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Boston University Medical Center

75 East Newton Street
Boston, Massachusetts 02118
617 247-5212

Radiation Protection Office

April 15, 1983

Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, PA 19406

Subject: License No. 20-02215-01
Docket No. 030-01845
Control No. 06012

Gentlemen:

This is in response to your December 14 letter concerning our renewal application dated November 25, 1980. We also wish to acknowledge our telephone conversation with you on the eight questions asked of us in this December 14 letter. Our delay in answering your December 14 letter was in part due to the unexpected death of a staff member who attended to these matters.

1. There have been no significant revisions that need to be updated. We would like to update the membership of the Radioisotope Committee. Curricula Vitae for the new members are enclosed.

   B. A. Burrows, M.D., Chairman
   F. M. Sinex, Ph.D., Vice-Chairman
   L. Siegelman, Management Representative
   C. Emerson, M.D.
   S. Genna, Ph.D.
   G. Krithivas, Ph.D.
   W. Lloyd, Ph.D.
   V. N. Evdokimoff, MS., CHP.
   A. McCall, M.D., Ph.D.
   W. McNary, Ph.D.
   S. Spira, Ph.D.
   P. Stark, R.N.

2. Enclosed is our revised procedure for safely receiving and opening radioactive packages.

3. A physician who wishes to be authorized to use radioisotopes on or in humans should have training in basic radioisotope handling techniques and experience with the clinical procedures and quantities of byproduct material being requested. The Radioisotope Committee would use appendix A regulatory guide 10.1 (REV 1 Oct. 1980) in determining the Physicians qualifications.

4. We do not presently calibrate non-Boston University Medical survey equipment. We could in the future do this.

5. We will provide quarterly inventories of therapeutically used sealed sources containing byproduct material.

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6. Syringe shields will be routinely used for preparation and administration of patient doses except in circumstances where their use would compromise the patient's well being.

7. Personnel who elute the M099/Tc-99m generator or prepare radiopharmaceutical kits, etc. monitor thermselves following each procedure. As an example, patients receiving intravenous chemotherapy may present difficulties with venipuncture. They utilize the high range GM meter in the hot lab for this purpose.

8. Enclosed is a copy of our ALARA program.

Regards,

Victor N Evdokimoff

Victor N. Evdokimoff MS.,CHP
Radiation Protection Officer

APPENDIX I

CURRICULUM VITAE

Anthony Leo McCall

Date and Place of Birth:

Education:

1968 A.B. - Clark University, Worcester, Massachusetts
1972 M.D. - Medical College of Wisconsin, Milwaukee, Wisconsin
1981 Ph.D. - Masachusetts Institute of Technology, Cambridge, Mass.

Professional Experience:

1980- - Assistant Professor of Medicine, Division of Diabetes and Metabolism, Boston University School of Medicine (University Hospital), Boston, Massachusetts

1977-80 - Resident Physician, Clinical Research Center, Massachusetts Institute of Technology, Cambridge, Massachusetts; Research Associate, Laboratory of Neuroendocrine Regulation, Department of Nutrition and Food Science, Massachusetts Institute of Technology, Cambridge, Massachusetts

1976-77 - Clinical Associate in Medicine, Boston University School of Medicine, Boston Massachusetts; Chief Medical Resident, University Hospital (Boston University Medical Center), Boston Massachusetts

1975-76 - Fellow in Endocrinology and Metabolism, University Hospital (Boston University Medical Center), Boston, Massachusetts

1972-75 - Intern, Junior Resident, Senior Resident in Medicine, University Hospital (Boston University Medical Center), Boston, Massachusetts

Honors:

Scarlet Key Honor Society, Clark University
NIH-NIAMDD Post-doctoral Fellowship, 1978
Received Distinction on Doctoral Examinations
Department of Nutrition and Food Science, 1978

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Model Program for Maintaining Occupational Radiation Exposures at Medical Institutions ALARA

Boston University Medical Center
(Licensee's Name)

4-15-83
(Date)

I. 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 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 judgement, 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.

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

II. 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 assure 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 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.

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 I below are exceeded. The principle 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 paragraph VI).[3]

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

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[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.

3. The RSC will evaluate our institutions 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.

III. 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 paragraph VI 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 an ALARA Program

1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

2. The RSO will assure that authorized users, workers and ancillary personnel, such as secretaries, 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 encourage procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and 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, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

IV. 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 the Authorized User to Those He Supervises

1. The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.

2. The authorized user will ensure that those under his supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

V. Persons Who Receive Occupational Radiation Exposure

a. The worker will be instructed in the ALARA concept and its relationship to his working procedures and work conditions.

b. The worker will know what recourses are available if he feels that ALARA is not being promoted on the job.

VI. 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 Radiation Safety Committee and/or the Radiation Safety Officer. The Investigational Levels that we have adopted are listed in Table 1 below. These levels apply to the exposure of individual workers.

TABLE I

	Investigational Level I (mrems per calendar quarter)
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	210
2. Hands and forearms; feet and ankles	3750
3. Skin of whole body*	1500

* 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 is required by 10 CFR 20, 20.401. The following actions will be taken at the Investigational Levels as stated in TABLE I:

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 I values for the Investigational Level I.

b. Exposure equal to or greater than Investigational Level I

The RSO will investigate in a timely manner the causes of all personnel exposures equaling or exceeding Investigational Level I and, of warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or it's equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be discussed. Management will be informed either by regular attendance at the RSC or by the RPO in the event of absence. The details of the investigation will be made available to NRC inspectors for review at the time of the next inspection.

c. Re-establishment of an individual occupational workers Investigational Level I above that listed in Table I.

In cases where a worker's or a group of workers exposures need to exceed Investigational Level I a new, higher Investigational Level I 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 I will be documented.

c. (cont.)

The Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Levels I. In such cases, when the exposure equals or exceed ; the newly established Investigational Level I those actions listed in paragraph b above will be followed.

VII. Signature of Certifying Official[4]

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

Richard H. Egdahl
SIGNATURE

RICHARD H EGDAHL, MD.
NAME (print or type)

DIRECTOR, BOSTON UNIVERSITY MEDICAL CENTER
TITLE

Institution (or Private Practice) Name and address:

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[4]The individual who is authorized to make commitments for the administration

APPENDIX 1

GURUSAMY KRITHIVAS

Home:

Office: Radiation Physics
University Hospital
75 E.Newton Street
Boston, MA. 02118
(617) 247-5157

Professional Experience

1980-	Assitant professor of Radiology
1977-	Physicist, University Hospital Consultant to several hospitals around Boston

Includes experience with a wide variety of teletherapy machines, calibration procedures, brachytherapy sources (afterloading and operating room procedures), and computerized dosimetry with several treatment planning systems.
Major research interest: in therapeutic radiological physics

Experience Highlights

1972-1976 — Ph.D. Candidate, Brandeis University

Ph.D. Research: Scattering of radiations produced by X-ray machines and radioisotope.

Instrumentation: Used extensively a variety of analog and digitized electronic instruments, designed and built digital equipment. Practical knowledge of super resolution radiation detectors.

Special Skills: Advanced computer programming

Degrees/diploma

1982	American Board of Radiology
1976	Ph.D. (Radiation Physics), Brandeis University, U.S.A.
1971	M.Sc. (Low-Temperature Physics) Dalhousie University, Canada
1963	M.Sc. (Physics) Madras University, India

Personal Data:

DOB:
Weight:

Professional Affiliations

American Association of Physicists in Medicine
American College of Radiology
Member of Digital Equipment computer Society

References

Available on request

APPENDIX II

RECEIVING and OPENING of RADIOACTIVE PACKAGES

1) Packages are received in the Radiation Protection Office according to the requirements of 10CFR 20.205 (a) (b) (c).

2) All packages are opened in the designated opening area containing protective covering and a thin window GM counter with aural indication. Each package is checked against this GM counter.

3) Packages that do not produce a detectable exposure over background such as weak beta emitters, RIA kits etc., are recorded as NA on the receipt record. Packages that do produce an exposure potential on the surface of the package are recorded as $<$0.5 mR/hr, $<$50mR/hr or $<$200mR/hr according to respective "bar labels". Any discrepancy higher than the bar label exposure limit is brought to the attention of the RPO.

4) For all packages, the following additional procedures for opening packages will be carried out:
   a) Put on gloves to prevent hand contamination
   b) Visually inspect package for any sign of damage (e.g. wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.
   c) Measure surface exposure rate and record. If greater than 200mR/hr, stop procedure and notify Radiation Safety Officer.
   d) Open the package with the following precautionary steps:
      1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.
      2) Open inner package and verify that contents agree with those on packing slip and label on bottle.
      3) Check integrity of final source container (i.e. inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
      4) Check also that shipment does not exceed possession limits.

5) The following are exempt from wipe testing on the final container:
   RIA kits
   H-3 $<$ 10mCi
   C-14 $<$ 5mCi

6) Wipe external surface of non-exempt final containment package and remove wipe to low background area. Assay the wipe on survey equipment that would detect the potential contaminant. Record the results. Notify Radiation Protection Officer if contamination exceeds 0.01 uCi/100 cm^2.