIP CODE patients and follow patients through diagnosis and/or course of treatment. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN NUMBER OF CUMMENTS CASES INVOLVING PERSONAL (Additional information or comments may CONDITIONS DIAGNOSED OR TREATED ISOTOPE PARTICIPATION be submitted in duplicate on separate sheets.] D 10 A 8 DIAGNOSIS OF THY ROLD FUNCTION 35 DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME LIVER FUNCTION STUDIES FAT ABSORPTION STUDIES KIDNEY FUNCTION STUDIES 4, 13 RIA IN VITRO STUDIES 733 136 DETECTION OF THROMBOSIS THYROID IMAGING 35 EYE TUMOR LOCALIZATION P-32 Se. 75 PANCREAS (MAG)NG 3 CISTERNOGRAPHY BLOOD FLOW STUDIES AND Xe 133 PULMONARY FUNCTION STUDIES BRAIN MAGING CARDIAC IMAGING 20 THYROLD IMAGING SALIVARY GLAND IMAGING Tc.99m BLOOD POOL IMAGING PLACENTA LOCALIZATION LIVER AND SPLEEN IMAGING LUNG IMAGING. IMaGING enal

NRC FORM 313M SUPPLEMENT B (9-81)

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Page 6

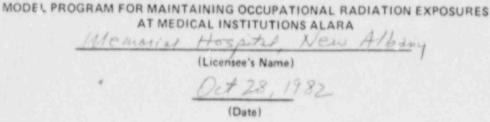
PRECEPTOR STATEMENT (Continued)

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2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued) NUMBER OF COMMENTS CASES INVOLVING PERSONAL (Additional information or comments may be CONDITIONS DIAGNO('D OR TREATED ISOTOPE PARTICIPATION submitted in duplicate on separate sheets,) C D A 8 P.32 TREATMENT OF POLYC (THEMIA VERA, (Soluble) LEUKEMIA, AND BONE METASTASES P.32 INTRACAVITARY TREATMENT (Collo-dal) TREATMENT OF THYROID CARCINOMA 1.1.31 TREATMONT OF HYPERTHYROIDISM INTRACAVITARY TREATMENT Au-198 INTERSTITIAL TREATMENT Co-60 C+137 INTRACAVITARY TREATMENT 1-125 INTERSTITIAL TREATMENT 17-192 Co-60 TELETHERAPY TREATMENT Cs-137 Sr-90 TREATMENT OF EYE DISEASE RADIOPHARMACEUTICAL PREPARATION Mo-99/ Tc-99m GENERATOR 12 Sn 113/ GENERATOR Tc-99m REAGENT KITS 12 3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING topproximately July 1976 700 hours charles x per reace September 1977 1977 February 1978 THE TRAINING AND EXPERIENCE INDICATED ABOVE | & PRECEPTOR'S SIGNATURE WAS OBTAINED UNDER THE SUPERVISION OF A NAME OF SUPERVISOR Henry N. Wellman, M.D. 7. PRECEPTOR'S NAME (Please type or print) Indiana University School of Medicine Henry N. Wellman, M.D. . MAILING ADDRESSNuclear Medicine a city 1100 West Michigan Street 8. DATE June 30, 1982 Indianapolis, IN 46223 5. MATERIALS LICENSE NUMBERISI 13-02752-03 Ind.Univ. at Indianapolis NRC FORM 313M SUPPLEMENT 8 19-811 Page 7





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Management Commitment

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- We, the management of this (medical facility, hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)¹ and a Radiation Safety Officer (RSO).
 - We will perform a formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or cutside consultants.
 - Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
- d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee (RSC)²

- a. Review of Proposed Users and Uses
 - (1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
 - (2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.
 - (3) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).
- b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

- The RSC will delegate authority to the RSO for enforcement of the ALARA concept.
- (2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

³ Private practice physician licenses do not include an RSC.

² The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section 2

Review of ALARA Program

- The RSC will encourage all users to review current procedure and develop new procedures as appropriate to implement the ALARA concept.
- (2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 0-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).³
- (3) The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

Radiation Safety Officer (RSO)

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- Annual and Quarterly Review
 - Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.
 - (2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authôrized users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program.
 - (3) Quarterly review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.
- h. Education Responsibilities for ALARA Program
 - The RSO will schedule briefings and educational sessions to inform workets of ALARA program efforts.

- (2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that manages. t, the RSC, and the RSO are committed to implementing the ALARA concept.
- Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

- The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
- (2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.
- Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.



Authorized Users

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- New Procedures Involving Potential Radiation Exposures
 - The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.
 - (2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.
- B. Responsibility of Authorized User to Persons Under His/Her Supervision
 - The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.
 - (2) The authorized user will ensure that persons under his/her supervision who are

³The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered softiciently important to justify further investigations.

subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

- Persor v Who Receive Occupational Radiation Exposure
 - a. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.
 - b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.
- Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures

This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table O-1 below. These levels apply to the exposure of individual workers.

Table 0-1

Investigational Levels (mrems per calendar quarter)

		Level I	Level II
1.	Whole body; head and trunk (active blood-forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	1875	5625
3.	Skin of whole body*	750	2250

Not normally applicable to nuclear medicine operations except those using significant quantities of beta-emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5. "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring not less than once in any calendar quarter as required by §20.401 of 10 CFR Part 20. The following actions will be taken at the Investigational Levels as stated in Table 0-1 Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table 0-1 values for the Investigational Level I.

 Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

> The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

Exposure equal to or greater than Investigational Level II.

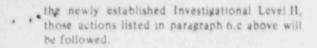
The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table 0-1.

> In cases where a worker's or a group of workers' exposures need to exceed Investigational Level II a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

> The RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds





7. Signature of Certifying Official⁴

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.

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Signature	0		
William V		MD	<u>.</u>
Name (print or type)	25		
Rodictoria	+ + 850		
Title			

Institution (or Private Practice) Name and Address

⁴The person who is authorized to make commitments for the dministration of the institution (e.g., hospital administrator) or, a the case of a private practice, the licensed physician.