



Veterans
Administration

Medical Center

DRSS
508 Fulton Street
Durham NC 27705

January 31, 1986

In Reply Refer To:
558/114B

Earl G. Wright
Senior License Reviewer
Nuclear Material Safety Section
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission
Region II
101 Marietta Street, N.W.
Atlanta, Georgia 30323

Reference: 50730; 030-02630

Dear Sir:

The information that you requested in your letter of Nov. 27, 1985 is given in the paragraphs below, with numbers matching the numbers of your requested items.

1. ALARA Plan. Please find enclosed a statement of the ALARA Program of Durham VA Medical Center.

2. Total Possession Limit and Expected Throughput of Licensed Material. We request that items 6A. through 8P. of our license be amended to read as follows:

- | | | |
|--|----------------------------------|-------------------------------------|
| "6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum poss. limit at one time. |
| A. Any byproduct material, atomic no. 3-83, incl. | A. any | A. 30 mCi, each atomic no. 3-83 |
| B. Iodine 131 | B. any | B. 300 mCi |
| C. Gold 198 | C. any | C. 150 mCi |
| D. Hydrogen 3 | D. any | D. 300 mCi |
| E. Carbon 14 | E. any | E. 200 mCi |
| F. Phosphorus 32 | F. any | F. 150 mCi |
| G. Iodine 125 | G. any | G. 800 mCi |
| H. Molybdenum 99 | H. any | H. 3 Curies |
| I. Technetium 99m | I. any | I. 5 Curies |
| J. Xenon 133 | J. any | J. 200 mCi |
| K. Iridium 192 | K. any | K. 100 mCi |
| L. Americium 241 | L. any | L. 50 mCi |
| M. Uranium 238 (depleted in U-235) | M. cadmium-plated metal | M. 160 kg |

We estimate that total possession of all byproduct material should not exceed 10 Curies at any one time. Total throughput for 1984 was 244.6 mCi for all isotopes combined, not including I-131 carried out by therapy patients (estimated at a maximum of 150 mCi). The throughput for

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REG2 LIC30
32-01134-01 PDR

"America is #1—Thanks to our Veterans"

Official Copy

FEE EXEMPT
190.11(4)(5)

Mr. Earl Wright

2. Total Possession Limit and Expected Throughput of Licensed Material. (continued):

1985 and 1986 are expected to be about the same. The request for increases in possession limits for iodine-125 and iridium-192 and maintaining the limits for gold-198 is in anticipation of increased uses of sealed seeds in therapy in the future. Annual throughput conceivably could increase due to the use of these isotopes. Delivery of high-use isotopes is estimated as follows:

Tc-99m: 190 Ci/yr; I-131: 175 mCi/yr; Xe-133: 3.65 Ci/yr.

3. Radiation Safety Program. Please find enclosed a Memorandum of Understanding between Durham VA Medical Center and the Department of Radiology, Duke University Medical Center describing the radiation safety services provided for by contract. Certain additional duties performed by the Radiation Safety Officer (RSO), whose services are covered by the contract, are stated in the attached document describing the ALARA program.

4. Administrative Procedures. A revision of the Radioisotope Safety Manual is well under way, and a draft copy of the current document will be sent to you in the near future. The Radioisotope Safety Committee (RSC) will perform a final review at a meeting in March, 1986. Bound copies of this revision will be distributed to authorized users, Head Nurses, the RSC, Associate Chief of Staff for R&D, Medical Center Administration and such others as deemed appropriate by the Medical Center Director no later than April 1, 1986. A draft copy of the cover letter to authorized users is attached. The Manual will be reviewed by the RSC for possible revision at the annual review of the radiation safety program, in January of each year.

5. Training of Personnel Who Work in or Frequent Restricted Areas. Technically speaking, our work areas are not "restricted areas" by the definition of 10 CFR 20.3 (14), because access is not limited for the purpose of radiation protection due to the low activity levels present. (An exception is the Nuclear Medicine Dispensing area, or "hot lab". This is a restricted area used only by properly trained nuclear medicine technologists, physicians or scientists.) While 10 CFR 19.12 technically may not apply to the majority of the people in our radioactivity work areas, we nonetheless understand the concern for proper training of persons at risk for exposure from radioactive materials in work areas or from patient burdens. Attached please find a letter to authorized users requiring that they respond, describing the training that their workers have received. It is our intent that in June, 1986 and each June thereafter, as needed, a training course will be offered which will include instruction in ALARA as well as fundamentals. All persons exposed to radiation from radioactive material will be expected to receive this instruction or its approved equivalent.

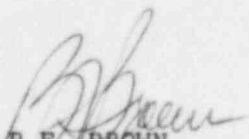
Mr. Earl Wright

6. Meeting Frequency and Record Maintenance for Radioisotope Safety Committee. The Radioisotope Safety Committee (RSC) will meet at least quarterly, normally in January, April, July and October. Exact periodicity may vary slightly due to scheduling meetings to meet availability of key members. Meeting minutes are distributed immediately after meetings to Committee members and to the Clinical Executive Board. Meeting minutes are kept by the Chairman. These actions are required as noted in the current revision of the Radioisotope Safety Manual (Section 1. I. A. 11) and in Medical Center Policy (see enclosed copy of Attachment B, Medical Center Memorandum 2.1).

7. Evaluation of Facilities and Equipment Utilized for Radioactive Gases and Potentially Volatile Materials Such as Iodine. The RSO has been instructed by the RSC to place in the Nuclear Medicine Radioisotope Authorization a record of the last evaluations of xenon-133 and iodine-131 releases to unrestricted areas in accordance with 10 CFR 20.103 ("hot lab") and 10 CFR 20.106 (other areas). When the move to a new Clinical Addition takes place in 1988, a survey of the type set forth in Appendix M, NRC Guidelines 10.8 will be made for xenon-133 removal before clinical operations begin. Additionally, iodine-131 releases via fume hoods will be evaluated before use begins. The RSC will be responsible to see that evaluations are made and recorded (Radioisotope Safety Manual, Section 1., I. A. 7)

8. Waste Disposal by Incineration. It is not anticipated that radioactive waste will be disposed of by incineration at Durham VA Medical Center in the immediate future. Waste will be disposed of in the same manner as in the past by outside contractor. In the event that disposal by incineration is initiated in the future, only waste from Durham VA Medical Center will be processed in our facility.

We trust that this response is adequate for your needs in evaluating our application for renewal of our license. Please do not hesitate to contact us if you need additional information.


B.E. BROWN

Medical Center Director

April 1, 1985
(114B)

SUBJECT: Medical Center Radioisotope Safety Committee

1. PURPOSE: The Radioisotope Safety Committee is established to review and approve all proposed clinical and research uses of radionuclides.
2. POLICY: The Radioisotope Safety Committee is responsible for establishing policies for the procurement, use, transport, storage and disposal of all radioactive materials (including discrete and sealed sources) at this station. The Radioisotope Safety Committee will review and approve all individual user applications for clinical and research uses of radioactive material for the U.S. Nuclear Regulatory Commission, the Veterans Administration Central Office and this station. The Radioisotope Safety Committee will establish procedures for handling of radioactive waste, including removal, transport, local storage and incineration.

3. LEADERSHIP:

Chairman:

C. Craig Harris, M.S.
Nuclear Medicine Scientist, Nuclear Medicine
Section, Durham VAMC, Associate Professor of
Radiology, Duke University Medical Center.

Members:

Frederick R. Cobb, M.D.
Chief, Cardiology, Durham VAMC, Professor of
Medicine, Assistant Professor of Radiology, Duke
University Medical Center.

R. Edward Coleman, M.D.
Director, Nuclear Medicine Section and Nuclear
Medicine Laboratory, Durham VAMC, Professor of
Radiology, Duke University Medical Center.

James A. Duncan
Research Coordinator
General Medical Research, Durham VAMC.

Ronald C. Greene, Ph.D.
Principal Scientist, Durham VAMC, Associate
Professor of Biochemistry, Duke University
Medical Center.

Geoffrey H. Kajcienski, Ed.D.
Administrative Assistant to the Chief of Staff,
Durham VAMC.

Conrad F. Knight, B.S.
Radiation Safety Officer, Durham VAMC, Associate
in Radiology, Radiation Safety Officer, Duke
University Medical Center.


Attachment "B"

3. MEMBERSHIP: (continued)

Mary Moorefield, R.N.
Head Nurse, 6-A, Nursing Service, Durham VAMC.

William H. Thompson, M.D.
Chief, Radiology Service, Durham VAMC, Professor
of Radiology, Duke University Medical Center

4. MEETINGS: The committee will meet at the call of the Chairman. Copies of minutes of meetings will be forwarded to Chairman, Clinical Executive Board.
5. REFERENCES: M-2, Part XX, Chapter 1, December 15, 1969.
6. RECISSION: Attachment "B", Hospital Memorandum No. 2.1, dated February 1, 1985.


B. F. BROWN
Medical Center Director

DISTRIBUTION: C



VETERANS ADMINISTRATION
HOSPITAL
508 FULTON STREET
DURHAM, NORTH CAROLINA 27705



August 20, 1975

IN REPLY
REFER TO: 558/11

Dr. Henry Kamin, Chairman
Duke University Medical Center
Radiation Control & Radioactive Drug Research Com.
Durham, North Carolina 27710

Dear Dr. Kamin:

From a recent discussion with Dr. Jack Davidson, I have learned that a special committee must be appointed to evaluate and either approve or disapprove all research proposals involving the use of radioactive substances at the Durham V. A. Hospital. Dr. Davidson also informs me that such a committee has already been formed to carry out this function at Duke. Research projects initiated from the Durham V. A. Hospital proposing the use of radioactive substances are relatively rare. It would seem reasonable therefore, for me to request that the Committee, already established at Duke, serve as the official body to review and evaluate the research proposals to be carried out at the Durham V. A. Hospital.

We, of course, would appreciate favorable response to this request as you present it to your Committee.

Sincerely,

Robert L. Green Jr.
ROBERT L. GREEN, JR., M. D.
Chief of Staff

PROGRAM FOR MAINTAINING EXPOSURE TO RADIATION FROM RADIOACTIVE
MATERIALS AS LOW AS REASONABLY ACHIEVABLE (ALARA)

DURHAM VETERANS ADMINISTRATION MEDICAL CENTER
DURHAM, NC

January 31, 1986

1. ADMINISTRATION COMMITMENT

a. We, the Administration of Durham VA Medical Center, are committed to the program described in this document for keeping individual and collective radiation exposures to radiation from radioactive materials as low as reasonably achievable (ALARA). In accord with this commitment we describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within Durham VAMC. The organization includes a Radioisotope Safety Committee (RSC) and a Radiation Safety Officer (RSO).

b. We will perform an annual review of the radioisotope safety program in January of the calendar year, including ALARA considerations. This shall include reviews of operating procedures, exposure records for the year just concluded, inspections, authorized users chronically delinquent in required record submission, and other topics as needed.

c. Modification to procedures, 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 have been implemented where reasonable. Modifications have already been made in the course of earlier, informal adherence to the ALARA principle; the Durham VA Medical Center's approach to ALARA is now several years old, particularly in those areas where personnel exposures typically are the highest. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for lack of implementation.

d. In addition to maintaining exposure to radiation 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 is inappropriate to hold the highest doses to some individuals to some stated fraction of the applicable limit at the expense of involving additional people and increasing the total radiation dose received by the group of involved individuals.

2. RADIOISOTOPE SAFETY COMMITTEE (RSC)

a. Review of Proposed Users and Uses.

(1) The RSC will review thoroughly the qualifications of each applicant for authorized use of radioactivity with respect to the types and amounts of activity and uses for which application is made to ensure that the applicant will be able to take the necessary measures to maintain exposures ALARA.

2. RADIOISOTOPE SAFETY COMMITTEE (RSC) (continued)

a. Review of Proposed Users and Uses. (continued)

(2) When considering a new use of radioactive material, the RSC will review the efforts of the applicant to maintain exposures ALARA. The user will be expected to have systematized procedures to ensure ALARA, including the use of appropriate equipment such as rubber gloves, syringe shields, lead aprons as needed.

(3) The RSC will insure that users take appropriate action to maintain ALARA as reflected in regular radiation exposure monitoring, considering both individuals and the sum of doses to a group.

b. Delegation of Authority

(1) The RSC delegates to the RSO authority for ALARA enforcement.

(2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert authority in ALARA enforcement. Where the RSO is overruled, the RSC will record the basis for its action in its meeting minutes.

c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement and maintain the ALARA concept.

(2) The RSC will perform a review at each of its meetings of current records of occupational radiation exposure from radioactive materials, with particular attention to trends which indicate exposures in excess of those levels in Table I. The RSC will decide on any necessary action when Investigational Levels are exceeded.

(3) The RSC will review annually the efforts of authorized users, the RSO and of management in the maintenance of the Durham VA Medical Center's ALARA program.

3. RADIATION SAFETY OFFICER (RSO)

a. Annual and Quarterly Reviews

(1) The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts.

(2) The RSO will review at least quarterly the external radiation exposures of authorized users and workers. The RSO will monitor the extent to which exposures indicate adherence to ALARA, and will inform the RSC of personal dosimeter readings which indicate exposures in excess of those listed in Table I.

3. RADIATION SAFETY OFFICER (RSO) (continued)

a. Annual and Quarterly Reviews (continued)

(3) The RSO will review records of radiation level surveys in all areas where radioactive materials are used on a quarterly basis to determine adherence to ALARA.

b. Educational Responsibilities for the ALARA Program

(1) The RSO will ensure that instruction in ALARA philosophy is provided for all personnel who may be exposed to radiation from radioactive materials and that such personnel are informed of the commitments of Medical Center Administration, the RSC and the RSO to the implementation of the ALARA program.

(2) The RSO will schedule briefing and educational sessions as needed to inform workers of ALARA program efforts.

c. Cooperative Efforts for Development of ALARA Procedures

(1) Persons subject to exposure to radiation from radioactive material will be given opportunities to contribute to the development of the ALARA concept.

(2) The RSO will ensure that procedures are established whereby radiation workers and other exposed personnel may offer suggestions for reduction of radiation exposure.

(3) The RSO will offer assistance as needed for ALARA in specific procedures involving exposure to radiation from radioactivity.

d. Reviewing Deviation from Good ALARA Practice

The RSO will investigate all indicated deviations from good ALARA practice and, if possible, determine the causes and take necessary action to maintain exposures ALARA.

4. AUTHORIZED USERS

a. New Procedures Involving Potential Radiation Exposure from Radioactive Material

The authorized user will evaluate all procedures before initiation to ensure that exposures will be kept ALARA, and will consult with the RSO or RSC as needed in the planning stages.

b. Responsibility of Authorized Users to Persons under their Supervision

Each authorized user will ensure that persons exposed to radiation from radioactivity working under the user's supervision are educated in ALARA concepts and good working practices, and in the commitments of the user and the Medical Center in maintaining exposures ALARA.

5. PERSONS WHO RECEIVE OCCUPATIONAL EXPOSURE TO RADIATION FROM RADIOACTIVE MATERIALS

- a. The worker will receive instruction in ALARA principles and their relationship in working procedures and work conditions.
- b. The worker will be informed about recourses available if he/she feels that ALARA is not properly in effect.

6. ESTABLISHMENT OF INVESTIGATIONAL LEVELS OF EXPOSURE TO RADIATION FROM RADIOACTIVE MATERIALS AS CAUSE FOR REVIEW AND INVESTIGATION

The Durham VA Medical Center hereby establishes the following review and investigational levels for occupational external exposure of individual workers to radiations from radioactive material which, when exceeded, will initiate review or investigation by the RSC and/or the RSO:

TABLE I

| | mrems per calendar quarter | |
|--|----------------------------|----------|
| | Level I | Level II |
| 1. Whole body, head and trunk, active blood-forming organs, lens of eyes, gonads | 150 | 300 |
| 2. Hands and forearms, feet and | 1500 | 4500 |
| 3. Skin of whole body | 750 | 2250 |

The RSO will record results of personnel monitoring not less than quarterly. The following actions will be taken at the levels in Table I:

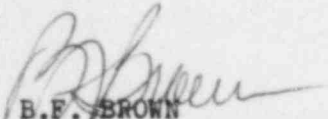
- a. No action will be taken for individual exposures less than Level I, unless deemed necessary by the RSO.
- b. The RSO will report all exposures greater than Level I to the RSC at its next meeting. Exposures greater than Level I but not greater than Level II will require no action unless deemed appropriate by the RSC. The RSC will, however, compare the exposure with that of other individuals performing similar work and record the review in the meeting minutes.
- c. The RSO will investigate in timely manner the causes of any exposure exceeding Level II and take action as needed. A report of the investigation and any action taken and the individual's occupational exposure record will be presented to the RSC at its next meeting, and the details will be recorded in the meeting minutes.
- d. RSC meeting minutes are sent to Medical Center Administration for review via submission to the Clinical Executive Board, and are available for NRC inspection.

6. ESTABLISHMENT OF INVESTIGATIONAL LEVELS OF EXPOSURE TO RADIATION FROM RADIOACTIVE MATERIALS AS CAUSE FOR REVIEW AND INVESTIGATION (continued)

- e. The levels in Table I may be revised as needed for maintenance of ALARA. In the event that higher levels are needed, The RSC will provide justification which will be recorded in the meeting minutes.

7. SIGNATURE OF CERTIFYING OFFICIAL

I hereby certify that the Durham Veterans Administration Medical Center has implemented the ALARA Program set forth above.



B.F. BROWN
Medical Center Director
Durham Veterans Administration Medical Center
508 Fulton Street
Durham, NC 27705

PROGRAM FOR MAINTAINING EXPOSURE TO RADIATION FROM RADIOACTIVE
MATERIALS AS LOW AS REASONABLY ACHIEVABLE (ALARA)

DURHAM VETERANS ADMINISTRATION MEDICAL CENTER
DURHAM, NC

January 31, 1986

1. ADMINISTRATION COMMITMENT

a. We, the Administration of Durham VA Medical Center, are committed to the program described in this document for keeping individual and collective radiation exposures to radiation from radioactive materials as low as reasonably achievable (ALARA). In accord with this commitment we describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within Durham VAMC. The organization includes a Radioisotope Safety Committee (RSC) and a Radiation Safety Officer (RSO).

b. We will perform an annual review of the radioisotope safety program in January of the calendar year, including ALARA considerations. This shall include reviews of operating procedures, exposure records for the year just concluded, inspections, authorized users chronically delinquent in required record submission, and other topics as needed.

c. Modification to procedures, 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 have been implemented where reasonable. Modifications have already been made in the course of earlier, informal adherence to the ALARA principle; the Durham VA Medical Center's approach to ALARA is now several years old, particularly in those areas where personnel exposures typically are the highest. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for lack of implementation.

d. In addition to maintaining exposure to radiation 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 is inappropriate to hold the highest doses to some individuals to some stated fraction of the applicable limit at the expense of involving additional people and increasing the total radiation dose received by the group of involved individuals.

2. RADIOISOTOPE SAFETY COMMITTEE (RSC)

a. Review of Proposed Users and Uses.

(1) The RSC will review thoroughly the qualifications of each applicant for authorized use of radioactivity with respect to the types and amounts of activity and uses for which application is made to ensure that the applicant will be able to take the necessary measures to maintain exposures ALARA.

2. RADIOISOTOPE SAFETY COMMITTEE (RSC) (continued)

a. Review of Proposed Users and Uses. (continued)

(2) When considering a new use of radioactive material, the RSC will review the efforts of the applicant to maintain exposures ALARA. The user will be expected to have systematized procedures to ensure ALARA, including the use of appropriate equipment such as rubber gloves, syringe shields, lead aprons as needed.

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3. RADIATION SAFETY OFFICER (RSO)

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3. RADIATION SAFETY OFFICER (RSO) (continued)

a. Annual and Quarterly Reviews (continued)

(3) The RSO will review records of radiation level surveys in all areas where radioactive materials are used on a quarterly basis to determine adherence to ALARA.

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(1) The RSO will ensure that instruction in ALARA philosophy is provided for all personnel who may be exposed to radiation from radioactive materials and that such personnel are informed of the commitments of Medical Center Administration, the RSC and the RSO to the implementation of the ALARA program.

(2) The RSO will schedule briefing and educational sessions as needed to inform workers of ALARA program efforts.

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(3) The RSO will offer assistance as needed for ALARA in specific procedures involving exposure to radiation from radioactivity.

d. Reviewing Deviation from Good ALARA Practice

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a. New Procedures Involving Potential Radiation Exposure from Radioactive Material

The authorized user will evaluate all procedures before initiation to ensure that exposures will be kept ALARA, and will consult with the RSO or RSC as needed in the planning stages.

b. Responsibility of Authorized Users to Persons under their Supervision

Each authorized user will ensure that persons exposed to radiation from radioactivity working under the user's supervision are educated in ALARA concepts and good working practices, and in the commitments of the user and the Medical Center in maintaining exposures ALARA.

5. PERSONS WHO RECEIVE OCCUPATIONAL EXPOSURE TO RADIATION FROM RADIOACTIVE MATERIALS

- a. The worker will receive instruction in ALARA principles and their relationship in working procedures and work conditions.
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TABLE I

| | | mrems per calendar quarter | |
|----|---|----------------------------|----------|
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| 2. | Hands and forearms, feet and | 1500 | 4500 |
| 3. | Skin of whole body | 750 | 2250 |

The RSO will record results of personnel monitoring not less than quarterly. The following actions will be taken at the levels in Table I:

- a. No action will be taken for individual exposures less than Level I, unless deemed necessary by the RSO.
- b. The RSO will report all exposures greater than Level I to the RSC at its next meeting. Exposures greater than Level I but not greater than Level II will require no action unless deemed appropriate by the RSC. The RSC will, however, compare the exposure with that of other individuals performing similar work and record the review in the meeting minutes.
- c. The RSO will investigate in timely manner the causes of any exposure exceeding Level II and take action as needed. A report of the investigation and any action taken and the individual's occupational exposure record will be presented to the RSC at its next meeting, and the details will be recorded in the meeting minutes.
- d. RSC meeting minutes are sent to Medical Center Administration for review via submission to the Clinical Executive Board, and are available for NRC inspection.

6. ESTABLISHMENT OF INVESTIGATIONAL LEVELS OF EXPOSURE TO RADIATION FROM RADIOACTIVE MATERIALS AS CAUSE FOR REVIEW AND INVESTIGATION (continued)

- e. The levels in Table I may be revised as needed for maintenance of ALARA. In the event that higher levels are needed, The RSC will provide justification which will be recorded in the meeting minutes.

7. SIGNATURE OF CERTIFYING OFFICIAL

I hereby certify that the Durham Veterans Administration Medical Center has implemented the ALARA Program set forth above.



B.F. BROWN
Medical Center Director
Durham Veterans Administration Medical Center
508 Fulton Street
Durham, NC 27705

**Veterans
Administration**

January 31, 1986

In Reply Refer To:
558/114B**MEMORANDUM OF UNDERSTANDING****To Whom It May Concern:**

It is the purpose of the undersigned to confirm our understanding of the radiological safety services provided as a part of the contract between the Duke University Medical Center Department of Radiology and the Durham Veterans Administration Medical Center.

1. These services shall include, but not be limited to:
 - a. Radiation Safety Officer. Provide the services of a Radiation Safety Officer (RSO).
 - b. Personnel monitoring (TLDs). Issuance, receipt, processing and records keeping of personnel monitoring devices issued to individuals assigned to the Department of Radiology, Durham VA Medical Center, or to a Durham VAMC laboratory utilizing radioactive materials.
 - c. Surveys (Machines and Packages). Annual survey of all X-ray machines to determine compliance with NCRP and BRH standards. Inspection and contamination testing of incoming radioactive material packages.
 - d. Radiation Monitoring. Semi-annual inspection of electron microscopes and high voltage supplies for determination of radiation leakage.
 - e. Laboratory Surveys. Monthly inspection of laboratories using radioactive materials to determine radiation levels and presence of contamination.
 - f. Microwave Oven Surveys. Inspection of microwave ovens to determine leakage of non-ionizing radiation.
 - g. Patient Precautions. Surveys of patients undergoing radioisotope therapy on wards. Includes determination of radiation levels in patients' rooms and adjacent rooms, instruction for nurses, collection of urine and monitoring of room upon discharge of patient.
 - h. Health Physics Consultation. Presentation of radiological safety lectures to investigators, technicians, nurses and housekeepers. Shielding design for x-ray rooms. Advice and assistance in radiation safety matters.

1. Services (continued):

1. Leak Testing. Semi-annual testing of sealed radioactive material sources to determine integrity of capsule.

The following specific information is furnished at the request of the Nuclear Regulatory Commission (NRC).

2. Duties and responsibilities of key personnel:

- a. Radiation Safety Officer - overall responsibility for the radiation safety program, with duties as specified in Section 1, I. B. of the Radioisotope Safety Manual of Durham VAMC.
- b. Secretary - issuance of TLDs and maintenance of dosimetry records.
- c. Technician - processing of personnel dosimeters, review of monthly receipt/disposal/inventory records.
- d. Technician - laboratory surveys, inspection of incoming packages.
- e. Technician - pickup and processing of radioactive waste.

3. Time commitment: It is expected that these services will require approximately 80 manhours per month.

4. Persons responsible for maintaining radiation protection program and Radioisotope Safety Committee (RSC) records:

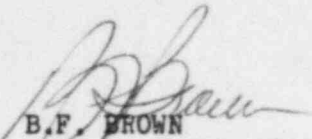
- a. The person responsible for maintenance of the radiation protection program is the Radiation Safety Officer. As of January 31, 1986 the incumbent RSO is Conrad M. Knight.
- b. The person responsible for maintaining RSC records is the Chairman of the RSC. The Chairmanship of the RSC is not a service provided under the contract, but is an institutional service provided by Durham VAMC. The incumbent Chairman is C. Craig Harris, Nuclear Medicine Scientist, Associate Professor of Radiology.
- c. Surveys -- frequency and records: Monthly laboratory surveys by Radiation Safety Office personnel include contamination wipes, instrument readings and visual inspection of signs and labels and general radiological conditions. Monthly survey records will be kept by the RSO.
- d. The status of the radiation safety program is reported to the Medical Center Director by submission of RSC meeting minutes to the Clinical Executive Board. Meeting minutes include a written summary of RSO activities. Additionally, the membership of the Committee includes a representative from Medical Center Administration.

- e. Radioactive Drug Research Committee. (This information is included at the request of the NRC.) The relationship of the Duke University Medical Center Radiation Control and Radioactive Drug Research Committee (RDRC) to research activities at the Durham VA Medical Center is not defined by the contract between the Duke Department of Radiology and the Durham VA Medical Center for provision of radiological safety services.

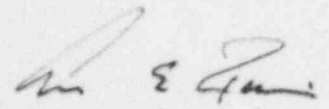
Additional to regulatory actions of the NRC, administrations of radioactive substances to human research subjects are regulated by the Food and Drug Administration (FDA). FDA regulations require that such uses in human subjects be approved by a radioactive drug research committee. At the request of Durham VA Medical Center, applications for use of radioactivity in human research subjects at Durham VA Medical Center are reviewed by the Duke University Medical Center RDRC. Applications may be submitted to the RDRC, which will forward the application to the Durham VAMC RSC with its recommendation. Requests may be submitted to the Chairman, Durham VAMC RSC, who will refer them to the RDRC for review.

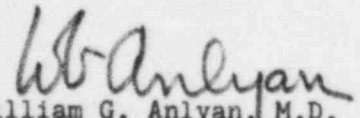
Applications for research use of radioactive materials in humans at the Durham VAMC must be approved by the Research and Development Committee and its Human Studies Subcommittee. Approval by the RDRC is necessary for final approval by these committees.

For Durham Veterans Administration Medical Center


B.F. BROWN
Medical Center Director

For the Department of Radiology and Duke University Medical Center


Carl E. Ravin, M.D.
Professor and Chairman
Department of Radiology


William G. Anlyan, M.D.
Chancellor for Health Affairs
Duke University Medical Center



Veterans
Administration

Memorandum

Date: January 31, 1986

To: Authorized Users of Radioactive Material

From: Chairman, Radioisotope Safety Committee (114B)

Subj: Radioisotope Safety Manual, new revision

1. Please find enclosed a copy of the Durham Veterans Administration Medical Center Radioisotope Safety Manual as revised January 31, 1986. This replaces any older versions that you might have.
2. Please note that Section III of the Manual is the Durham VAMC's program for maintaining exposure to radiations from radioactive materials As Low As Reasonably Achievable (ALARA).
3. All authorized users of radioactive materials are required to become familiar with the Manual and the ALARA program, and are additionally responsible to require the same of all persons working under their supervision.
4. Compliance with all provisions of the Manual and of ALARA is expected of all authorized users of radioactive materials and of persons working in the users' laboratories.
5. There are few changes from the Jan. 1980 version, but many changes compared with the version prior to that. Waste disposal procedures, which may change with little notice, are removed from the body of the Manual to an Annex.
6. If assistance is needed with specific requirements of the Radioisotope Safety Manual or the ALARA program, contact the Radiation Safety Officer, Conrad Knight at 684-2194 or me at extension 6154, or 684-5247 or on Duke beeper 4251.


Craig Harris



Veterans
Administration

Memorandum

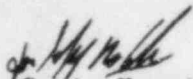
Date: January 31, 1986

To: Authorized Users of Radioactive Materials

From: Chairman, Radioisotope Safety Committee (114B)

Subj: Training of persons using radioactive materials

1. We have been required by the Nuclear Regulatory Commission as a part of the requirements of our institutional license to affirm that all persons handling radioactive materials have had adequate training in such handling.
2. Additionally, we are required to insure that all persons subject to exposure to radiation from radioactive materials have been instructed in the concepts of Durham VAMC's program to maintain radiation exposures As Low As Reasonably Achievable (ALARA).
3. We are preparing to offer in the near future, a training course in fundamentals and in ALARA to persons needing such training.
4. To assist us in planning for the course, please respond no later than March 1, 1986, listing all persons handling radioactive materials under your authorization and supervision. Please list for each person the training that they have previously received, noting location, duration, and whether a formal course. If instruction was given by you, please furnish as well as possible the content of such instruction.
5. The Radiation Safety Officer and the Radioisotope Safety Committee are prepared to give you every assistance in ensuring that all persons handling radioactive materials are properly instructed.


Craig Harris