Henry
Heywood
Memorial
Hospital

Paul E Corcoran
Administrator

1981 JUL 2 AM 10 06

June 29, 1981

Mr. John E. Glenn
Material Licensing Branch
Division of Full Cycle and
Material Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

RE: License No. 20-16804-01, NRC letter of May 21, 1981, No control No. issued

Dear Mr. Glenn:

Pertaining to your letter of May 21, 1981 requesting additional information relative to the Henry Heywood Hospital license renewal:

1. Supplements A and B to be completed by Dr. Melvin Farmelant of St. Vincent Hospital, Worcester, MA NRC License No. 20-12869-01 are enclosed.

2. Mr. Ascoli is authorized under St. Vincent Hospital license No. 20-12869-01 to calibrate survey meters. The appropriate section of that license is enclosed. The sources are housed at the St. Vincent Hospital and calibration is done at the St. Vincent Hospital using procedures in Appendix D, Section 1.

3. A revised Hot Lab diagram is enclosed indicating the shielding thickness. Periodic surveys of the storage area and surrounding unrestricted areas are performed by the consulting physicist and documented, along with the weekly surveys performed by the Nuclear Medicine technologist. Radiation levels do not exceed the limits specified in 10 CFR 20.105.

4. The first elution from a new TC-99M/MO-99 generator will be used for linearity testing. The procedures in Appendix D have previously been submitted.

5. Radiation workers attend a yearly in-service lecture given by the consulting Physicist. Radiation protection and safety are discussed. Also, the Nuclear Medicine technologist attends all RIC meetings and participates in the discussion of specific safety related matters and film badge monitering results.

Ancillary personnel in the Nuclear Medicine area receive individual instruction to insure that they observe proper radiation safety precautions. (Memo enclosed).

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6. See enclosed memo.

7. Air flow rates are measured twice yearly with a velometer by the consulting physicist.

   The pulmonary exhaust is monitored weekly with a low-level GM counter. Replacement of the trap filter will be made when saturation is present.

   The saturated filters will be changed according to manufacturing procedures and stored in the fume hood (with inherent $\frac{1}{8}$ inch lead shielding) for 10 half-lives. The trap will be monitored for background and disposed of.

8. This request is withdrawn.

9. The ALARA prgram of Appendix O will be adopted. However, the investigational levels for the hands of the Nuclear Medicine technologist will be changed to 4,000 MREM level 1, and 12,000 MREM level 2, per calendar quarter. This is due to the fact that essentially one technologistis involved in milking the TC-99 M/MO-00 generator, and administering the patient doses. The revised levels for this category represent more realistic action levels at this individual institution.

If I may be of any further assistance, please do not hesitate to contact me.

Joseph A. Guzzetta, M.D.
Chairman Nuclear Medicine and Radiation
Safety Committee

Paul E. Corcoran
Administrator

FORM NRC-313M-SUPPLEMENT A (8-78) — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
STEPHEN PECK, M.D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Diagnostic Radiology	June, 1980

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	St. Vincent Hospital Worcester, MA 01604 Mar'79- may'79	85	
b. RADIATION PROTECTION	" plus 2yr. Physics course	40	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	40	
d. RADIATION BIOLOGY	"	40	
e. RADIOPHARMACEUTICAL CHEMISTRY	"	40	

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Group I, II, III	clinical studies	St. Vincent Hospital Worcester, Ma.	3 yr. residency program, including nuclear medicine	

FORM NRC-313M-SUPPLEMENT B
(8-78)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B 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.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME
STEPHEN PECK

STREET ADDRESS
HENRY HEYWOOD HOSPITAL
242 GREEN ST.

CITY | STATE | ZIP CODE
GARDNER, MASS 01440

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

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 patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	35	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES	6	
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	35	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY	15	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	40	
OTHER			
Tc-99m	BRAIN IMAGING	150	
	CARDIAC IMAGING	25	
	THYROID IMAGING	25	
	SALIVARY GLAND IMAGING	5	
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING	40	
	BONE IMAGING	100	
OTHER			

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	100	
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	100	
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

March 1979 thru May 1979 - 550 hours

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Melvin H. Farmelant, M.D.

b. NAME OF INSTITUTION
St. Vincent Hospital

c. MAILING ADDRESS
25 Winthrop Street

d. CITY
Worcester, MA 01604

5. MATERIALS LICENSE NUMBER(S)
20-12869-01

6. PRECEPTOR'S SIGNATURE
Melvin H. Farmelant, M.D.

7. PRECEPTOR'S NAME *(Please type or print)*
Melvin H. Farmelant, M.D.

8. DATE
June 23, 1981

FORM NRC 313M SUPPLEMENT B
(8-78)

St. Vincent Hospital
25 Winthrop Street
Worcester, MA 01604
License # 20-12869-01

(2)

METHODS, FREQUENCIES AND STANDARDS USED FOR

CALIBRATING INSTRUMENTS LISTED IN ITEM 9

I. CALIBRATION OF SURVEY INSTRUMENTS

1. Survey instruments will be calibrated at least annually and following repair.

2. Calibration will be performed at two points on each scale. The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10% or the calculated or known values for each point checked. Readings within ± 20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

3. Survey instruments will be calibrated at the licensee's facility.

(i) Calibration source Cs^{137}

Manufacturer's name Nuclear Associates

Model No. 67-802

Activity in millicuries 27.6

Accuracy +4.7% to -3.3%

Traceability to primary standard NBS

(ii) The calibration procedures in Appendix D, Section A will be used.

II. CALIBRATION OF DOSE CALIBRATOR

1. Sources used for linearity test:

40CmCi Tc^{99m} - Gamma Diagnostics Lab

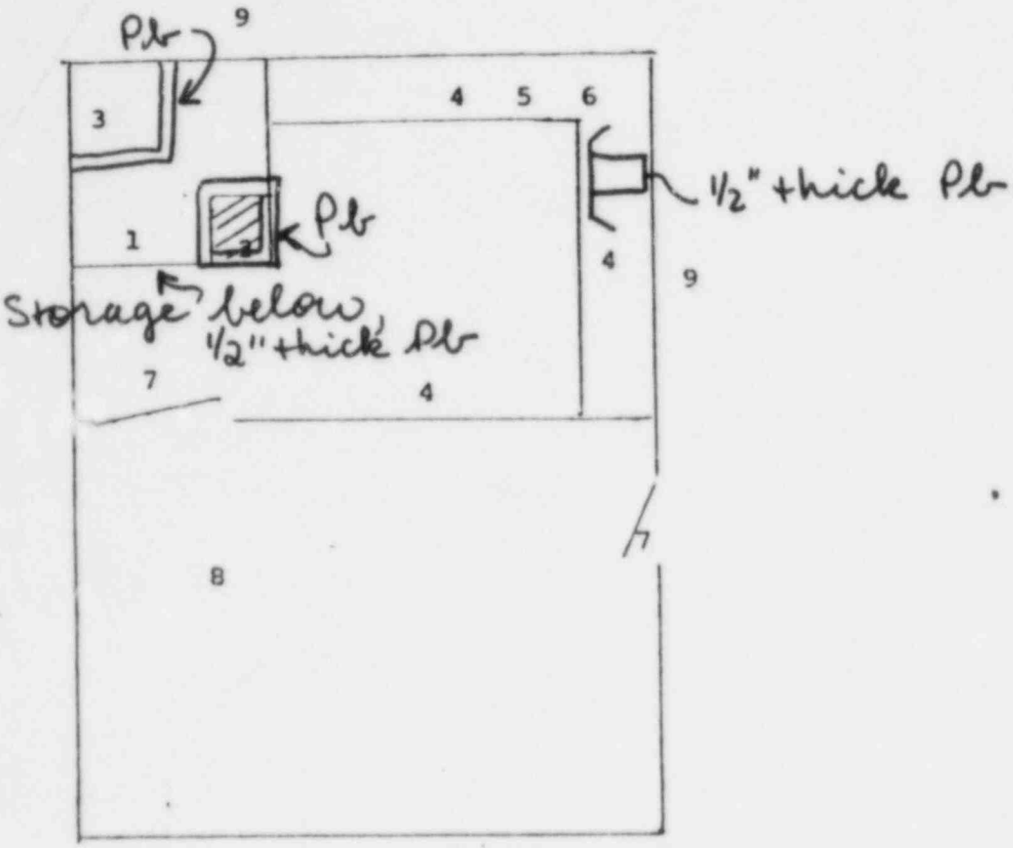
2. Sources used for instrument accuracy:

See enclosures from Janine & Gayles

(3)

HENRY HAYWOOD MEMORIAL HOSPITAL

HOT LABORATORY



1. Hood
2. Lead Shielding, 2" thick
3. Tc-99m Generator Storage, 2" thick
4. Calibration, Dispensing Area, and Formulation
5. Dose Calibrator
6. Leaded Glass Shield
7. Door
8. Patient Scan Room (Thyroid)
9. Hall
10. Storage Area

(5)

HENRY HEYWOOD MEMORIAL HOSPITAL

INTER-OFFICE MEMORANDUM

Date: February 17, 1981

To: Dan Dupuis

From: Gary Wheeler GW

Subject: Disposal of rubbish from the Nuclear Medicine Hot Lab

The following recommendation has been made by our consulting physicist for removal of non-radioactive trash from the Nuclear Medicine Hot Lab. This is necessary so that we may comply with the Nuclear Regulatory Commission Guide Lines.

A housekeeper should be under the supervision of the Nuclear Medicine Technologist when removing trash from the hot lab. Would you please have the housekeeper contact the Nuclear Medicine Technologist, presently, Rebecca Cox, prior to entering the hot lab for removal of non-radioactive trash.

Your help in this matter would be appreciated, if I can be of any further assistance, please do not hesitate to contact me.

(6)

HENRY HEYWOOD MEMORIAL HOSPITAL

INTER-OFFICE MEMORANDUM

Date: May 29, 1981

To: Judy Dymek, Director of Admitting

From: Gary Wheeler, R.T., Chief Technologist GW

Subject: Delivery of Radiation Isotopes

Radioactive Isotopes are frequently delivered to the hospital during odd shifts, specifically, weekends or evenings. Recently, Isotopes have been delivered through Purchasing and the Emergency Room. This procedure is inconsistent with the department policy and the following procedure should be followed for all Nuclear Medicine Generators or Isotopes delivered to the hospital:

> "All Generators and Isotopes are delivered to the main switchborad operator in the hospital entrance. During routine working hours the operator should directly contact the Nuclear Medcine Department (Ext. 233). During evenings and weekends the switchboard operator should contact the hospital firemen who will deliver the Generator or Isotope to the Nuclear Medicine Hotlab and lock the Isotope in the room."

The following personnel should be contacted if questions arise regarding this procedure:

Joseph Guzzetta, M.D., Radiation Safety Officer
Telephone No. Home: 632-2034
Business: 632-3420 Ext. 284

Gary N. Wheeler, R.T., Chief Technologist
Telephone No. Home: 297-1604
Business: 632-3420 Ext. 391

Denise Jaillet, R.T., Nuclear Medicine Technologist
Telephone No. Home: 632-5531
Business: 632-3420 Ext. 233

The above procedure is necessary for compliance with the Nuclear Regulatory Commission and Joint Commission for Accreditation of Hospitals. For your convenience, I have attached a memorandum from Frank Yavorsky dated November 19, 1980 related to the above procedure. If I may be of any further assistance, please do not hesitate to contact me.

GW/sat

cc: Richard Smith
Frank Yavorsky

(6)

HENRY HEYWOOD MEMORIAL HOSPITAL

INTER-OFFICE MEMORANDUM

Date: November 19, 1980

To: Mrs. Dymek, Director of Admitting

From: Mr. Yavorosky, Director of Purchasing

Subject: Nuclear Medicine Generators

Shipments of nuclear medicine generators are delivered weekly from Squibb on Sundays.

It has been the policy in the past that when the generator is delivered, security had delivered it, at the request of the switchboard, to the radiology reception area where it was kept until Monday. Although this generator is well shielded and emits a very small amount of radioactivity, it is not considered to be the best method of handling and storage.

Room 072 in the radiology area is considered to be a "hot room" and is designed to be a protective area for storage of radioactive materials.

Request the following procedures be implemented: Upon arrival of the shipment of the generator, the switchboard operator will contact the firemen in the boiler room to unlock the hot room; and the security men be contacted to deliver the generator to the hot room for storage. The shipment/packing slip will then be placed in the purchasing/receiving distribution box at the switchboard.

This procedure has been coordinated with individuals listed below.

Your cooperation in this matter will be appreciated.

cc: Mr. McEwen, Director of Fiscal Services
Mr. Smith, Director of Maintenance
Mr. Dupuis, Environmental Control
Mr. Wheeler, Radiology

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

Henry Heywood Memorial Hospital License # 20-16804-01

(Licensee's Name)

6-30-81

(Date)

1. Management Commitment

a. 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).

b. 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 outside consultants.

c. 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.

[1] Private practice physician licenses do not include an RSC.

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.)

(1) 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.

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

c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures 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.

3. **Radiation Safety Officer (RSO)**

a. Annual and Quarterly Review

(1) 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 authorized 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.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers 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 management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. 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.

(1) 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.

d. 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.

4. **Authorized Users**

a. New Procedures Involving Potential Radiation Exposures

(1) 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

(1) 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

[3] The 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 sufficiently important to justify further investigations.

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

5. **Persons 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.

6. **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 0-1 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~~ 4000	~~5625~~ 12000
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:

a. 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.

b. 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.

c. 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

the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. **Signature of Certifying Official**[4]

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

Paul E. Corcoran
Signature

Name (print or type)

Title

Institution (or Private Practice) Name and Address:
Henry Heywood Memorial Hospital
242 Green Street
Gardner, MA 01440

License # 20-16804-01

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