



**Veterans
Administration**

June 11, 1987

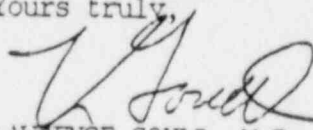
In Reply Refer To:

U.S. Nuclear Regulatory Commission
Region 1
631 Park Avenue
King of Prussia, PA 19406

To Whom It May Concern:

After review of Mr. Arnot E. Erb III credentials the Radiation Safety Committee unanimously recommends that he be made the Radiation Safety Officer at this institution. He has the full support of this committee to assume the responsibilities of this position.

Yours truly,


LAWRENCE GOULD, M.D.
Chairman, Radiation Safety Committee

ATTACHMENT A (Items 8 - 11) June 12, 1987

Item 9.1

We have developed a training program for your review that is appended as ATT. 8.1

Item 9.1 See ATT 9.1

Item 9.2

Survey meters will be calibrated at least annually and following repair by one of the following consulting firms.

- (1) BIO-MED ASSOCIATES, INC.
4 Main Street
Flemington, New Jersey 08822

Procedure and sources have been approved by the NRC and are on file in License Number 29-1497-01

- (2) VA Medical Center
Philadelphia, PA

Procedures and sources have been approved by the NRC and are on file in License Number 37-00062-07

- (3) By Manufacturer.

Item 9.31, 9.32

We have developed a dose calibrator calibration procedure for your review that is appended as ATT. 9.31, 9.32, 9.33.

Item 9.4

We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2.

Item 9.5 N/A

Item 9.6 N/A

Item 10.1

We will establish and implement the model procedures for establishing and operating a Radiation Safety Committee that was published in Appendix F to Regulatory Guide 10.8, Revision 2.

Item 10.2

We will establish and implement the Model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2.

Item 10.3

We have developed a leak test procedure for your review that is appended as ATT. 10.3.

Item 10.4

We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as ATT 10.4.

ATTACHMENT CONT'D: ATT: A (8 - 11) June 12, 1987

Item 10.5

We have developed spill procedures for your review that are appended as ATT 10.5., and append your spill procedures.

Item 10.6

We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2.

Item 10.7

We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2.

Item 10.8

We will establish and implement the model procedure for a unit dosage record system that was published in Appendix M1 to Regulatory Guide 10.8, Revision 2.

Item 10.9

We have developed a procedure for a multidose vial record system for your review that is appended as ATT 10.9.

Item 10.10

We have developed a procedure for measuring and recording Molybdenum concentrations for your review that is appended as ATT. 10.10.

Item 10.12, 10.12A

We have developed survey procedures for your review that are appended as ATT. 10.12.

Item 10.13.

Only applicable use is DTPA Aerosol Studies. The N.M.S. has a separate closed air exchange system, therefore, there will be no release to unrestricted areas. In the event of a suspected release the scanning area will be evacuated. Reentry will occur only under the authority of the RSO or his designee.

Item 11.11

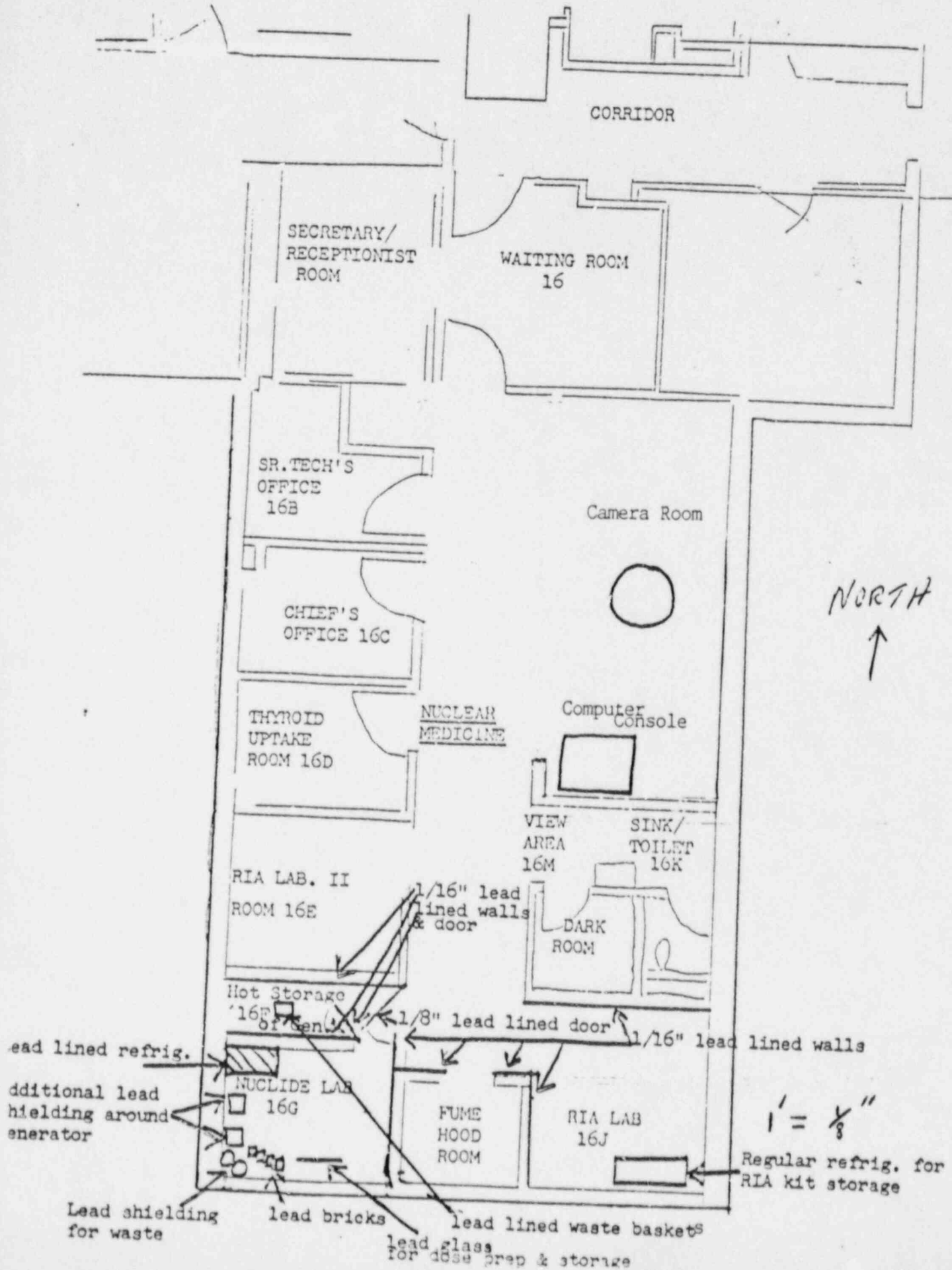
We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2.

PERSONNEL TRAINING PROGRAM

- I. Individuals who work in or frequent restricted areas will be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

This instruction will include:

- a. All terms of the license pertinent to radiation safety.
 - b. Areas where radioactive material is used or stored.
 - c. Potential hazards associated with radioactive material.
 - d. Radiological safety procedures appropriate to their respective duties.
 - e. Pertinent NRC regulations.
 - f. Rules and regulations of the license.
 - g. Obligation to report unsafe conditions to the radiation safety officer.
 - h. Appropriate response to emergencies or unsafe conditions.
 - i. Right to be informed of their radiation exposure and bioassay results.
 - j. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.
- II. Individuals whose duties may require them to work in the vicinity of licensed material will be informed about radiation hazards and appropriate precautions at the time of initial employment and at least annually thereafter.
- III. Groups of workers to receive training will include Nuclear Medicine physicians/radiologists, Nuclear Medicine technologists, and various other ancillary personnel. Ancillary employees will include clerical, nursing, housekeeping and firefighters. Methods of training will consist of lectures or demonstrations.



ATT: 9.31 June 12, 1987

DOSE CALIBRATOR CALIBRATION PROCEDURE

DAILY CONSTANCY TEST OF DOSE CALIBRATOR

The constancy of the dose calibrator will be checked for several radionuclides such as Cs-137, and Co-57, using appropriate reference standards whose activity is traceable to NBS. This will be done each day the dose calibrator is used and prior to assaying of patient doses. The activity levels of the reference sources used should approximate those levels normally encountered, giving adequate attention to source configuration.

1. Assay the reference standard in the dose calibrator at the appropriate setting and subtract the background level to obtain the net activity.
2. The activity determined in step 1 should agree with the certified activity of the reference source within $\pm 5\%$ after decay corrections.
3. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.
4. Keep a log of these calibration checks. This log will include the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide, the activity measured, the date of the check and initials of person performing the check. The RSO will review accuracy and constancy checks on a quantity basis.

YEARLY ACCURACY TEST OF DOSE CALIBRATOR

An annual accuracy test will be performed for the reference standards indicated earlier. This will be conducted as follows:

1. Assay each reference standard on the appropriate dose calibrator setting three times, subtracting background to yield net activity.
2. Average the results of the three readings.
3. The average activity is compared to the decay corrected activity for each standard. A deviation of greater than $\pm 5\%$ will warrant recalibration and/or repair.

QUARTERLY LINEARITY TEST OF DOSE CALIBRATOR

The linearity of the dose calibrator should be ascertained over the entire range of activities employed. This test will utilize a vial of Tc 99m whose activity is equivalent to the maximum anticipated activity to be assayed. It will use the total initial eluate of that week's generator, on the first working day after delivery.

1. Assay the Tc 99m vial in the dose calibrator and subtract background level to obtain net activity in millicuries.
2. Repeat step 1 at the time intervals of 4, 8, 24 hours and 48 hours after the initial assay until the assayed activity is less than 10 microrcuries.
3. Using the decay formula $A=A_0e^{-KT}$ ($K=\frac{.693}{T_{1/2}}$) calculate the predicted activities at the above hourly intervals.
4. Plot the measured net activity for each time interval versus the decay predicted activity on log-log graph paper as illustrated.
5. The activities plotted should be within $\pm 5\%$ of the decay predicted curve if the instrument is linear and functioning properly. Errors greater than $\pm 5\%$ indicate the need for repair or adjustment of the instrument.
6. Keep a log of this calibration check. This log will include the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the RSO.

Note: After repair or adjustment of the dose calibrator, repeat all of the appropriate tests listed above (dependent upon the nature of the repairs).

GEOMETRICAL VARIATION TEST FOR DOSE CALIBRATOR - AT INSTALLATION

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than $\pm 2\%$ (even though correction factors may be provided by the manufacturer, the accuracy of these should be checked).

To measure variation with liquid volume, a 20 cc vial containing 20 mCi of the Tc 04 or other appropriate radionuclide in a volume of 1 ml will be used.

1. Assay the vial at the appropriate instrument setting and subtract background level to obtain net activity.
2. Increase the volume of liquid in the vial in steps to 10 cc and 20 cc by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1.
3. Use the initial 1 cc volume as a standard and check if there is greater than a 2% error in the subsequent vial readings. If correction factor is necessary, contact Biomedical Engineering Section to repair or adjust instrument.
4. Keep a log of these calibration checks. This log will include the model and serial number of the dose calibrator, the correction of the source measured, the activity measured for each volume measured, the date of the test and the signature of the RSO.

APPENDIX G

Model Program for Maintaining Occupational Radiation Exposure
at Medical Institutions ALARA
(See § 35.30.)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own ALARA program for NRC review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.30. Say on your application, "We have developed an ALARA program for your review that is appended as ATT 10.2.", and append your program.

ALARA Program

Veterans Administration Medical Center, Lyons, New Jersey
(Licensee's Name)

June 12, 1987
(Date)

1. Management Commitment

- a. We, the management of this (medical facility, hospital, etc.), are committed to the program described herein for keeping individual and collective doses 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) and a Radiation Safety Officer (RSO).

- b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.
- c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if 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 when reasonable. If 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

- 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 methods of use for which application has been made 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.

- (3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

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 when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the 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 in which the investigational levels in Table 1 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 below for a discussion of investigational levels).*

*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 investigations.

Table 1
Investigational Levels

	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 medical use operations except those using significant quantities of beta-emitting isotopes.		

- (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

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 methods of use 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 and will prepare a summary report for the RSC.

- (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 and will prepare a summary report for the RSC.

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 formulating 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 Methods of Use 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 method of use.
- (2) The authorized user will evaluate all methods of use before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced by using trial runs.

b. Authorized User's Responsibility to Supervised Individuals

- (1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
- (2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Exposure

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will know what recourses are available if they feel 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 hereby establishes investigational levels for occupational external radiation dose 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 1. These levels apply to the exposure of individual workers.

The RSO 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 1:

- a. Personnel dose 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 dose is less than Table 1 values for the Investigational Level I.

- b. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose 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, review each such dose 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. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's Form NRC-5 or its

equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

- d. Reestablishment of Investigational Level II to a level above that listed in Table 1.

In cases where a worker's or a group of workers' doses 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*

I hereby certify that this institution has implemented the ALARA Program set forth above.

Signature

A. PAUL KIDD
Name (print or type)

Medical Center Director
Title

*The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

ATT: 10.3 June 12, 1987

Leak Test

1. Leak testing will be performed on all beta and gamma emitting sealed sources exceeding 100 microcuries at intervals not to exceed 6 months
2. Sealed sources stored and not in use will be exempt from the requirement.
3. Wipes will be taken from the sealed sources and analyzed with a detector system capable of detecting the presence of 0.005 microcuries of radioactive material on the sample.
4. A record of test results will be maintained for a period of 5 years. The records will contain the model number, and serial number if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample, the date of the test and the signature of the Radiation Safety Officer.
5. If the leakage test reveals the presence of more than .005 microcuries of removable contamination the source will be removed from use. The Radiation Safety Officer will be notified.

ATT: 10.4 June 12, 1987

LABORATORY RULES FOR THE USE OF RADIOACTIVE
MATERIALS IN THE NUCLEAR MEDICINE DEPARTMENT

1. Wear laboratory coats, or other protective clothing at all times in areas where radioactive materials are used
2. Wear disposable gloves at all times while handling radioactive materials.
3. Monitor hands, feet and clothing for contamination frequently and immediately upon suspected contamination with a G.M. survey meter.
4. Use syringes shields for preparation of patient doses and administration to patients, except in circumstances such as pediatric cases, where their use would compromise the patient's well-being.
5. Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used. Do not store food, drink or personal effects with radioactive material.
6. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10 percent.
7. Wear personnel monitoring devices (film badges or TLD) at all times while in areas where radioactive materials are used or stored. These should be worn at the chest or waist level and on the front of the body.
8. Wear TLD finger badges during elution of the generator and preparation, assay and injection of radiopharmaceuticals.
9. Dispose of radioactive waste only in specially designated receptacles.
10. Never pipette by mouth.
11. Survey generator, kit preparation and dose preparation areas daily with a G.M. survey meter and log readings. If necessary, reposition sources and/or shielding to maintain exposure levels less than 2.5 mR/hr.
12. Combine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity and radiation levels, if applicable.

13. Always transport radioactive material in shielded containers.
14. Always use disposable coverings (with plastic backing) on work surfaces where radioactive materials in solution are prepared.
15. Always use remote handling tongs when handling or assaying unshielded sources, especially if in quantities greater than or equal to patient doses. This is extremely important for the elution of a generator.

EMERGENCY PROCEDURES

MINOR SPILLS:

1. Notify: Notify persons in the area that a spill has occurred.
2. Prevent the Spread: Cover the spill with absorbent paper.
3. Report: Report the incident to the Radiation Safety Officer.
4. Clean Up: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Include all other contaminated materials such as disposable gloves.
5. Survey: If appropriate, check the area around the spill, your hands and clothing for contamination with a G.M. survey meter. Perform a wipe test to assure the absence of removable contamination before resuming normal operations.

MAJOR SPILLS:

1. Clean the Area: Notify all uninvolved persons to vacate the room.
2. Prevent the Spread: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.
3. Close the Room: Leave the room and lock the door(s) to prevent entry.
4. Call for Help: Notify the Radiation Safety Officer immediately.
5. Personnel Decontamination:
 - a. Contaminated clothing should be removed and stored for evaluation.
 - b. Rinse the affected area promptly with water.
 - c. If a shower is warranted, have someone bring a G.M. survey meter to assure that decontamination is effective.
 - d. Wash thoroughly with a non-abrasive detergent.
 - e. Scrub the areas thoroughly using detergent and a suitable brush, but being careful not to abrade the skin.

- 3
- f. Continue these procedures until there is no further reduction in the level of contamination, or until the possibility of damage to the skin makes further scrubbing inadvisable.

Radiation Safety Officer: *

Office Phone: *

Home Phone: *

* On the actual instructions, this information will be filled in and updated as necessary.

ATT: 10.9 June 12, 1987

RECORDS OF BYPRODUCT MATERIAL USE

A record will be made of all multidose vials that are received from a supplier or prepared in house. This record will include the following:

1. Radionuclide;
2. Chemical form or its abbreviation or trade name;
3. Date of receipt or preparation;
4. Date and time of initial activity assay and activity in millicuries and volume;
5. Supplier or kit manufacturer;
6. If administered,
 - a. Date and time dosage was drawn,
 - b. Prescribed dosage,
 - c. Measured activity in millicuries,
 - d. Patient name and identification number if one has been assigned;
7. If discarded, the method of disposal and date; and
8. Initials of the individual who made the record.

ATT: 10.10 June 12, 1987

MEASURING AND RECORDING MOLYBDENUM CONCENTRATION

This procedure will be done every day after milking the generator. The log book is located next to the dose calibrator. The reading for Mo 99 breakthrough must be below .07 ~~ACi~~ of Mo 99 per 1 mCi of Tc 99m.

Procedure:

1. Put on gloves.
2. Push Mo 99 assay dial in on dose calibrator.
3. Peak to zero with background dial, using the correct range.
4. Put Tc 99m vial alone into the lead Mo 99 cannister with the aid of forceps and cover it.
5. Put this cannister into dose calibrator.
6. Multiply reading by 3.5 to obtain Mo 99 breakthrough.
7. Calculate the Mo-99 to Tc-99m ratio.
8. If the ratio is greater than .07 microcuries Mo-99 per millicurie Tc-99m notify the RSO.

ATT: 10.12 June 12, 1987

SURVEY PROCEDURES

1. A survey with a radiation detection instrument at the end of each day of use will be conducted in areas where radiopharmaceuticals are prepared or administered. (Areas A.B.C.)
2. A weekly survey will be conducted where radiopharmaceutical wastes are stored.
3. Survey equipment will be capable of detecting dose rates as low as 0.1 millirem per hour.
4. Wipe tests will be conducted on a weekly basis with radiation detection equipment capable of measuring 2000 disintegrations per minute. (Area ABCDEFG)
5. Trigger levels will be established for surveys and wipe samples. In the event a trigger level is exceeded the RSO or his representative will be immediately notified.
6. Records of each survey will be retained for a period of 2 years. This record will include the date of the survey, the survey area plan, the trigger level for each area, the dose rate detected in each area, or the removable contaminations expressed in counts per minute per 100 square centimeters, the instrument used to make the survey or analyze the sample and the initials of the individual who performed the survey.

ATT: 10.12a June 12, 1987

AREA SURVEY PROCEDURES

DAILY (mR/Hr)

Equipment:

Date:

Surveyor:

Std. check source (before):

Background:

Area A:

Area B:

Area C:

Std. check source (after):

Date:

Surveyor:

Std. check source (before):

Background:

Area A:

Area B:

Area C:

Std. check source (after):

Date:

Surveyor:

Std. check source (before):

Background:

Area A:

Area B:

Area C:

Std. check source (after):

Date:

Surveyor:

Std. check source (before):

Background:

Area A:

Area B:

Area C:

Std. check source (after):

WEEKLY

Equipment: (1)

Equipment: (2)

Date:

Surveyor:

Std. check sources (before):

Background:

Location
(Area)

Survey Meter (1) Wipe (2)
(exp. rate mR/hr) CPM

A (dose prep):

B (dose calib):

C (Injec. cart):

D (lead refrig):

E (Hot storage Ext.):

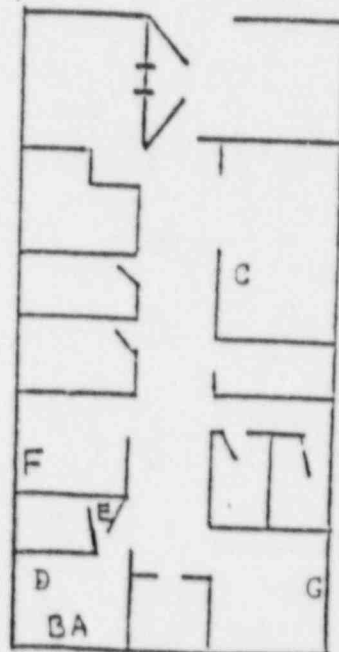
F (RIA work area):

G (RIA work area):

Std. check sources (after):

Any corrective action indicated:

What:



MATERIALS LICENSE

Amendment No. 10

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. V. A. Medical Center</p> <p>2. Lyons, New Jersey 07939</p>		<p>In accordance with letter dated September 23, 1986,</p> <p>3. License number 29-17045-01 is amended in its entirety to read as follows:</p>	
		<p>4. Expiration date July 31, 1987</p>	
		<p>5. Docket or Reference No. 030-12104</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35</p> <p>B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35</p> <p>C. Any byproduct material listed in Section 31.11(a) of 10 CFR 31</p>	<p>7. Chemical and/or physical form</p> <p>A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35</p> <p>B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35</p> <p>C. Prepackaged kits</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As necessary for uses authorized in Subitem 9.A.</p> <p>B. 2 curies of each byproduct material authorized in Subitem 6.B.</p> <p>C. 3 millicuries of each byproduct material authorized in Subitem 6.C.</p>	
<p>9. Authorized use</p> <p>A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100, Title 10, Code of Federal Regulations.</p> <p>B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.</p> <p>C. <u>In vitro</u> studies.</p>			

CONDITIONS

10. Licensed material shall be used only at V. A. Medical Center, Lyons, New Jersey.
11. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Arnold Olefson M.D.

Group I, II, and III
In vitro studies

Jyoti M. Shah, M.D.

Group I, II, and III
In vitro studies

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

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030-12104

Amendment No. 10

(11. Continued)

CONDITIONS

Lawrence Gould, M.D.

Group I, II, and III
In vitro studies

12. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
- A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
 - B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
13. For a period not to exceed 60 days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:
- A. Has the prior written permission of the hospital's Administrator and Radiation Safety Committee, and
 - B. Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and
 - C. Performs only those procedures which the physician is specifically authorized to perform pursuant to a license issued by the Nuclear Regulatory Commission.

The licensee shall maintain for inspection by the Commission copies of the written permission specified in A. above and of the license(s) specified in B. and C. above for a period of 5 years from the date permission is granted under A. above.

14. Each radiopharmaceutical dose shall be assayed in the dose calibrator prior to patient administration.
15. Syringe shields shall be used for preparation and administration of radiopharmaceuticals to patients.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

29-17045-01

Docket or Reference number

030-12104

Amendment No. 10

(Continued)

CONDITIONS

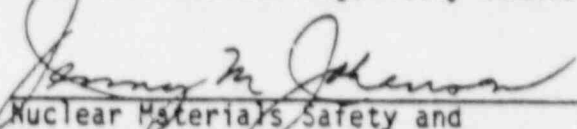
16. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated May 17, 1982
- B. Model ALARA Program, Appendix O, Regulatory Guide 10.8 (Rev. 1) October, 1980
- C. Letter dated March 30, 1984
- D. Letter dated May 22, 1984
- E. Letter dated September 27, 1984
- F. Letter dated August 12, 1985
- G. Letter dated April 17, 1986
- H. Letter dated July 18, 1986
- I. Letter dated September 5, 1986
- J. Letter dated September 23, 1986
- K. Letter dated October 28, 1986
- L. Letter dated November 24, 1986

For the U.S. Nuclear Regulatory Commission

Date DEC 24 1986

By


Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406