DL-090895_01

COLUMBIA/HCA
Healthcare Corporation

CHIPPENHAM MEDICAL CENTER
JOHNSTON-WILLIS HOSPITAL

September 8, 1995

U.S. Nuclear Regulatory Commission, Region II
Nuclear Materials Licensing Section
101 Marietta Street, Suite 2900
Atlanta, Georgia 30323
Phone: 404-331-5083
FAX: 404-331-5559

ATTN: Division of Radiation Safety

RE: Notification of authorized user to License 45-02888-01

Pursuant to 35.14, we would like to notify you that Jeffrey Scott Roberts, M.D. was approved by the Radiation Safety Committee on September 8, 1995 for material uses listed under 10 CFR 35.300 and 35.400. Dr. Roberts, is an authorized user on Materials License No 45-15249-01 for 10 CFR 35.300 and 35.400.
If there are any questions concerning this matter, please contact me at (804) 323-8796.

Sincerely,

Lenna Deletis
Director of Nuclear Medicine

control #
256931

CHIPPENHAM MEDICAL CENTER
7101 Jahnke Road
Richmond, Virginia 23225
Telephone (804) 323-8911
FAX (804) 323-8953 - Main FAX
FAX (804) 323-8049 - Administration

JOHNSTON-WILLIS HOSPITAL
[illegible] Willis Drive
Richmond, Virginia 23235
Telephone (804) 330-2000
FAX (804) 330-2233 - Main FAX
FAX (804) 330-2313 - Administration

Table of Contents

Training and Experience for Individual Users 1

Procedure for Calibrating Survey Instruments 2

Procedure for Calibrating Dose Calibrator 3

Personnel External Exposure Monitoring Program 6

Facilities Description 7

RADIATION SAFETY COMMITTEE 17

Procedure for Leak-Testing Sealed Sources 19

Rules for Safe Use of Radiopharmaceuticals 20

Emergency Procedures 21

Procedure for Ordering and Receiving 22

Procedure for Safely Opening Packages Containing 23

Procedure for a Unit Dosage Record System 25

Procedure for a Multidose Vial Record System 26

Molybdenum Concentration 27

Procedure for Inventory of Implant Sources 28

Procedure For Area Surveys 29

Air Concentration Control 31

Procedures for Radiation Safety During Therapeutic 32

NURSING CARE FOR PATIENTS RECEIVING RADIOACTIVE IODINE 35

Procedures for Radiation Safety During Implant Therapy 37

PATIENTS RECEIVING INTERSTITIAL RADIATION THERAPY 38

Radioactive Waste Disposal Procedures 40

Control #
256931

ATT 7.1
Training and Experience for Individual Users

All new employees will receive general radiation safety training during the new employees' orientation and will be given a handout which contains general radiation safety information.

Personnel who work with or in the vicinity of radioactive material will be instructed

1. By their supervisor before assuming duties with, or in the vicinity of radiation.
2. By their supervisor or the Radiation Safety Officer or his designee whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals will include the following subjects:

1. Applicable regulations and license conditions.
2. Areas where radiation is used or stored.
3. Potential hazards associated with radiation in each area where the employees will work.
4. Appropriate radiation safety procedures.
5. Hospital's in-house work rules
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer
7. Appropriate response to emergencies or unsafe conditions.
8. Worker's right to be informed of occupational radiation exposure and bioassay results.
9. Location where notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions are available, as required by 10 CFR Part 19

Personnel classified as radiation workers (radiology and nuclear medicine staff) will receive an annual refresher course which will reemphasize the initial training given and cover any changes in the license, State law or the general philosophy regarding radiation safety

Ancillary personnel who work with or in the vicinity of radioactive material will receive periodic refresher training which re-stresses those areas of radiation protection which are pertinent. This training may be incorporated into ongoing departmental or hospital wide safety training programs were appropriate

ATT 9.2
Procedure for Calibrating Survey Instruments

All survey instruments will be calibrated annually or following repair by the Radiation Safety Office at VCU according to the procedures on file with the NRC under license # 45-00048-17 issued to Virginia Commonwealth University, or by an outside contractor who follows the model procedures published in Appendix B of Regulatory Guide 10.88, Revision 2.

ATT 9.3
Procedure for Calibrating Dose Calibrator

Procedure

1. Test for the following at the indicated frequency and for the suggested tolerance:

   a. Constancy at least once each day prior to assay of patient dosages (±10 percent).

   b. Linearity at installation and at least quarterly thereafter (±10 percent).

   c. Geometry dependence at installation (±10 percent).

   d. Accuracy at installation and at least annually thereafter (±10 percent).

2. After repair, relocation or adjustment, repeat the above tests as appropriate.

3. **Constancy** means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Ba-133, Co-57, or Ra-226 using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

   a. Assay the reference source(s) using a frequently used setting (i.e., Tc-99m may be the most frequently used setting).

   b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

   c. Weekly, using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Log the results.

   d. The tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician and Radiation Safety Officer of suspected malfunction of the calibrator will be ± 10%. These action levels should be written in the log book.

   e. If the value does not agree, within ± 10%, the dose calibrator <u>must</u> be repaired or replaced.

4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

5. **Linearity** means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of activity which is at least as large as the highest dosage that will be administered to a patient, in a unit dosage syringe, or as a therapeutic radiopharmaceutical (whichever is largest).

   Decay Method

   a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicurie. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at, for example, 8 a.m.

   b. Repeat the assay at about noon, and again at about 4 p.m. Record the time of the assay. Continue on subsequent days until the assayed activity is less than 30 microcurie. For dose calibrators on which you select a range with a switch, select the range you would

   c. Convert the time and date information you recorded to hours elapsed since the first assay

d. Plot or calculate the predicted activity versus the measured activity using a reading near a millicurie value frequently used for patient doses for a starting point.

e. If an error greater than ±10% is noted between the predicted and measured activities, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

6. **Geometry independence** means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.

b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicurie indicated on the Dose Calibrator Geometry and Accuracy Form.

c. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicurie indicated.

d. Repeat the process until you have assayed a 2.0-cc volume.

e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicurie by the millicurie indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 10 percent error lines above and below the chosen "standard volume."

f. If any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence", and note the date of the test and the model number and serial number of the calibrator.

g. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicurie indicated.

h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicurie indicated.

I. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicurie by the millicurie indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 10 percent error lines above and below the chosen "standard volume."

k. If any correction factors are greater than 1.1 or less than 0.9 or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence" and note the date of the test and the model number and serial number of the calibrator.

7. **Accuracy** means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. The activity of at least one reference source should be within the range of activities normally assayed. At least two sources with different principal photon energies (such as Co-57, Ba-133, and Cs-137) should be used. The regulations require that, if a Ra-226 source is used, it must be at least 10 microcurie, if any other source is used, it must be at least 50 microcurie.

   a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.

   b. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference source, mathematically corrected for decay.

   c. Repeat the procedure for other calibrated reference sources.

   d. If the average value exceeds ± 10%, the dose calibrator <u>must</u> be repaired or replaced.

   e. At the time of the test the source used for daily constancy will be assayed on all commonly used setting and the results recorded.

8. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

ATT 9.4
Personnel External Exposure Monitoring Program

Program

1. The Radiation Safety Officer or his/her designee, will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low.

2. Individuals who are occupationally exposed to radiation on a regular basis and who are likely to receive in excess of 10% of the annual occupational limit will be issued a whole body monitor that will be processed by a contract service on either a monthly or a quarterly* basis. The determination for monitoring will be made by the Radiation Safety Officer.

3. Individuals who handle radioactive material on a regular basis and who are likely to receive in excess of 10% of the annual occupational limit to the extremities will be issued a film or TLD finger monitor that will be processed by a contract service on either a monthly or a quarterly basis.

4. All technologist working in radiology or nuclear medicine will be considered radiation workers and likely to receive in excess of 10% of the annual occupational limits and are therefore required to be monitored in accordance with items 2. and 3. above.

5. Individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for patients, will be issued a whole body monitor when caring for those patients if the exposure is likely to exceed 10% of the individual's annual occupational limit.

6. Other individuals who are exposed to radiation on an occasional basis such as secretarial personnel who work in the vicinity of nuclear medicine but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages, will not normally be issued exposure monitors.

7. Any individual receiving occupational radiation exposure as a result of employment by any other person during the current calendar year must advise the RSO in writing of that exposure and provide in writing a quarterly summary of their exposure. Annually, they must also provide a copy of the NRC 5 form from each person providing personnel monitoring.

* All quarterly monitors will be of the TLD type

ATT 9.6.1
Facilities Description

CHIPPENHAM MEDICAL CENTER

1. The Nuclear Medicine facilities are in hospital's north tower, on the fourth floor. The unit has (4) camera rooms, 1 dexa BMC bone densitometer, hot lab, a dark room, computer tech area, reception, offices, and a break room. (See diagram).

2. All radioactive materials will be received in the hot lab. After hour deliveries will be placed in the hot lab by the radiopharmacy personnel. All radioactive doses will be drawn in the hot lab. The doses received by the department come in shielded containers.

3. Fixed shielding in the department consists of 3/16" lead-lined walls of the hot lab along with similar shielding in the storage cabinet within the hot lab. This cabinet is used for storage of sealed sources, radioactive waste, and some doses. Large lead boxes are used in the hot lab to ensure waste being held will not expose personnel to levels over those set in 10 CFR 20. Daily and weekly surveys are done to ensure compliance. An L-shield is used on the counter top in the hot lab for handling of doses prior to calibration and patient injection.

4. An outside Hot Trash storage is used for decay and storage of low level radioactive wastes, located inside the mechanical quadrangle of the first floor of the medical center (see diagram). This is an open area of mechanical equipment and acc. is restricted. The waste is held in large jobsite chests within the fenced area. The chests are weather resistant and are padlocked. The two inside area immediately adjacent to the fenced in area are both mechanical spaces with limited access. All waste placed in the chest are sealed in plastic bags providing a secondary barrier from moisture. The sheer size and weight of the chest ensure that the unit itself will not be stolen. The majority of the waste stored in the chest is low level and presents minimal risks to the general public. Using the definitions in Part 20 for "Radiation Area" and "Restricted Areas" the fenced in area is labeled as a restricted area and the chests are labelled as containing radioactive waste materials.

5. The stress department is located on the 4th floor, north tower, next to the elevators. See attached diagram.

6. See additional Radiation Safety procedures located in Radiation Safety Notebook for further detailed policies and procedures.

JOHNSTON-WILLIS HOSPITAL

1. The Nuclear Medicine facilities are located on the first floor of the main hospital. The unit has (3) camera rooms, hot lab, a dark room, and an office. (See diagram).

2. All radioactive materials will be received in the hot lab. After hour deliveries will be placed in the hot lab by the radiopharmacy personnel. All radioactive doses will be drawn in the hot lab. The doses received by the department come in shielded containers.

3. Fixed shielding in the department consists of 3/16" lead-lined walls of the hot lab along with similar shielding in the storage cabinet within the hot lab. This cabinet is used for storage of sealed sources, radioactive waste, and some doses. Large lead boxes are used in the hot lab to ensure waste being held

will not expose personnel to levels over those set in 10 CFR 20. Daily and weekly surveys are done to ensure compliance. An L-shield is used on the counter top in the hot lab for handling of doses prior to calibration and patient injection.

4. An outside Hot Trash storage area is used for decay and storage of low level radioactive wastes adjacent to our administration building (see attached diagram). The waste is held in large jobsite chests within the fenced area. The chests are weather resistant and are padlocked. All waste placed in the chest are sealed in plastic bags providing a secondary barrier from moisture. The sheer size and weight of the chests ensure that the unit itself will not be stolen. The majority of the waste stored in the chest is low level and presents minimal risks to the general public. Using the definitions in Part 20 for "Radiation Area" and "Restricted Area" to post the area, the fenced in area is labeled as a restricted area and the chests are labelled as containing radioactive waste materials.

5. The stress department is located on the second floor in the Special Procedures Department. See attached diagram.

6. See additional Radiation Safety procedures located in Radiation Safety Notebook for further detailed policies and procedures.

CHIPPENHAM MEDICAL CENTER
Nuclear Medicine - 4th Floor

Uptake Probe

ZLC Camera Area

Patient Waiting Area

Restroom Dark Room

Staff Lounge

Raytheon Camera Area

Restroom Hot Lab

File Storage

GENYSIS Camera Area

Storage

Tech Office Physician Office

VISION Camera Area

Hot Lab

Cardiac Stress Area

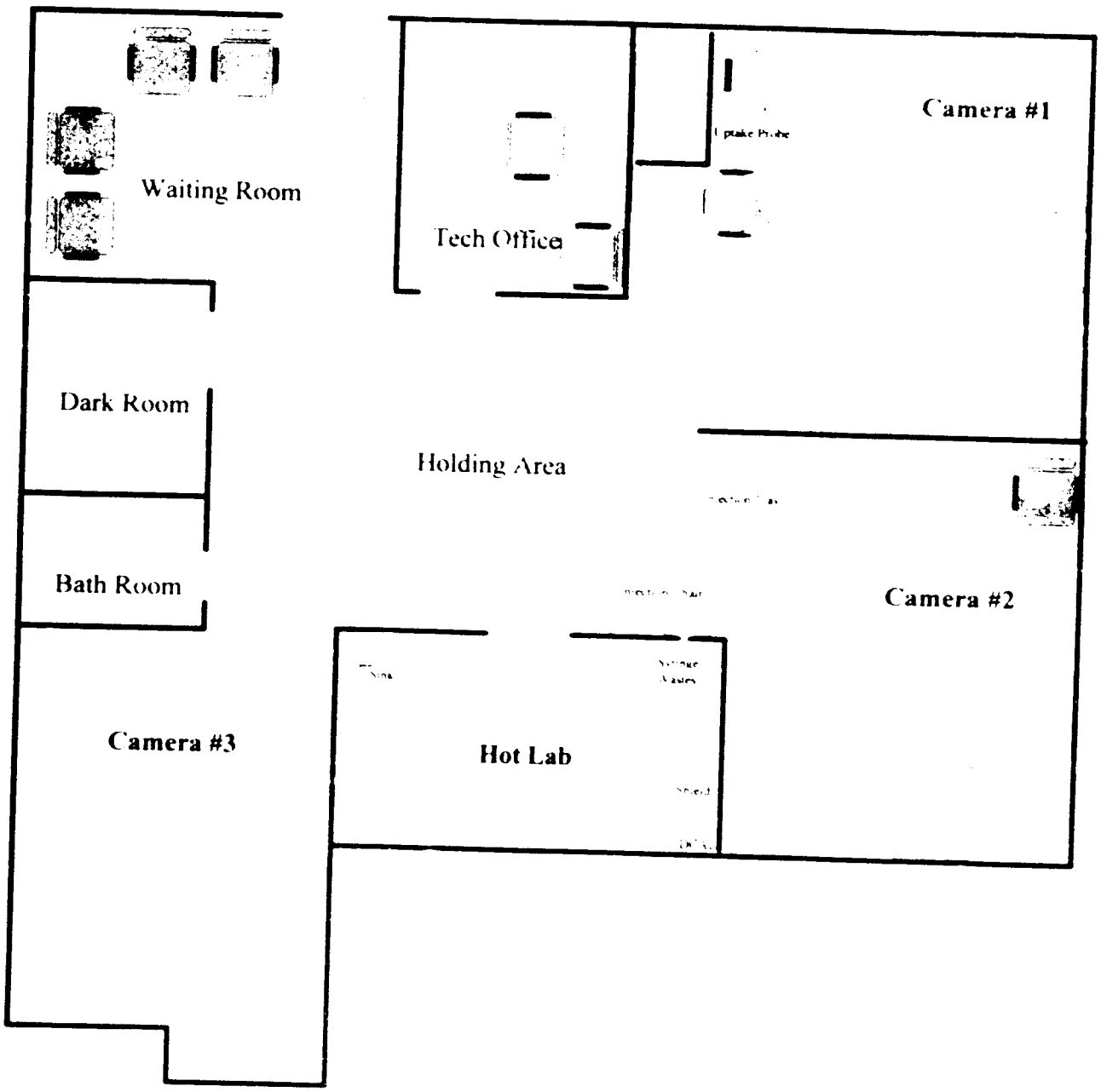
Chippenhman Medical Center
Decay-in-Storage Area

DIS Box #1

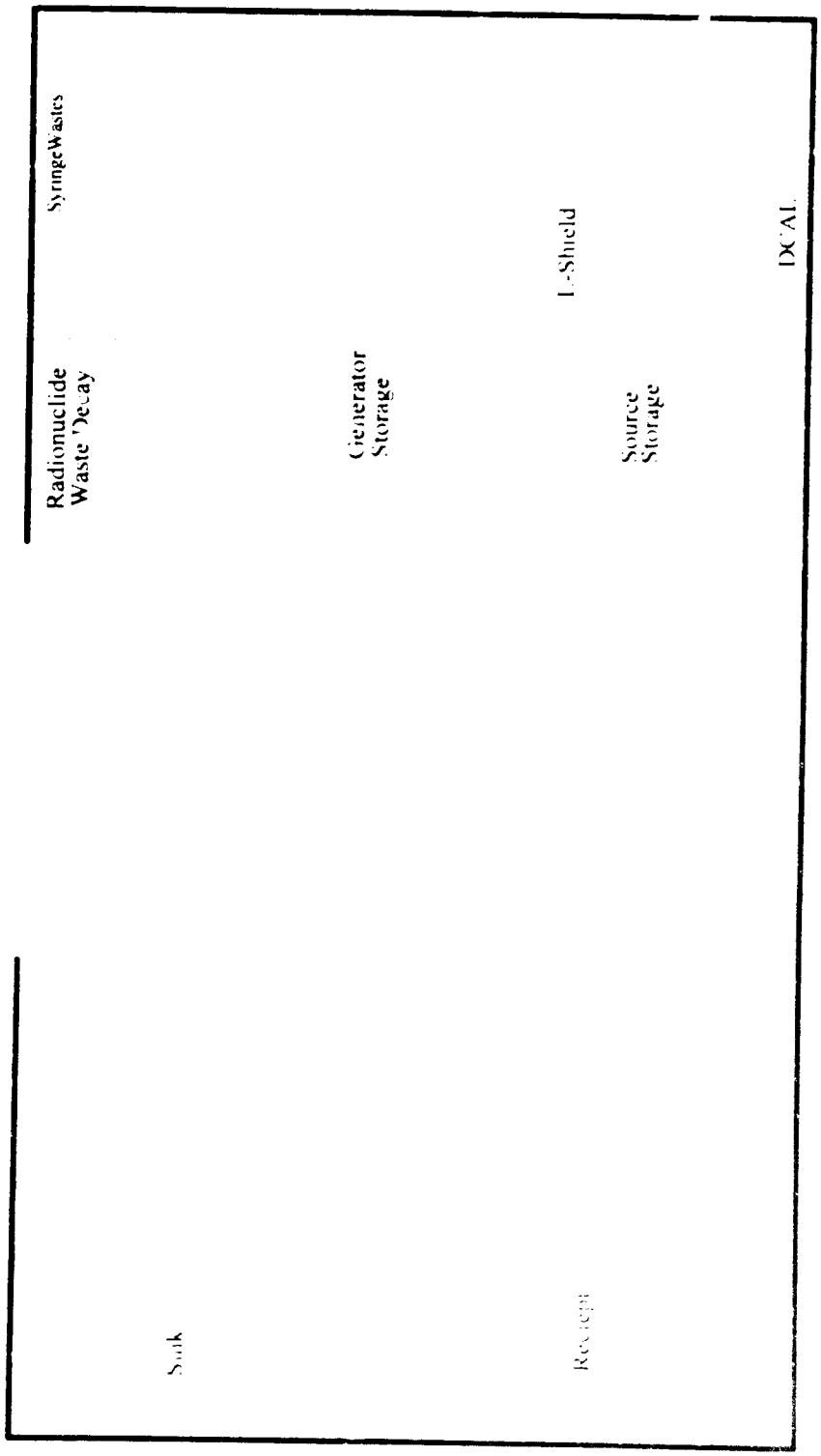
DIS Box #2

NUCLEAR MEDICINE

Johnston Willis Hospital



Nuclear Medicine Hot Lab - Johnston Willis Hospital



Dean W. Bloga, PhD

Johnston Willis Hospital

Cardiovascular Services

Stretcher

EKG

Room 1

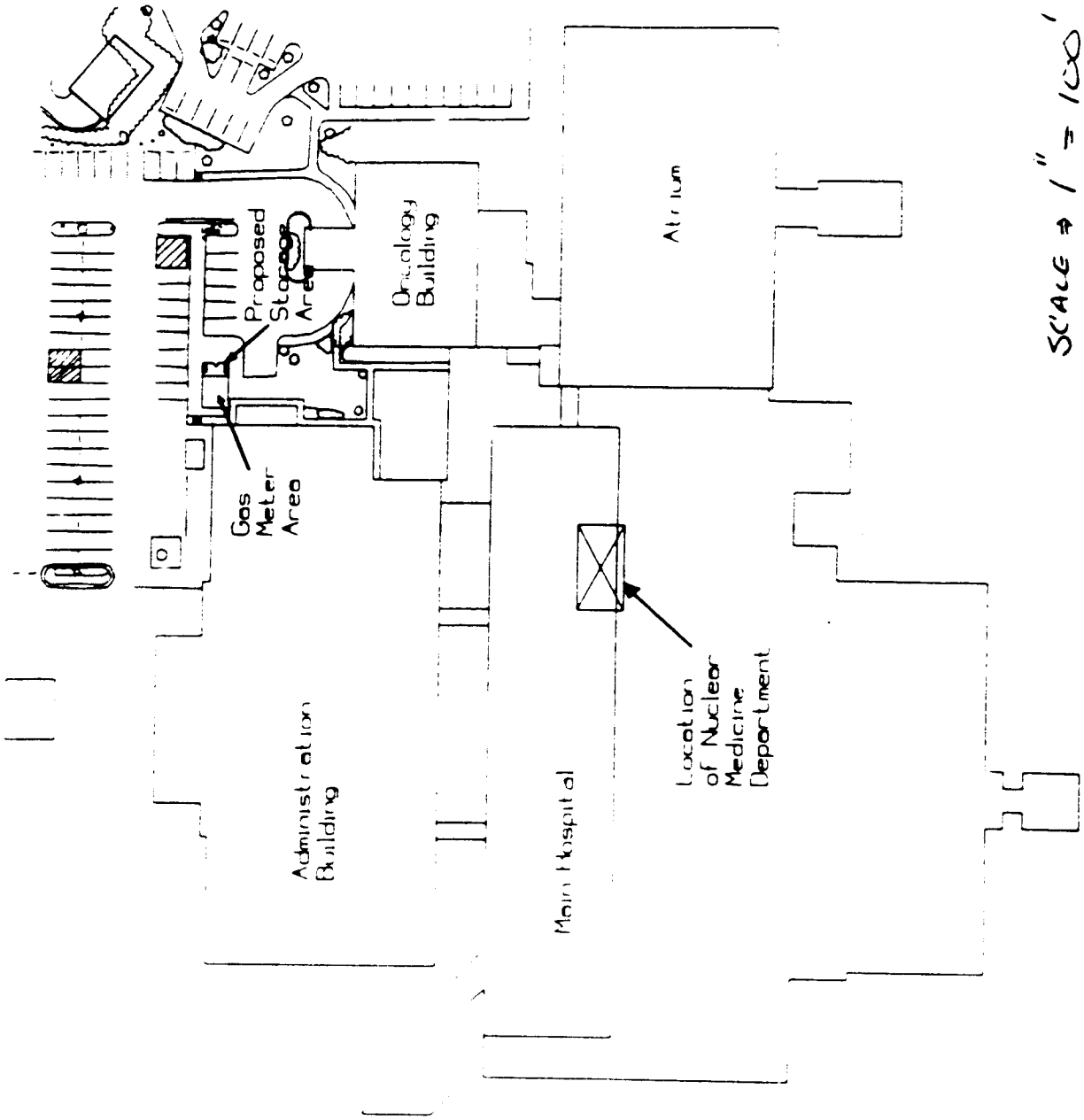
Treadmill

EKG

Treadmill

Room 2

Stretcher

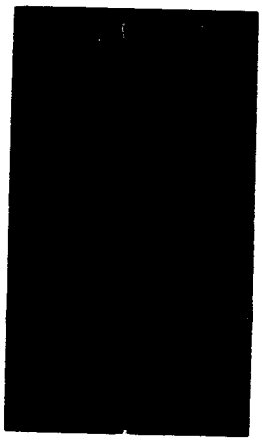

Gas Meter Area
Proposed Storage Area
Oncology Building
Atrium
Administration Building
Main Hospital
Location of Nuclear Medicine Department
SCALE ⇒ 1" = 100'

Johnston Willis Hospital

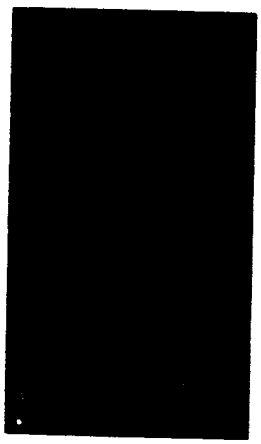
Decay-In-Storage Area

Hospital Side

Gate Door



Gas Meter Area



Parking Lot Side

ATT 10.1
RADIATION SAFETY COMMITTEE

Charge. The Committee is charged with identifying radiation safety problems; initiating, recommending, or provide corrective actions; and verifying the implementation of corrective actions The Radiation Safety Committee is hereby delegated the authority to meet this charge

The committee shall:

1. Review recommendations on ways to maintain individual and collective doses as low as reasonably achievable (ALARA).

2. Review, on the basis of safety and with regard to the training and experience standards in Subpart J of 10CFR35, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or a Teletherapy Physicist before submitting a license application or request for amendment or renewal, or

   Review, pursuant to § 35 13 (b)(1) through (b)(4), on the basis of the board certification, the license, or the permit identifying and individual, and approve or disapprove any individual prior to allowing that individu. ' to work as an authorized user or authorized nuclear pharmacist

3. Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under Sec. 35 31 of 10CFR35.

4. Review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of all personnel working with radioactive material or a radiation producing device;

5. Review quarterly, with the assistance of the Radiation Safety Officer [illegible] incidents involving radioactive material or a radiation producing devices with respect to cau[illegible] subsequent actions taken, and

6. Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program to ensure compliance with the NRC regulations, the institutions license(s) and the goals of the ALARA Program

Administrative Information

1. Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor the Radiation Safety Officer Other members may be included as the licensee deems appropriate

2. The Committee must meet at least quarterly

3. To establish a quorum and to conduct business, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative

4. The minutes of each Radiation Safety Committee meeting must include:

   (i) The date of the meeting;
   (ii) Members present;
   (iii) Members absent;
   (iv) Summary of deliberations and discussions;
   (v) Recommended actions and the numerical results of all ballots; and
   (vi) ALARA program reviews described in § 35.20 (c).

5. The committee must promptly provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

ATT 10.3
Procedure for Leak-Testing Sealed Sources

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. If you will be testing high-activity sources, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

   a. For small sealed sources, it is easiest to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

   b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.

   c. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care to touch neither field light and mirror nor cross hairs. Also wipe the primary and secondary collimators and trimmers.

   d. If you are testing radium or iodine sources at the same time, you are testing NRC-licensed sources, they should also be checked for radon leakage and volatile iodine. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.

4. The samples will be analyzed as follows:

   a. Select a suitable detector that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a rate meter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

   b. Assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum in order to estimate the detection efficiency of the analyzer used to assay the wipe samples.

   c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

   d. Calculate the estimated activity in microcurie on the wipe sample.

   e. Continue same analysis procedure for all wipe samples.

   f. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the NRC must be notified.

   g. Record the wipe sample results on the list of sources, and sign and date the list.

A[illegible]

Rules for Safe Use of [illegible]opharmaceuticals in Nuclear Medicine

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. Either after each procedure or before leaving the area, monitor your hands and clothing for contamination in a low-background area with a crystal probe or camera.
4. Use syringe shields for routine preparation of patient dosages and administration to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.
8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.
9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
10. Never pipette by mouth.
11. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.
12. With a low-range GM survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.
13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or patient's name and identification number.
14. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 10 percent off from the prescribed dosage, except for prescriptions of less than 10 microcurie. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.
15. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
16. Use a cart, wheelchair, or shielded carrier box to move flood sources, syringes, waste, and other radioactive material.

ATT 10.5

Emergency Procedures

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a GM survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.
5. Report the incident to the Radiation Safety Officer.
6. The Chief Technologist will supervise the cleanup of the spill and will complete a Radioactive Spill Report and a final survey of the area.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the Radiation Safety Officer. The RSO will be responsible to supervise clean-up.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

Relative Hazards of Common Nuclides

Spills above these millicurie levels are considered major, below are minor

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	10	Tc 99m	100
Cr 51	100	In 111	10
Co-57	100	I 123	10
Co-58	10	I 125	1
Fe 59	10	I 131	1
Co-60	1	Yb-169	10
Ga 67	100	Hg 197	100
Se 75	10	Au 198	10
Sr 85	10	Tl 201	100

Surface Contamination Levels (dpm/100 cm²)

Area	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
Unrestricted & Personal Clothing	200	2,000
Restricted	2,000	20,000

ATT 10.6
Procedure for Ordering and Receiving
Radioactive Material

Procedure

1. All orders for radioactive materials will be placed by either the nuclear medicine technologist or the radiation oncology dosimetrist. All deliveries of radioactive material will be made to Nuclear Medicine or Radiation Oncology. Nuclear Medicine or Radiation Oncology will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

   a. For routinely used materials:

      (1) Written records that identify the isotope, chemical form, activity, and supplier will be made.

      (2) The above records will be checked by the nuclear medicine technologist to confirm that material received was ordered through proper channels.

   b. For occasionally used materials (e.g., therapeutic dosages for Nuclear Medicine):

      (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, compound, activity, and supplier.

      (2) The physician's written request will be checked by the technologist to confirm that the material received is what was ordered by the radiopharmacy technologist.

3. For deliveries during normal working hours carriers will be directed to deliver radioactive packages directly to Nuclear Medicine or Radiation Oncology.

4. Deliveries are not encouraged during off-duty hours, however, deliveries which do arrive during off-duty hours are directed to security. Security has been instructed to take the package to either nuclear medicine and to place it in the hot lab, or to radiation oncology and to place it in the treatment planning room. Security has been instructed in the safe receipt of the packages and what action to take if the package is damaged.

ATT. 10.7
Procedure for Safely Opening Packages Containing Radioactive Material

Procedure

1. The following procedure will be used for all radioactive packages received displaying a Radioactive White I, Yellow II or Yellow III labels which are less than Type A quantities (see listing below).

   a. Put on gloves to prevent hand contamination.

   b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).

   c. wipe the external surface of the package (not required for gases) If there is contamination >2,200 dpm/100 cm^2, stop and immediately notify the Radiation Safety Officer.

   d. Open the package with the following precautionary steps:

      (1) Remove the packing slip.

      (2) Open the outer package following the supplier's instructions, if provided.

      (3) Open the inner package and verify that the contents agree with the packing slip.

      (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

      (5) If anything is other than expected, stop and notify the RSO.

   e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe to determine if there is any removable radioactivity by using the GM survey meter. If contamination is found:

      (1) Notify the RSO.

      (2) Take precautions against potential spread of contamination

   f. Check the user request to ensure that the material received is the material that was ordered

   g. Monitor the packing material and the empty packages for contamination before discarding

      (1) If contaminated, treat this material as radioactive waste

      (2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.

      (3) If contaminated, go back to e. of this section.

   h. Make a record of the receipt

2. The following procedure will be used for all radioactive packages received displaying a Radioactive White I, Yellow II or Yellow III labels which are equal to or greater than Type A quantities (see listing below):

a. Follow all of the steps delineated in 1. with the additional requirement added to step c. Monitor the exposure levels at 3' from the package and at the surface of the package. If the exposure rate exceeds 10 mR/hr at 3 feet, or 200 mR/hr at the surface, or there is significant contamination, immediately notify the Radiation Safety Officer.

Listing of Type A Quantities
(if nuclide is not listed, refer to 10 CFR 71.4)

Nuclide	Activity in Curies
133 Ba	10
57 Co	90
60 Co	7
51 Cr	600
137 Cs	10
59 Fe	10
67 Ga	100
153 Gd	100
123 I	50
125 I	70
129 I	2
131 I	10
111 In	25
113m In	60
190 Ir	10
192 Ir	10
99 Mo	20
32 P	30
226 Ra	0.05
186 Re	20
188 Re	10
222 Rn	2
97 Ru	80
103 Ru	25
105 Ru	20
106 Ru	2
153 Sm	20
89 Sr	10
90 Sr	0.4
99m Tc	100
201 Tl	100
133 Xe	1000

ATT 10.8
Procedure for a Unit Dosage Record System for Nuclear Medicine

Procedure

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide.
2. Chemical form or its abbreviation or trade name.
3. Date of receipt.
4. Activity in millicurie or microcurie as recorded on the unit dosage or packing slip and its associated time.
5. Supplier.
6. Lot number or control number if assigned.
7. Date of administration or disposal.
8. If administered.
   a. Time of administration,
   b. Prescribed dosage
   c. Measured activity in millicurie or microcurie,
   d. Patient name, and,
   e. Patient identification number if one has been assigned,
9. If discarded, the method of disposal, and
10. Initials of the person who made the record

ATT 10.9
Procedure for a Multidose Vial Record System

Procedure

For each multidose vial that you receive from a supplier or that you prepare, make a record of the:

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 millicurie and volume.
5. Supplier or kit manufacturer.
6. If administered.
   a. Date and time dosage was d. wn.
   b. Prescribed dosage.
   d. Calculated volume that is needed for the prescribed dosage
   e. Measured activity in millicurie.
   f. 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
Procedure for Measuring and Recording
Molybdenum Concentration

Procedure

For each generator elution, make a record of the

1. Date the generator was received.
2. Date and time of elution
3. Measured Mo-99 activity in microcurie
4. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer
5. Measured Tc-99m activity in millicurie
6. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and check-mark that the ratio is less than 0.07 microcuries of Mo-99 per millicurie of Tc-99m. If the level exceeds this amount, stop and notify the RSO
7. Initials of the person who made the record

ATT 10.11
Procedure for Inventory of Implant Sources

1. All implant sources will be stored in the locked storage area provided in the physics area. Long lived sources will be stored in the locked safe. Short-lived sources will be store in their shipping container.

2. A list of individuals allowed to handle implant sources will be maintained in the log book used to record the use of these sources. All individuals on the list will initial beside their name.

3. A map of the storage drawer showing the activity and location of each long-lived source will be maintained in the source log book and on the front of the L-shield located in the storage area. When short-lived source are stored in the storage area, their location will be noted on the inventory sheet.

4. Each time sources are removed, a record of the number of sources and activity will be entered in the source log book along with the patients room number or name, and the time and date they were removed from storage; initial the record.

5. Each time sources are returned to storage, an immediate count of the sources must be made. A record of the number of sources and activity, and the time and date they were returned to storage should be entered in the source log book on the appropriate line (verify the patients name or room number); initial the record.

6. If at any time you perceive there is a discrepancy in the record and the number of sources in use and in storage, notify the RSO.

ATT 10.12
Procedure For Area Surveys

1. Area Surveys

a. All radiological elution, preparation, and administration areas, will be surveyed at the end of each day of use with a low-range survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcurie at a time), surveys will be performed monthly for removable contamination.

c. All radiopharmaceutical use, storage and waste storage areas will be surveyed weekly with a low-range survey meter for exposure levels and by swipe for removable contamination.

d. If any unexpectedly high or low levels are found, the RSO will be notified immediately.

e. The swipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm per swipe of removable contamination.

2. Records

a. A record will be kept of exposure rate and contamination survey results. Included will be:

1) The date, area surveyed and equipment used.

2) The name or initials of the person who made the survey.

3) A diagram of the areas surveyed and contamination and exposure rate action levels as established by the RSO.

4) Measured exposure rates in mR/hr or contamination levels in dpm per swipe (100 cm^2), as appropriate.

5) Actions taken in the case of excessive exposure rates or contamination and follow-up survey information.

3. Action Levels

a. Radiation Dose Rates: a general action level of 5 mR/hr is set for all restricted and 0.5 mR/hr for all non-restricted areas. Specific action levels may be lower than these values if the RSO deems it appropriate

b. Radioactive Contamination Levels: unrestricted and restricted areas will be limited to the levels set in the following table. More restrictive levels may be set at the discretion of the RSO.

ACTION LEVELS
Surface Contamination
(dpm/100 cm^2)

Area	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Ti-201
Unrestricted, Personal Clothing	200	2,000
Restricted	2,000	20,000

ATT 10.14
Procedures for Radiation Safety During Therapeutic Use of Radiopharmaceuticals

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.

2. Prepare the room for the procedure as follows:

   a. Cover, with leak-proof absorbent paper, large surfaces (the bed, chairs, and the floor around the toilet), and with plastic wrap, small items (telephone, door knobs, bed remote control, television control, and nurse call cord) that are likely to be contaminated.

   b. Prepare separate containers for linen, disposable waste, and non-disposable contaminated items. Place a single large reclosable plastic bag in each box, or supply several small plastic bags.

   c. Determine whether urine will be collected or release into the sanitary sewage system. If urine is to be collected, prepare collection containers.

      (1) Containers should be unbreakable and closable.

      (2) If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.

      (3) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper or vermiculite.

      (4) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately 3 mm of lead.)

      (5) Supply a wide-mouth anti-splash funnel.

   d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing and nuclear medicine personnel.

3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.

4. If applicable, supply the nurses with film badges, TLDs, or pocket ionization chambers (see ATT 9.4, Personnel Exposure)

5. Brief the nurses on radiation safety precautions. Use the attached form, "Nursing Instructions for Patients Treated With Iodine-131." Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.

6. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable

7. Only those persons needed for medical, safety, or training purposes should be present during the administration.

ATT 10.13
Air Concentration Control

All aerosol studies will be done using a shielded delivery system which collects spent aerosols in a shielded trap. Only single use traps will be used and no aerosol will be vented to the room or the outside air. After any procedure in which the patient is uncooperative or there is suspected contamination, the technologist will monitor themselves to ensure they are not contaminated

8. Following administration of the dosage, measure the exposure rate at the mouth, along the esophagus, and at the stomach to ensure that the dosage reached the stomach and didn't adhere to the tissue in the mouth. Then measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, and in the surrounding hallways and rooms (limit in unrestricted areas is 2 mrem/hr). Record this and any other necessary information on the nursing instructions form and patient history form. Post the room with a "Caution Radioactive Materials" sign.

   If the exposure rate in any of the surrounding areas approaches 2 mR/hr the following should be done:

   a. The estimated exposure to personnel and patients in the area must be considered. The occupancy of the area and the expected duration of the therapy can be used to estimate the dose. Since the patient will excrete a significant amount of the radionuclide in the first 8 to 12 hours, this may be considered in the estimate. The following limits must be met:

      (1) The dose to any individual present in the area during a period of 1 year must be less than 100 mrems.

      (2) The estimated dose to any individual over the of period one year must all sources including other therapies and x-ray sources.

   b. If the estimated exposure to any individual exceeds this limit the RSO must be immediately notified any corrective action must be taken.

   c. A survey must be made early the next day to verify that any dose reduction due to excretion has been accurately accounted for. If the radiation level exceeds the estimated level the RSO must be immediately notified and corrective action taken.

   d. Records of all estimated doses, including the parameters used and the results of all surveys must be recorded on the patient history form.

9. Measure exposure and mark a visitors' "safe line" on the floor with tape as far from the patient as possible but a least at a location of 2 mrem/hr or less.

10. For patients treated with 30 mCi or more of I-131, within 3 day of the administration, measure the thyroid burden of all personnel who helped prepare or administer the dose. Also, if a substantial contamination problem is identified in the patients room, consider a thyroid burden assay for patient care personnel within 3 days of the administration. Make a record of the worker's name, amount of I-131 activity in a thyroid phantom in microcuries and associated counts per minute, the counts per minute from the worker's thyroid, the calculated thyroid burden, and date.

11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.

12. Do not release any patient until the exposure rate from the patient is less than 5 mR hr at 1 meter. Measure this exposure rate with an ionization-type survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.

    a. Remove all absorbent paper, and place it in the appropriate container.

    b. Transfer all containers to a decay-in-storage or decontamination area.

    c. Use a low-range GM survey meter and swipes to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm^2. If the contamination is fixed, exposure rates will be less than 1 mR/hr with the GM detector in contact with the contaminated surface. All swipes should be counted using a NaI detector.

    d. If a significant contamination problem is found, either the nuclear medicine staff or housekeeping under the supervision of the nuclear medicine staff, clean the room using isolation procedures. The room should then be resurveyed.

    e. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

ATT 10.14

NURSING CARE FOR PATIENTS RECEIVING RADIOACTIVE IODINE

1. Nurses may spend whatever time is necessary near the patient for ordinary nursing care unless special restrictions have been established. During the first 24 hours, private duty nurses remaining in the patient's room should stay about two meters (6 feet) away from the bed except during actual nursing procedures. Call the Nuclear Medicine Division with any questions about the care of the patient.

2. Personnel under 18 years of age shall not care for patients having iodine therapy.

3. Nursing personnel and attendants who are pregnant or planning to become pregnant shall not care for patients undergoing I-131 therapy.

4. The patient should remain in his room at all times. If emergency diagnostic procedures are required (e.g., X-rays, blood work, ekg, etc.), or if the patient requires emergency surgery or should die, the Radiation Safety Officer should be notified.

5. Visitors are allowed only with the approval of the Radiation Safety Officer.

6. All personnel shall wear disposable gloves when entering the patient's room. The gloves should be disposed of in the trash can provided by the Radiation Safety Officer or his designee.

7. Nursing personnel should use disposable items when possible. These items may be disposed of when their use is no longer needed (e.g., plastic dishes, plastic bedpans, etc.). These items should be placed in the designated waste container. The Radiation Safety Officer will arrange for the proper disposal of the contents of the container.

8. Plastic dishes and utensils should be used and then discarded in special trash cans provided by the Radiation Safety Officer.

9. Plastic mattress covers and plastic pillow covers must be utilized to protect mattress and pillow from becoming contaminated.

10. The Radiation Safety Officer or his designee will put protective plastic wrap on items in the patient's room that are used most often by the patient. This is to protect these items from becoming contaminated. Such items may be the toilet seat, flush handle, telephone, call button, etc. Protective leak-proof absorbent paper may also be placed on the floor in areas where contamination may be a problem.

11. All linen, trash and other items in the room shall be held for monitoring by the Radiation Safety Officer or his designee.

12. Surgical dressings should be changed only as directed by the physician. Such dressings should not be discarded but should be collected in plastic bags and left in the room to be monitored by the Radiation Safety Officer or his designee. Handle these dressings only with tongs or tweezers.

13. If urine from Iodin -131 patients is collected, a special container will be provided by the Nuclear Medicine Division. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bed pan should be provided. If the nurse helps to collect the excreta, disposable gloves should be worn. Afterwards, hands should be washed with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste container provided by the Radiation Safety Officer.

14. A separate bed pan or toilet shall be kept for the patient to use until discharged. It should be washed thoroughly with soap and hot water, with gloves being worn during this procedure. After the patient's discharge, the bed pan or toilet should be monitored by the Radiation Safety Officer or his designee before being returned to use.

15. All vomitus from a patient receiving an oral administration of Iodine-131 must be kept in the patient's room for disposal by the Radiation Safety Officer. Feces need not be routinely saved, unless ordered on the chart.

16. If the patient received the dose intravenously and subsequently vomits, no special precautions are necessary.

17. Vomiting within 24 hours after oral administration, urinary incontinence, or excessive perspiration within the first 48 hours may result in serious contamination of linen and even of the floor. In addition, precautions must be taken to see that no urine or vomitus is spilled from the containers. If such a situation arises, the RADIATION SAFETY OFFICER or NUCLEAR MEDICINE SHOULD BE NOTIFIED.

18. Excessive sputum should be collected in waterproof containers and disposed of in the sanitary sewer system

19. If a nurse, attendant, or anyone else knows or suspects that his or her skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer immediately. This person should remain in an area adjacent to the patient's room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.

20. There must be a written approval by the Radiation Safety Officer or his designee for a patient to be discharged from the hospital. (Indicated on patient's chart).

21. After the patient has been discharged, housekeeping shall not be allowed to clear the room until the Radiation Safety Officer or his designee monitors for contamination. At this time, housekeeping may clear the room under the Radiation Safety Officer's supervision.

22. The room shall not be cleared for further use until cleared by the Radiation Safety Officer or his designee

ATT 10.15

Procedures for Radiation Safety During Implant Therapy

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room unless the dose rate at one meter from the implant meets the requirements in paragraph 20.105(b) of 10 CFR Part 20.

2. If indicated by RSO, supply the nurses with film badges, TLDs, or pocket ionization chambers.

3. Brief the nurses on radiation safety precautions. Use the form, "Nursing Instructions, Therapeutic Use of Sealed Sources". Allow time for questions and answers during the briefing.

4. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable consistent with good medical care.

5. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.

6. If applicable, mark a visitors' "safe line" on the floor with tape as far from the patient as possible.

7. Following the implant, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in paragraph 20.105(b)). Record this and any other necessary information in the monitoring record.

8. Do not release any patient who has received a temporary implant from the hospital until both a radiation survey of the patient and a count of implant sources confirm that all sources have been removed from the patient and are accounted for. Perform this check immediately after the removal of the sources. Keep a record confirming the source count and radiation survey in the monitoring record. For low activity seeds (less than 1 millicurie), use an individual seed to check the survey meter to be sure it will easily detect a seed that has not been removed or has been lost.

9. Do not release any patient who has received a permanent implant from the hospital until the exposure rate from the patient is less than 5 mR/hr at 1 meter. Measure this exposure rate with an ionization-type survey meter at a distance of 1 meter from the umbilicus with the patient standing.

ATT 10.15b

Nursing Care Instructions

PATIENTS RECEIVING INTERSTITIAL RADIATION THERAPY

1. If needles, capsules, radioactive seeds or ribbons become loose r fall out, do not try to replace them. Call Radiation Oncology (see next page). If a source falls out do not handle it directly use forceps provided to transfer to a lead container provided for this purpose Notify Radiation Oncology (see next page).

2. Each patient receiving interstitial treatment is to be assigned to either room 300 or 354. The patient should not be allowed outside the assigned space during the course of the treatment

3. Signs will be placed on the door and the front of the patient's chart; this signs may be taken off only when the implant is removed.

4. When issued, film badges should be worn by nursing personnel caring for the patient most frequently.

5. Time spent near the patient should be limited to the amount necessary for adequate nursing care Always maintain the farthest practical distance from the patient during nursing care. Any special restrictions will be noted in the patient's chart. Private duty nurses remaining in the patient's room will be instructed by the doctor as to the distance to maintain when not performing any actual nursing procedures.

6. Surgical dressings and bandages should be changed only as directed by the radiation oncologist or the physician designated by him or her.

7. ___ Visitors are <u>not</u> allowed.
   ___ Adult visitors are allowed for 20 minutes per day as long as they shall sit or stand at the designated location.

8. Perineal care is not given during the radiation treatment of this area but the perineal pad may be changed when necessary If the pad is changed, be sure the radioactive sources or source containers are not disturbed or loosened. Bag the soiled pad and place it in the trash container for monitoring before disposal

9. During intracavitary therapy of the perineal area, once each shift, an inspection should be made of the perineal area to ensure that the applicator is still in place and that no sources have been dislodged If there appears to be a problem contact radiation oncology (see below)

10. Patients undergoing intracavitary therapy of the perineal area are allowed to use bedpans The excreta should be checked for dislodged sources and the perineal area should be examined to ensure that the applicator is still in place.

11. Instruments and containers used in handling radioactive sources do not become radioactive These special instruments are used only to simplify handling and to maintain suitable distances between the hands and the sources They also simplify the handling process

12 No special precautions are needed for sputum, urine, vomitus, feces, dishes*, instruments, utensils, or bedding.

13 Hold all dirty linen, towels, sleepwear, etc for inspection by the Radiation Oncology

14 The room must be monitored by Radiation Oncology before it can be release for other use

15 The patient should not be discharged without notifying Radiation Oncology

16. Pregnant personnel are prohibited from working with this patient This includes housekeeping, dietary, nursing, lab, or other personnel.

17 A portable shield is used at the bedside to provide protection during nursing care Stay behind this shield as much as possible

*FOOD TRAYS DO NOT NEED TO BE HELD IF THE PATIENT IS RECEIVING INTRACAVITARY TREATMENT OF THE PERINEAL AREA

- CALL PROCEDURES -

Working Hours

Radiation Oncology 2164

After Hours

Mike Caisse 748-9866
Beeper (Digital) 323-8770 #628

Dr Belgrad 739-3444
Page PBX

Dr Zarkoob 745-4450
Page PBX

ATT 11.1

Radioactive Waste Disposal Procedures

All radioactive materials with a physical half-life of less than 65 days will be held for decay-in-storage before being disposed of in the ordinary trash. The following procedures will be adhered to:

1. Hold all byproduct material for a minimum of ten half-lives.

2. Monitor [illegible] at the surface of the container, with no interposed shielding, at the time of disposal, a[illegible] determine that its radioactivity cannot be distinguished from background radiation l[illegible]s. This will be done with a radiation detection survey meter set on the most sensitive sca[illegible]

3. Remove or obliterate all radiation labels.

4. Separate and monitor all generator columns individually with all radiation shielding removed to ensure that it has decayed to background radiation levels.

5. Make a record of the above steps including initial date placed into storage, radionuclides, general description of the materials, date of disposal, survey meter used, background reading, measured dose rate, ultimate disposition and the initials of the individual performing the survey.

Except for disposal by decay, as indicated above, all other radioactive waste materials will be transferred to a burial site or returned to the manufacture. All appropriate packaging requirements will be met and a copy of the consignment sheet from the transfer agent will be kept as a record.

Program for Maintaining Radiation Exposure to Occupational Workers and Member of the General Public As Low As Reasonably Achievable (ALARA)

1. Management Commitment

   a. We, the management of this facility 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 the Radiation Safety Committee (RSC) and the 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

      (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 does overrule 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 dev[illegible] new procedures as appropriate to implement the ALARA concept.

      (2) The RSC will perform a quarterly review of occupational radiation exposure with pa[illegible]ular 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.

(3) The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include efforts of the RSO, authorized users, and workers as well as those of management.

Table 1

Investigational Levels (mrem per calendar quarter)		
Area of Body	**Level I**	**Level II**
Total effective dose equivalent, general.	125	375
Total effective dose equivalent , for physicians involved in angiography or cardiology.	125	900
Shallow-dose equivalent; to skin or to any extremity.	1,250	3,750
Eye dose equivalent	375	1,125
Deep-dose equivalent and committed dose equivalent to any individual organ or tissue other than the lens of the eye.	1,250	3,750

3. Radiation Safety Officer

a. Annual, Semi-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 report to the RSC.

(3) **Semi-annual 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 two quarters and will report to the RSC.

(4) **Annual review of doses to members of the general public.** The RSO will review the releases of both gaseous and liquid radioactive materials to determine that doses to members of the general public are ALARA in accordance with the provisions of Section 7 of this program and will report to the RSC.

b. Education Responsibilities for ALARA Program

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

(2) The RSO will ensure that authorized users, workers, and auxiliary 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 in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will receive and evaluate 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 ensure investigation of 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 § 20.2106 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. This institution hereby establishes investigational levels for radiation dose to members of the general from releases of gaseous or liquid radioactive materials which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are 20% of the values listed in Appendix B, Table 2, Columns 1 and 2, to §§ 20.1001-20.2401. These levels apply to all members of the general public who may be exposed as a result of the release of radioactive materials from this facility.

8. Signature of Certifying Official

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

Marilyn B. Lavenner

Signature

Marilyn Lavenner

Name (print or type)

CEO

Title

9-8-95

Date

CHIPPENHAM MEDICAL CENTER
JOHNSTON-WILLIS HOSPITAL

QUALITY MANAGEMENT PROGRAM - RADIONUCLIDE THERAPY

Purpose:
The following program has been established to ensure that the radionuclide therapy procedures carried out at these facilities are of the highest quality and in compliance with Title 10, Code of Federal Regulations, Part 35.32 (10 CFR 35.32).

Policy:
Prior to administration, a written directive must be prepared, dated, and signed by an authorized user for:

- Any brachytherapy radiation dose,
- Any administration of quantities greater than 30 microcuries of either sodium iodine I-125 or I-131; or
- Any therapeutic administration of a radiopharmaceutical, other than sodium iodine I-125 or I-131.

Definitions:

Misadministration means the administration of:

1. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodine I-125 or I-131:
   - Involving the wrong patient or wrong pharmaceutical, or
   - When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceed 30 microcuries.
2. A therapeutic radiopharmaceutical dosage, other than sodium iodine I-125 or I-131:
   - Involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or
   - When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.
3. A brachytherapy radiation dose:
   - Involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);
   - Involving a sealed source that is leaking;
   - When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
   - When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.
4. A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodine I-125 or I-131, both.

- Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and;

- When the dose to the patient exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

Prescribed dosage means the quantity of radiopharmaceutical activity as documented:

1. In a written directive; or

2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

Prescribed dose means:

1. For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

Written directive means an order in writing for a specific patient, dated and signed by the authorized user prior to the administration of a radiopharmaceutical or radiation, containing the following information:

1. For any administration of quantities greater than 30 microcuries of either sodium iodine I-125 or I-131: the dosage;

2. For a therapeutic administration of a radiopharmaceutical other than sodium iodine I-125 or I-131: the pharmaceutical, dosage, and route of administration;

3. For all other brachytherapy:

   - Prior to implantation: the radioisotope, number of sources, and source strengths; and

   - After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength, and exposure time [or, equivalently, the total dose].

Recordable event means the administration of;

1. A radiopharmaceutical or radiation without a written directive where a written directive is required;

2. A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record.

3. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodine I-125 or I-131 <u>where both</u>:

   - The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

   - The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;

4. The therapeutic radiopharmaceutical dosage, other than sodium iodine I-125 or I-131, where the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

5. The brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

Procedures:

1. Prior to administration, a written directive must be prepared, dated, and signed by an authorized user for:

   - Any brachytherapy radiation dose,
   - Any administration of quantities greater than 30 microcuries of either sodium iodine I-125 or I-131; or
   - Any therapeutic administration of a radiopharmaceutical, other than sodium iodine I-125 or I-131.

   If, because of patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and revised written directive is signed by the authorized user within 48 hours of the oral revision.

   Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.

   If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

2. Prior to each administration, the patient's identity must be verified as the individual named in the written directive by more than one method. This may be done by asking the patient's name and confirming it, and by at least one of the following methods; comparison with corresponding information in the patient's record: birth date, address, social security number, or signature; comparison with the name on the Patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, or a photograph taken of the patient's face for ID purposes.

3. The final plans of treatment and related calculations for brachytherapy must be reviewed by the authorized user or a qualified person under the supervision of the authorized user to ensure that they are in accordance with the respective written directive.

   Computer-generated dose calculations will be checked by examining the computer printout to verify that the correct data for the patient were used in the calculation including the position applicator or sealed sources, the number of sources, total source strength, or source loading sequence.

4. Prior to each administration, it shall be verified that the administration is in accordance with the written directive.

In the case of radiopharmaceutical, the radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical. The dosage should be measured in the dose calibrator and the result compared with the prescribed dosage in the written directive.

In the case of brachytherapy dose, the authorized user or qualified person under the supervision of the authorized user shall verify that the radioisotope, number of sources, source strength(s) to be used are in agreement with the written directive and plan of treatment before implanting the radioactive sealed sources.

For temporary brachytherapy implants, radiographs or other comparable images of fixed geometry applicators, brachytherapy radioactive sources or nonradioactive "dummy" sources in place shall serve as the basis for verifying the position of the sources and calculating the exposure time or total dose. Except in the case of fixed geometry applicator, non-radioactive "dummy" sources will be used, whenever possible, before inserting the radioactive sources.

5. All unintended deviations from a written directive must be identified and evaluated, and appropriate actions taken, (see misadministration and recordable events).

6. If at any time a worker needs guidance or is unclear as to how a written directive is to be carried out, they should seek advise from the authorized user rather than continuing with a procedure.

7. Immediately after administration, the authorized user or a qualified person under the supervision of the authorized user, shall:

   - In the case of radiopharmaceuticals, make, date, and sign or initial a written record that documents the administered dosage in the patient's chart or other appropriate record.

   - In the case of brachytherapy, the authorized user or qualified person under the supervision of the authorized user, make, date, and sign or initial a written record that documents the radionuclide, treatment site, total source strength, and exposure time (or, equivalently, the total dose) in the patient's chart or other appropriate record.

8. An annual review of the Quality Management Program will be performed by the Radiation Safety Officer (RSO) or his designee. The RSO or designee should not review their own work independently. If this is not possible, they should review the program with another person as a team. The review should include an evaluation of:

   - A representative sample of patient administrations based on 10% table of lot tolerance percent defects in 10 CFR 32.110 (b)(8).

   - All recordable events, and

   - All misadministrations to verify compliance with all aspects of the Quality Management Program.

   - For each case reviewed, the reviewer(s) should determine whether the administered radionuclide dosage was in accordance with the written directive.

     - If during the review, any previously unidentified misadministrations or recordable events are discovered, the representative sample of patients will be expanded to the 5% level. If an additional unidentified misadministrations or recordable events are discovered, all cases shall be reviewed.

- A representative sample of patient administrations based on the table of lot tolerance percent defects in 10 CFR 32.110 (b)(8),

Number of Written Directives	Sample Size 10%	5%
1 to 25	All	All
26 to 50	17	30
51 to 100	20	37
101 to 200	22	40
201 to 800	23	45

A record of each review, including the evaluations and findings of the review, will be reported to be the Radiation Safety Committee and will be kept in an auditable form for three years. The report should identify deviations from the written directive, the cause of each deviation, and the action(s) required to prevent recurrence. The action(s) may include new or revised policies, new or revised procedures, additional training, or increased supervisory review of work.

Each of these reviews will be evaluated by the Radiation Safety Committee to determine the effectiveness of the Quality Management Program and, if required, the committee will make modifications to meet the objectives of the program.

If modifications are made to the program, a copy of the modified program must be submitted to the regional NRC office within 30 days.

9. ***Recordable events,*** within 30 days after the discovery of a recordable event, the Radiation Safety Officer shall:

   - Assemble the relevant facts including the causes;

   - Identify what, if any, corrective action is required to prevent recurrence; and

   - Make an auditable record of the relevant facts and what corrective action, if any, was taken.

10. ***Misadministration,*** the Radiation Safety Officer or his designee will immediately follow the steps outlined in 10 CFR 35.33 and make all appropriate reports and notification as well as advising administration of the incident.

11. ***Record Retention,*** each written directive, a record of each administered radiation dose and a record of each administered radiopharmaceutical dosage shall be retained for three years after the date of administration.

12. ***Acceptance Testing,*** will be performed before the first use of treatment planning or dose calculating computer program for brachytherapy dose calculations.

Effective Date of Implementation:
June 29, 1993 (CMC) October 5, 1994 JWH; Combined and Revised January 10, 1996.

Lenna B. Deletis, CNMT
Radiation Safety Officer
Chippenham Medical Center/Johnston-Willis Hospital

1/15/96
Date

Marilyn B. Tavenner, CEO

1/17/96
Date