

**MEDICAL
RADIATION SAFETY
PROCEDURES
MANUAL**



2007 EDITION

HOW TO USE THIS MANUAL

Applications for medical radioactive material licenses must include a written set of radiation safety procedures which describe how the applicant plans to comply with pertinent rules regarding radiation protection. The procedure manual must be written in the form of instructions from management to all personnel involved in the use of radioactive material, and should include instructions for the management of patients containing therapeutic quantities of radioactive material. The manual actually becomes a policy of the institution, and is submitted with the application for review only.

Writing a radiation safety manual for nuclear medicine to cover all aspects of radiation protection can become an involved project, particularly for someone who has not attempted to write such a document before.

It is the purpose of this manual to provide assistance in this area. This manual is considered by the Alabama Office of Radiation Control to represent a set of radiation safety procedures which would be acceptable for the issuance of a radioactive material license. It is important to understand that variation of procedures described in this manual may also be considered. This manual simply represents one method which is adequate and addresses all areas of the Alabama Office of Radiation Control's "Guide for the Preparation of Applications for Licenses for Medical Programs."

An institution applying for a radioactive material license, license renewal, or amendment of their current procedures, may use this manual in the following ways:

1. The manual may be used as a guide by the applicant in preparing nuclear medicine radiation safety procedures. The applicant would write radiation safety procedures and submit them for review by the Agency.
2. The applicant may choose to adopt certain parts of this manual, and write new procedures for parts not adopted. The applicant must submit a radiation safety manual which includes adopted parts of the manual and applicant written parts, for review by the Agency.
3. The applicant may choose to adopt this manual, as written, as their institution's radiation safety requirements. The applicant should adopt only those sections of the manual that are appropriate to their nuclear medicine program. For example, if no sealed source therapy procedures are performed, Section XII should not be adopted.

To adopt this manual, the applicant must submit a copy of the signed and dated Administrator's Statement page, and a statement regarding sections of the manual that are not adopted (as appropriate to the program). In addition, copies of the following pages of the manual must be completed and submitted with the application:

1. Page 6 of Section I
2. Page 4 of Section II
3. Page 2 of Section V
4. Page 1 of Section VI
5. Page 1 of Section XVI

NOTE: Other information is required on the application form (Form RM), and must also be submitted.

RADIATION SAFETY PROCEDURES
MANUAL FOR NUCLEAR MEDICINE
FOR (Name of Institution)

Compiled by: Office of Radiation Control
Licensing Branch
Alabama Department of Public Health
Montgomery, Alabama

with

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ADMINISTRATOR'S STATEMENT

This institution has been granted a license to possess and use radioactive material for the detection and treatment of diseases in patients.

State Board of Health Rules for Radiation Control govern the use of radioactive material in Alabama. This manual establishes specific procedures to be followed by all individuals in this institution to assure that our radiation safety program complies with State Board of Health Rules. It is also very important to understand that these rules were established primarily to protect all persons health and safety. PROCEDURES IN THIS MANUAL SHALL BE FOLLOWED. Following these procedures is the responsibility of all persons in this institution.

Procedures described in this manual are made a part of the conditions on our radioactive material license. Procedures cannot be changed without prior approval of the Alabama Office of Radiation Control. Violation of these procedures constitutes a violation of our radioactive material license and established radiation safety procedures of this institution.

If you do not understand any requirements outlined in this manual or conditions of our radioactive material license, assistance can be obtained by contacting our Radiation Safety Officer, _____, the Chairman of our Radiation Safety Committee, _____, or the Alabama Department of Public Health, Office of Radiation Control, P.O. Box 303017, Montgomery, Alabama 36130-3017. (Phone 334-206-5391).

Date

Signature of Administrator

Date

Signature of Chairman of RSC

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I. PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE AS LOW AS REASONABLY ACHIEVABLE (ALARA).

A. Management Commitment

1. We, the management of this medical facility, are committed to the program described in this manual 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 instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).
2. 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 and/or outside consultants.
3. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgement, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
4. 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.

B. Radiation Safety Committee

1. Review of Proposed Users and Uses
 - (a) 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.
 - (b) When considering a new use of radioactive material, the RSC will

review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and should have incorporated the use of special equipment such as syringe shields and rubber gloves in the proposed use.

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

2. Delegation of Authority

- (a) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

3. Review of ALARA Program

- (a) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- (b) At each meeting, the RSC will perform a 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.
- (c) 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.

C. Radiation Safety Officer

1. Annual and Quarterly Review

- (a) 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.
- (b) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph F of this section and will prepare a summary report for the RSC.

(c) 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.

2. Education Responsibilities for ALARA Program

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

(b) 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.

3. 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.

(a) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(b) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for the improving health physics practices and will encourage use of those procedures.

4. 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.

D. Authorized Users

1. New Methods of Use Involving Potential Radiation Exposures

(a) 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.

(b) 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.

2. Authorized User's Responsibility to Supervised Individuals

- (a) The authorizer user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
- (b) 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.
- (c) Unless physical presence as described in Rule 420-3-26-.07 is required, the authorized user shall be immediately available (by telephone within 10 minutes) to communicate with the supervised individual, and be able to be physically present within one hour of notification.

E. Individuals Who Receive Occupational Radiation Exposure

- 1. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.
- 2. Workers will know what recourse is available if they feel that ALARA is not being promoted on the job.

Table 1 Investigation Levels
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	5675

F. 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 results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigational levels as stated in Table 1:

1. Quarterly dose of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

2. Personnel doses 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, consider 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.

3. Exposure 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 and any actions taken will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. Committee minutes will be sent to the management of this institution for review. The minutes containing details of the investigation will be made available to State inspectors for review at the time of the next inspection.

4. Reestablishment Investigational of an individual occupational worker's 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 F.3. above will be followed.1-5

G. Signature of Hospital Administrator

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

Signature (Hospital Administrator)

Name (Print or Type)

II. RADIATION SAFETY COMMITTEE

In compliance with Rule 420-3-26-.07(19)(f) this organization has appointed a Radiation Safety Committee.

A. Charge. The Committee shall:

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facilities, supplies, and procedures;
2. Ensure that licensed material is used in compliance with State rules and the institutional license;
3. Ensure that the use of licensed material is consistent with "as low as reasonably achievable" (ALARA) philosophy program;
4. Identify program problems and solutions.

B. Responsibilities. The Committee shall:

1. Be familiar with all pertinent State of Alabama rules, the license application, the license, and amendments;
2. Review the training and experience of the proposed authorized users, authorized medical physicists and the Radiation Safety Officer (RSO) to determine that their qualifications meet the requirements of Rule 420-3-26-.07 and the license, and are sufficient to enable the individuals to perform their duties safely;
3. Review on the basis of safety and approve or deny, consistent with the limitations of the radiation protection rules, the license, and the ALARA philosophy, all requests for authorization to use radioactive material under the conditions of the license;
4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures;
5. At each meeting review the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposures appear excessive;
6. Establish a program to ensure that all individuals whose duties may require them to work in or frequent areas where radioactive materials are used (e.g.,

nursing, security, housekeeping, physical plant) are appropriately instructed as required in Rule 420-3-26-.10(3);

7. At each meeting review, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;
8. Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer;
9. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with State of Alabama rules and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of State inspections, written safety procedures, and the adequacy of the management control system;
10. Recommend remedial action to correct any deficiencies identified in the radiation safety program; and
11. Ensure that the radioactive material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.
12. The Committee shall approve all visiting authorized users. The Committee, prior to giving written approval should ascertain:
 - a. That the visiting authorized user is authorized to practice medicine pursuant to an Alabama radioactive license. Do not accept licensure by another state or the U.S. Nuclear Regulatory Commission.
 - b. That the visiting authorized user understands that he may perform only those procedures which he is authorized to perform pursuant to the radioactive material license authorizing him to use radionuclides in nuclear medicine procedures and which also appears on this institution's radioactive material license.
 - c. That the visiting authorized user is not establishing a full time practice at this institution but is likely to conduct nuclear medicine procedures at this institution for less than sixty (60) days per calendar year.
 - d. That at least one (1) physician authorized by the radioactive material license issued to this institution continues to be engaged in the regular practice of nuclear medicine at this institution.

NOTE: Prior to conducting nuclear medicine procedures in the hospital, the visiting physician must also have the written approval of this institution's administrator. Copies of these approvals must be maintained by the Committee and be available for review.

C. Administrative Information

1. The Committee shall meet as often as necessary to conduct its business but shall meet at intervals not to exceed six (6) months.
2. Membership must include an authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service (if applicable), and a representative of management who is neither an authorized user nor a RSO. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing as adjunct members representatives from security, physical plant, housekeeping, and other departments. (Adjunct members should abstain from balloting on purely technical questions such as Items 2 through 5 in the "Responsibilities" section above.)
3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.
4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.
5. The minutes of each Radiation Safety Committee meeting shall include:
 - (i) The date of the meeting;
 - (ii) Members present;
 - (iii) Members absent;
 - (iv) Summary of deliberations and discussions;
6. The Committee shall provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

D. Committee Membership

Specialty	Representative	Date Appointed
Radiation Safety Officer		
Management		
Nursing		

III. RADIATION SAFETY OFFICER

In compliance with the Rules of the State Board of Health, Radiation Control, this institution has appointed a Radiation Safety Officer.

A. Charge. The Radiation Safety Officer shall:

1. Implement the radiation safety program, and ensure that radiation safety activities are performed in accordance with approved procedures and regulatory requirements in the daily operation of the radioactive material program.

B. Responsibilities. The Radiation Safety Officer shall:

1. Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, misadministrations, transfers, disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary.
2. Implement the written policy and procedures for:
 - a. Authorizing the purchase of radioactive material;
 - b. Receiving and opening packages of radioactive material;
 - c. Storing radioactive material;
 - d. Keeping an inventory record of radioactive material;
 - e. Using radioactive material safely;
 - f. Taking emergency action if control of radioactive materia] is lost;
 - g. Performing radiation surveys;
 - h. Performing checks of survey instruments and other safety equipment;
 - i. Disposing of radioactive material;
 - j. Training personnel who work in or frequent areas where radioactive material is used or stored; and
 - k. Keeping a copy of all records and reports required by the written procedures and Agency rules, a current copy of the Agency rules, a copy of each licensing request, licenses and amendments, and the

written policy and procedures required by the rules.

3. When a Radiation Safety Committee exists, assist the Committee in the performance of its duties.
4. When a Radiation Safety Committee is not required, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the Agency for licensing action.

IV. PHYSICIAN-TECHNICIAN RESPONSIBILITIES

All orders authorizing the administration of radioactive material dosages, or radiation from radioactive materials shall be by an authorized user whose name appears on this institution's radioactive material license, and shall be in writing.

If, because of the emergent nature of the patient's condition, a delay in providing a written order would jeopardize the patient's health, an oral order will be acceptable, provided that the information contained in the oral order is documented as soon as possible in writing in the patient's record and a written order is prepared within 48 hours of the oral order.

The responsibility for nuclear medicine procedures may not be delegated to nuclear technologists or other physicians.

A. Trained technicians are permitted to:

1. standardize the radiopharmaceutical dosage prior to administration;
2. administer the material to the patient; and
3. calibrate and use counting equipment or other radiation measuring instruments to obtain necessary data for the responsible authorized user.

B. The responsibilities of the authorized user are to include:

1. Select patients to receive radioactive material dosages, or radiation from radioactive material;
2. prescribe the type of radionuclide and dosage and/or dose to be administered through issuance of a written directive, written reference to the diagnostic clinical procedures manual or a written prescription;
3. direct the administration of radiopharmaceuticals or radioactive material; and
4. interpret the results of the tests, studies or treatments.

C. Approval of the conduct of each procedure involving radioactive material must be based on an authorized user doing one or more of the following:

1. examining the patient; or
2. reviewing the patient's clinical history; or
3. discussing the patient's clinical condition with the referring physician.

In all cases, approval of an authorized user is required prior to conduct of tests, studies or treatments involving radioactive material.

V. TRAINING REQUIREMENTS

Rule 420-3-26-.10(3) establishes minimum requirements regarding the instruction to be given all individuals working in or frequenting any portion of a restricted area. Such individuals may be technicians, physicians, nurses, aides, custodial staff, security, students, or others.

All individuals who elute generators, prepare radiopharmaceuticals from kits, prepare dosages, inject dosages or administer doses to patients, prepare brachytherapy applicators, and/or load and remove such applicators, or operate radiation therapy devices shall receive instruction from the Radiation Safety Officer.

A. Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

B. Instruction for individuals in attendance will include the following subjects:

1. Applicable rules and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the individuals will work.
4. Appropriate radiation safety procedures.
5. This institution'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. 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 Rule

420-3-26-.10(2).

C. Instructions for custodial personnel working in nuclear medicine and departments using radioactive material.

1. Personnel will be permitted to clean the floors, restroom, etc., usual unless instructed otherwise by the Radiation Safety Officer.
2. Never handle anything labeled "Radioactive Material."
3. Never reach behind lead shielding or into hoods to do any cleaning.
4. All trash cans and linen containers unless they are labeled "Radioactive." labeled "Radioactive." may be emptied as usual Do not empty trash cans
5. In the case of any hazardous areas that you should avoid, your supervisor will be notified by the Radiation Safety Officer who will issue any special instructions necessary.
6. Never leave the Nuclear Medicine Laboratory or other Departments unlocked after you finish cleaning.
7. In case of any emergency or questions, notify the Radiation Safety Officer. Any spillage of material labeled radioactive should be reported immediately to the Radiation Safety Officer. Follow his instructions carefully until he arrives in the Department.
8. The Radiation Safety Officer is _____. His/her office phone number is _____. His/her home number is _____. If you cannot contact the RSO, call _____ at _____.

D. Nursing personnel instructions are discussed in Sections XI and XII of this manual.

E. Physicians wishing to use radioactive material in the diagnosis and/or treatment of diseases in patients must meet the training and experience requirements of Appendix B of this manual.

F. Physicists wishing to use radioactive material to perform authorized medical physicist duties as specified in Rule 420-3-26-.07 must meet the training and experience requirements of Appendix C of this manual.

VI. PROCEDURES FOR ORDERING RADIOACTIVE MATERIAL, FOR RECEIPT OF MATERIALS DURING NORMAL DUTY AND OFF-DUTY HOURS, AND FOR NOTIFICATION OF RESPONSIBLE PERSONS UPON RECEIPT OF MATERIALS.

A. Ordering Procedures

The possession and use of radioactive material is authorized by a license issued by the State Department of Public Health. This license specifies the radioactive material, the chemical form, and the maximum quantity that can be possessed at any one time. The license also specifies the authorized uses of each radioactive material listed on the license.

A copy of the license will be kept in all departments using radioactive material within this institution.

No radioactive material will be ordered unless it meets the following conditions:

1. The radioactive material appears on the license; and,
2. The department that is ordering the material has been approved to use the material by the Radiation Safety Committee.

B. Receipt During Normal Duty Hours

All deliveries of radioactive material during normal working hours are made directly to the Department of Nuclear Medicine or other Departments which ordered the material. Upon receipt of material, packages are checked in accordance with Section VII of this manual, "Instructions for Safely Opening Packages, to comply with Rule 420-3-26-.03(32)."

C. Receipt During Off-Duty Hours

During off-duty hours radioactive material will be received by the Security Department. Security personnel will look at the outside of the package to determine if the package is damaged or leaking. If any package appears to be damaged, wet, or leaking, Security shall immediately notify the Radiation Safety Officer,

_____	_____
Name	Phone
_____	_____
Name	Phone

(An alternate should also be named in case the RSO cannot be located).

If the packages do not appear to be leaking or damaged, Security personnel shall transport the package to the appropriate department. The package shall be left in the department. Doors to the department must be locked. Personnel of the department shall survey package(s) for possible contamination in accordance with Section VII of this manual as soon as practicable. A copy of these instructions (VI.C.) must be made available to Security personnel by the Radiation Safety Officer.

VII. INSTRUCTIONS FOR SAFETY OPENING PACKAGES TO COMPLY WITH RULE 420-3-26-.03(32).

Certain packages must be surveyed for radiation levels and contamination of external surfaces within a specified time after receipt (see Rule 420-3-26-.03(32)(c). Rule 420-3-26-.03(32)(e) requires that procedures be established for safely opening packages of all licensed material with no exceptions. The procedures given below are to be followed for complying with Rule 420-3-26-.03(32) (e).

A. General Set-Up

1. Packages shall be delivered to the Department of Nuclear Medicine or to the department that ordered the material where personnel are knowledgeable in safe handling. Establish a specific location within the lab for receipt and inspection. Treat as contaminated until proven otherwise, especially if damaged. Place package on surface covered with absorbent material for surveying. Inspect packages as soon as possible after receipt, but under no condition later than times specified in B.3. below.
2. Before handling packages perform surveys as required by Items B.4. and B.S. below. Such surveys will alert personnel to the intensity of the radiation field in which they are working.
3. Make a record of results. Pass the record on to the final user to alert him to the condition of the shipment. This record is also useful in communication with the vendor in case of problems. (receipt form is on page 3)
4. For the protection of the surveyor and to minimize the spread of contamination, plastic or other protective gloves and lab coats shall be worn when opening packages .
5. If the manufacturer's directions for opening or unpacking radioactive material are provided, follow those directions in addition to those in this procedure.
6. Packages containing radioactive material with associated high exposure levels may require that some or all of the following steps be performed behind a radiation shield and/or using other appropriate safety measures.

B. Procedures for Package Inspection

1. Receive in prepared, protected place.
2. Look for mechanical damage or wetness.
3. Inspect packages within:

- a. three (3) hours if received during normal working hours;
 - b. three (3) hours for the beginning of the next working day if received after normal working hours.
4. Measure exposure rate at 1 meter from package surface with a thin end window meter before handling or opening package.
 - a. If the exposure rate is 10 mR/hr or greater--proceed with caution--expedite notification.
 5. Measure surface exposure rate and record.
 - a. If the surface exposure rate is 200 mR/hr or greater--proceed with caution--expedite notification¹.
 6. Observe outer package for leakage stains.
 - a. If stains are present--wipe a 100 cm² area with dry wipe and assay--record.
 - b. If wipe has radiation levels above background--proceed with caution. If greater than three times background expedite notification.² Assay wipe with low level GM survey meter, with beta shield removed, in an area away from all sources.
 7. If outer package is not contaminated, open the outer package and remove the packing slip. Open inner package to verify contents (compare requisition packing slips, label on bottle) and integrity of final source container (inspect for breakage of seals or vials, loss of liquid, discoloration of packing material). Check also that shipment does not exceed possession limits.
 8. Wipe external surface of final source container with moistened cotton swab or filter paper held with forceps and assay with low level GM survey meter as in 6.b. above. Take action as in 6.b. above.
 9. Monitor the packing material and packages with GM survey meter for contamination before discarding:
 - a. If contaminated, treat as radioactive waste.

¹Notify immediately:

- a. The public carrier that delivered the package.
- b. Alabama Office of Radiation Control 334-206-5391

- b. If not, obliterate radiation labels before discarding in regular trash.

VIII. GENERAL INSTRUCTIONS

A. Permission to Use Radioactive Material

Permission to use radioactive materials shall be obtained in the following manner:

1. The application or proposal is submitted to the Radiation Safety Officer or the Radiation Safety Committee, as appropriate, for review and approval.
2. Upon approval of the Radiation Safety Officer and/or the Committee, the application is forwarded to the State Department of Public Health, Office of Radiation Control for evaluation and approval.
3. Use of radioactive material is authorized only when approved by the Office of Radiation Control.
4. Note that all applications for amendments must be signed by the licensee's Administrator or his designee.

B. Laboratory Apparel

Lab coats and disposal gloves shall be worn during all procedures involving the receipt of packages, opening and surveying of packages, elution of generators, preparation of doses, preparation and administrations of radiopharmaceuticals and waste disposal operations. Radioactive material should be used on nonporous surfaces which are covered with absorbent disposable material.

Lab coats, gloves, hands, and shoes shall be monitored prior to leaving the Department. Frequent monitoring during the day is advisable.

C. Use of Shielding and Remote Handling Equipment

All physicians and technicians shall use syringe shields, vial shields, and tongs, when applicable, while preparing and/or administering radiopharmaceuticals. In addition, patient dosages shall be prepared behind protective barriers.

D. Radiopharmaceutical Kit Preparation

Manufacturer's directions shall be followed for preparation and use of radiopharmaceuticals from kits. Syringe shields, vial shields, and any accessories recommended by the manufacturer shall be used.

Occasionally technetium 99m does not tag or bind properly to the material contained in the kit. When this occurs, a certain percentage of the prepared radiopharmaceutical is free or unbound pertechnetate. Use of this material results in unnecessary exposure to certain

organs of the body which may be outside of the physician's clinical interest area. To avoid as much unnecessary exposure as practicable, proper tagging of technetium 99m to contents of kits shall be checked on each batch (even if for only one dose) prepared using radiochromatography methods.

E. Elution of Generators and Procedures for Checking for Molybdenum 99 Breakthrough

All generators shall be eluted in accordance with the manufacturer's directions. The manufacturer's directions will be followed for determining molybdenum 99 concentrations in the eluate after each elution. If manufacturer's directions are not included with the generator, a radiometric molybdenum test will be performed. This procedure is based upon the principle that most of the 140 keV radiations from technetium 99m can be shielded with lead allowing only the more energetic 740 and 780 keV molybdenum 99 gamma rays to be counted. Radiometric molybdenum tests shall be performed in the following manner after each generator elution:

1. Peak the dose calibrator to the 600-900 keV range (Mo-99 range) using a known activity cesium 137 source.
2. Determine background in cpm (counts per minute).
3. Place the vial containing the extracted technetium 99m in a suitable lead container.
4. Determine activity in counts per minute by placing the container with technetium 99m in the well of the dose calibrator, subtract background counts.
5. By placing the cesium 137 standard in the same lead shield that the technetium 99m was in, determine activity in cpm of a cesium 137 standard utilizing the same geometry. Subtract background.
6. Calculate the molybdenum background using the formula.

$$\text{uCi Mo-99} = \frac{\text{uCi Cs-137 Standard} \times \text{Net cpm Unknown (Value from Step 4)}}{\text{net cpm Cs-137 Standard (Value from Step 5)}}$$

The eluate will not be used if the molybdenum 99 activity exceeds 0.15 microcurie (5.55 kBq) of molybdenum 99 per millicurie (MBq) of technetium 99m. There are no exceptions to this rule.

A record of each breakthrough test must be maintained for 5 years. The record shall include, for each elution or extraction of technetium 99m:

- a. The measured activity of the technetium expressed in mCi;
- b. The measured activity of the molybdenum expressed in uCi;
- c. The ratio of the measures expressed as uCi of molybdenum per mCi of technetium;
- d. The date and time of the test, and
- e. The initials of the individual who performed the test.

If the molybdenum 99 activity exceeds 0.15 microcurie of molybdenum 99 per millicurie of technetium 99m, the Alabama Division of Radiation Control will be notified immediately.

F. Movement of Material Between Rooms, Halls, or in Corridors

Any radioactive material which is transported or moved between rooms, in halls, or in corridors shall be placed in a container which provides adequate shielding as described in Rule 420-3-26-.03(14) and labeling as described in 420-3-26-.03(30).

The container shall not be left unattended. Transportation of such containers shall be made by individuals having received instruction regarding proper transport requirements. The Radiation Safety Officer shall provide the required instructions. The movement shall be made as rapidly as practicable without unnecessary delays.

G. Storage of Materials, Labeling of Containers, and Identification of Areas Where Radioactive Materials Are Used

1. All radioactive material shall be stored behind lead bricks or lead shielding and/or in lead protected containers. The adequacy of shielding provided by lead bricks and containers can be determined by procedures described in Section IX of this manual, "Method and Frequency of Conducting Surveys."

Rooms containing radioactive material shall be locked when left unattended.

2. Labeling of Containers

Rule 420-3-26-.03(30) establishes the requirements for labeling of containers. In general (advisable in all cases) each container shall be labeled with the radiation symbol and the words "CAUTION: RADIOACTIVE MATERIAL", the type of material contained therein (i.e., I-131, Tc-99m, sulfur colloid, etc.), activity, and

date of measurement. This includes elution vials, calibration standards, preparation vials, etc.

3. Identification of Areas Where Radioactive Materials Are Used

Unless otherwise specified, the entrance(s) to each room containing radioactive material shall be posted with a sign bearing the radiation symbol and the words "CAUTION: RADIOACTIVE MATERIAL". The storage area shall also be posted with a sign bearing the radiation symbol and the words "CAUTION: RADIOACTIVE MATERIAL".

Refrigerators containing radioactive material shall be labeled with a sign bearing the radiation symbol and the words "CAUTION: RADIOACTIVE MATERIAL"-
-"STORAGE OF FOOD AND DRINK PROHIBITED".

The "hot waste" sink drain shall be labeled "CAUTION: RADIOACTIVE MATERIAL" to advise plumbers of possible contamination problems. This sign should also advise the plumbers to contact the Radiation Safety Officer prior to working on the sink.

H. Personnel Monitoring Requirements

Requirements for personnel monitoring are addressed in Rule 420-3-26-.03(18). When handling sources of radiation: (1) exposure to the whole body, (2) head and trunk, (3) active blood forming organs, (4) lens of eyes, (5) gonads, and (6) the hands are of most concern.

Each individual using sources of ionizing radiation (eluting generators, preparing doses, preparing radiopharmaceuticals from kits, administering radiopharmaceuticals, loading applicators, inserting sealed sources into patients, and removing sealed sources from patients, etc.) shall wear both whole body and extremity dosimetry. If a dosimeter is lost, misplaced or damaged the individual must stop work immediately and report the situation to the Radiation Safety Officer. Dosimetry must be replaced prior to continuing work. Personal dosimeters are to be distributed and collected by the Radiation Safety Officer. He shall also review reports from the service company for excessive and abnormal exposures in accordance with Section I of this manual. Rule 420-3-26-.03(6) establishes exposure limits; however, Rule 420-3-26-.03(5)(b) (ALARA) shall be applied in evaluating all exposure results in accordance with Section I of this manual.

A copy of the service company report shall be made available for each individual assigned a personnel monitoring device to review. Remember, a personnel monitoring device indicates to the individual how much exposure he or she received. Dosimeters must be worn properly. (Instructions shall be given by the Radiation Safety Officer regarding the proper way to wear dosimeters and the frequency of exchange of dosimeters.)

We are required to report overexposures [Rule 420-3-26-.03(53)] to the Alabama Office of Radiation Control and to the overexposed individual. Requirements for these reports are contained in Rule 420-3-26-.03(53) and Rule 420-3-26-.10(4).

I. Restrictions

Radiation exposure can occur in two ways in a laboratory where radioactive materials are used. First, exposure may result from a source of radiation being outside the body--commonly called external exposure. Second, radioactive material may enter the body in many ways--cuts and abrasions, inhalation, through the skin, accidental injections, and by mouth. This is commonly referred to as internal exposure.

We can detect and shield sources of radiation when they are outside the body and move away from them for protection. However, we may be totally unaware of minute quantities of material on hands, countertops, pencils, note books, refrigerator door handles, etc.

For this reason the following rule shall be observed by each individual working in areas where radioactive material is being stored and/or used;

Smoking, eating, drinking, or applying of cosmetics will not be permitted in restricted areas. Further, refrigerators used to store radioactive materials will not be used to store food or drink. Wash your hands prior to leaving the restricted area.

J. Waste Disposal Procedures

Radioactive waste will be generated in the form of used vials, syringes, needles, cotton, paper, test samples, old generators, unused radioactive material, etc. Many methods of waste disposal are discussed in Rules 420-3-26-.03(34), (35), (36), (37), (38), and 420-3-26-.07(44). (It is also important to refer to Rule 420-3-26-.03(5)(b) when choosing the method to be used.)

Most radioactive materials used in nuclear medicine procedures have relatively short half-lives. Storage of a large percentage of waste for a period of two to four weeks reduces the total activity greatly. Decay presents the most logical method of waste disposal for most medical users today.

1. Long lived material:

Material with a half-life greater than 120 days must be transferred to a burial site for proper disposal. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

2. Certain in vitro test kits:

Waste from in vitro test kits that are generally licensed pursuant to Rule 420-3-26-.02(7)(h) is exempt from waste disposal regulations. Radioactive labels shall be defaced or removed prior to disposal in all cases.

3. Short-lived material:

Short-lived material (physical half-life less than 120 days) may be disposed of by decay in storage.

Radioactive waste to be held for decay in storage shall be separated and placed into at least two separate containers according to half-life. One container shall contain only wastes with a half-life of less than 30 hours, such as technetium 99m and iodine 123. This container shall be used for disposing waste for a two-week period. At the end of this period the container shall be set aside and not used for the next two weeks while a second container is being used. After the container has not been used for a two-week period the contents shall be surveyed with a low range GM survey meter, with the beta shield removed.

If radiation levels do not exceed background levels, the contents can be disposed of as normal hospital waste. If radiation levels exceed background, store for further decay. By using two containers for short-lived material, waste should not be accumulated and stored for more than a four-week period. This should account for the majority of waste generated. All radioactive labels shall be defaced or removed prior to disposal in all cases.

4. Longer lived material:

Radioactive waste with a half-life greater than 30 hours but less than 65 days shall be placed in a separate waste container. When full or otherwise desired, this container shall be set aside in an appropriately shielded and placarded area and allowed to decay for a minimum of the (10) half-lives of the longest lived isotope in the container. (Ex. iodine 125 held for 600 days). An empty container is used to replace this container. After the proper time interval the container shall be surveyed in the same manner as described for short-lived material above. Criteria for disposal is the same. In all cases, all radioactive labels shall be defaced or removed prior to disposal.

5. Used generators:

Generators shall be held for 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a low-range GM survey meter at the work area. Dismantle the oldest generator first then work forward chronologically. Hold each individual column

in contact with a low-level survey instrument in a low-background (less than 0.05 mR/hr) area. Do not dispose if radiation levels exceed background.

Remove or deface the radiation labels on the generator shield.

Generators may also be returned to the supplier as per supplier instructions.

CAUTION: BE SURE THAT WASTE CONTAINERS ARE PROPERLY LABELED AND IDENTIFIED.

CAUTION: SHIELDING MATERIAL FROM SYRINGES, VIALS, ETC., SHALL BE REMOVED PRIOR TO WASTE BEING PLACED IN CONTAINERS.

6. Records for radioactive waste decayed in storage will be maintained for 3 years and will include:
 - a. The date of disposal,
 - b. The date on which the radioactive material was placed in storage,
 - c. The model and serial number of the survey instrument used,
 - d. The background radiation level,
 - e. The radiation dose rate measured at the surface of each waste container, and
 - f. The name of the individual who performed the disposal.

K. Procedures For Controlling Spills

1. Minor Spills

- a. Notify persons in the area that a spill has occurred.
- b. Prevent the spread of contamination by covering the spill with absorbent paper.
- c. Wearing disposable gloves and using absorbent paper, clean the spill working from the areas of least contamination towards the areas that are most contaminated. 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.

- d. Survey the area with a low-range GM survey meter. Check the area around the spill. Also check your hands, clothing and shoes for contamination.
- e. Report the incident to the Radiation Safety Officer (RSO).

2. Major Spills

- a. Clear the area. Notify all persons not involved in the spill to vacate the room.
- b. 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.
- c. Shield the material if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
- d. Close the room and lock or otherwise secure the area to prevent entry.
- e. Notify the RSO immediately.
- f. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarr 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.
- g. The RSO will supervise the cleanup of the spill.

IX. RULES AND PROCEDURES TO BE FOLLOWED TO ENSURE SAFE USE OF RADIOACTIVE MATERIAL

The purpose of these procedures are to provide a safe working environment for laboratory personnel, ensure public safety, and avoid contamination of equipment and facilities.

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.
4. Use syringe shields for routine preparation of patient dosages and administration to patients, except in those circumstances in which such 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 personal dosimetry devices at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the Radiation Safety Officer.
8. Wear an extremity dosimetry during the elution of generators; and during the preparation, assay, and injection of radiopharmaceuticals.
9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
10. Never pipette by mouth.
11. With a low-range GM survey meter, survey the kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.
12. Wipe-test radioactive materials storage, preparation and administration areas daily for contamination. If necessary, decontaminate or secure the area for decay.

13. Confine radioactive solutions in shielded containers that clearly are labeled. Radiopharmaceutical multi-dose diagnostic vials and therapy vials shall be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book shall be used to record the preceding information and total prepared activity, specific activity as mCi/cc (or MBq/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 not intended for immediate use shall 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 differs by more than 20% from the prescribed dosage. 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 or wheelchair to move flood sources, syringes, waste, and other radioactive material.

X. METHODS AND FREQUENCY FOR CONDUCTING SURVEYS

Often the question arises, how frequently should surveys be performed and how should they be made? It is important to first realize the purposes of surveys. Basically two reasons exist for making surveys.

First, surveys are made to inform workers in restricted areas of the conditions under which they are required to work. This in turn relates directly to their personal safety for without surveys they may handle contaminated objects, etc. These may then provide a route for radioactive material entering employees' bodies as well as being carried throughout the institution and employees' homes.

Second, contamination and high radiation levels can interfere with the quality of the results obtained from patient studies. It can also cause the entire department to be shut down for decontamination. This can be an extensive period of time particularly if cameras and scanners become contaminated.

The frequency of surveys should be obvious. The possibility of contamination exists every time radioactive material is handled in the department regardless of how carefully it is handled. Technetium 99m, the isotope most often used, has a half-life of only six (6) hours. A survey made on Tuesday afternoon will not tell you whether or not you had technetium 99m contamination on Monday morning due to the short half-life of technetium 99m.

Based on the need for surveys and the short half-lives of isotopes used being used, this institution's requirements for performing radiation surveys are as follows:

A. Contamination Surveys

A series of wipes shall be taken in all areas where radioactivity is handled in unsealed form. The location where wipes are to be obtained shall be defined by the Radiation Safety Officer on a contamination survey form, copies of which shall be supplied to each department using radioactive material.

Designated areas shall be wiped at least once each working day, preferably following conclusion of the day's greatest activity. A record of each survey shall be retained for 3 years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey and the name of the individual who performed the survey.

As a general rule, contamination is any radiation above normal background levels. It is realized that contamination will occur within the department. It is important that we know when it occurs and take necessary action to prevent its spread. Decontamination procedures shall always be taken when contamination levels are more than twice background levels.

Analysis of the wipes can be made by one of three separate methods listed below in order of priority:

1. Analysis in well counter.
2. Analysis by using camera or scanner.
3. Analysis by using G.M. survey meter with beta shield removed.

In any case, the method of analysis shall be capable of detecting contamination on each wipe sample of 2000 disintegrations per minute.

A G.M. survey meter, with beta shield removed, can be used to locate "hot spots" of contamination. However, care should be used because the survey meter cannot distinguish radiation contamination from stored radioactive material and waste material.

B. Area Surveys

Radiation exposure limits are established for unrestricted and restricted areas within this institution.

An unrestricted area means any area, access to which is not controlled by the licensee for the purposes of protection of individuals from exposure to radiation and radioactive materials, and any area used for residential quarters.

A restricted area means any area to which access is limited by the licensee for purposes of protection of individuals from undue risks from exposure to radiation and radioactive materials.

1. Unrestricted Area Limits

In unrestricted areas personnel must not receive radiation greater than 2 millirem (20 uSv) in anyone hour, or greater than 100 millirem (1 mSv) in a year. Surveys shall be made and recorded at least once each week to assure that radiation levels are within limits defined in Rule 420-3-26-.03(14). In practice, the radiation levels should be kept as low as practicable and always below applicable limits [refer to Rule 420-3-26-.03(S)(b)].

Particular survey emphasis should be placed on areas adjacent to the storage, preparation, generator, and waste disposal areas as the greatest quantity of material will be in these areas.

2. Restricted Area Limits

Personnel working in the restricted area are continually monitored by film badges or TLD's. However, these devices can only advise the wearer of the exposure received. They do not prevent the wearer from receiving exposure. Therefore, at the end of each day of use, meter surveys shall be made in all areas where radioactive drugs were prepared or administered. In addition, at least once each week, meter surveys shall be made of areas where radioactive drugs and/or wastes are stored. A record of all meter surveys will be retained for 3 years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey and the name of the individual who performed the survey. Control of radiation exposure within the restricted area can best be accomplished by shielding radioactive material and using proper techniques in eluting generators, preparing kits, administering dosages, and handling waste. By following proper procedures personnel can reduce the time they are exposed to radiation.

Radiation exposure limits shall be established within the restricted area. Radiation levels in the areas of generator storage and elution, isotope storage area, and waste storage area shall not exceed 5 mrem/hr (50 uSv/hr) at a distance of one (1)

foot from the surface of the areas. When these limits are exceeded, additional shielding material shall be used or the isotopes within the areas shall be re-arranged in order to lower the radiation levels below the action level.

3. Survey Meter Requirements

Unrestricted and restricted area meter surveys shall be made with calibrated instruments capable of detecting radiation energies likely to be encountered and able to measure dose rates as low as 0.1 mrem (1 uSv) per hour. Each survey instrument will be calibrated at intervals not to exceed 1 year. Refer to Section XIII for the survey meter requirements.

XI. PROCEDURES FOR RADIATION SAFETY DURING THERAPEUTIC USE OF RADIOPHARMACEUTICALS

The following procedures shall be used for reducing worker and public dose during radiopharmaceutical therapy.

- A. 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 shall be a private room with private sanitary facilities and should be without carpet.
- B. Post the patient's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room~ In addition, a sign posted on the patient's door and chart shall indicate that women who think they are pregnant should contact the hospital staff prior to entering the room.
- C. Visitation by individuals under the age of 18 may be authorized only on a patient-by-patient basis by the approval of the authorized user after consultation with the Radiation Safety Officer.
- D. Prepare the room for the procedure as follows:
 - 1. Cover, with absorbent paper, large surfaces and small items that are likely to be contaminated. Examples are chairs, floors around bed and toilet, door knobs, remote controls and nurses call control.
 - 2. Prepare separate boxes for linen, disposable waste, and non-disposable waste. Place a single large reclosable plastic bag in each box, or supply several small plastic bags.
 - 3. Prepare collection containers if urine will be collected.
 - a. Containers should be unbreakable and sealable.
 - b. Unless urine is to be assayed, it should not be held for decay in storage. If volumetric determination of urine is required, urine should be disposed of by flushing into the sanitary sewerage after the volume is recorded.
 - c. 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.
 - d. Supply a few half-value layers of shielding for each container. (For 1-131, one half-value layer is approximately 3 mm of lead.)
 - e. Supply a wide-mouth anti-splash funnel.
 - 4. Stock additional disposable gloves, absorbent paper, radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and safety personnel.
- E. Order disposable table service for the duration of the patient's stay. Notify housekeeping to stay out of the room until otherwise notified.

- F. All nursing staff caring for the patient must receive appropriate radiation safety training prior to attending to radiopharmaceutical therapy patients. Training shall be provided by the Radiation Safety Officer.
- G. Supply the nurses with film badges, TLD's, or pocket ionization chambers.
- H. Brief the nurses on radiation safety precautions. Use the form, "Nursing Instructions for Patients Treated with Unsealed Radiopharmaceuticals" in this section. 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.
- I. Brief the patient on radiation safety procedures for the dosage administration, visitor control, radioactive waste, and other items as applicable.
- J. Only those persons needed for medical, safety, or training purposes should be present during the administration.
- K. Mark a visitor's "safe line" on the floor with tape as far from the patient as practicable.
- L. Following administration of the dosage, measure the exposure in mrem/hr (uSv/hr) at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms [the last exposures must conform to requirements in Rule 420-3-26-.03(14)]. Record this and any other necessary information on the nursing instructions form.
- M. For patients treated with I-131, 24 to 72 hours after the dosage administration, measure the thyroid burden of all personnel who were present for the administration (see Section XVII). Also consider a thyroid burden assay for patient care personnel two (2) days after the administration.
- N. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.
- O. Do not release any patient unless the requirements of Rule 420-3-26-.07(41) are met. Documentation of the basis for authorizing the release of the patient shall be recorded. Instructions to assist in determining if a patient can be released are found in Appendix B.
- P. Before authorizing their release, provide the patient, or the patient's parent or guardian, with oral and written instructions on actions recommended to maintain radiation doses to other individuals as low as reasonably achievable.
- Q. Before using the room for general occupancy, it must be decontaminated and released to the admitting office.
 - 1. Remove all absorbent paper and place in the appropriate container.
 - 2. Transfer all containers to a decay-in-storage area.
 - 3. Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument. The room must not be reassigned until removable contamination is less than 200

disintegrations per minute (3.33 Bq) per 100 square centimeters. If the contamination is fixed, exposure rates must be less than 1 mrem/hr (10 uSv/hr) with a GM detector at "near contact" with the contaminated surface.

4. Call the housekeeping office to remove the cleaning restriction and call the admissions office to return the room to the vacant list.

Nursing Instructions for Patients Treated With Unsealed Radiopharmaceuticals

Patient Name _____ Patient ID _____ Room Number _____
Authorized User Physician (AU) _____ Phone _____ Pager _____
Dose _____ mCi (MBq) of _____ in the form of _____ was administered at _____ (AM/PM)
Signature _____ Date _____

Radiation Exposure Rates

Patient is supine in bed or is oriented/located _____
Unrestricted areas: Patient Door _____ mrem/hr Hallway Outside Patient Room _____ mrem/hr
Adjacent Rooms: Room # _____ mrem/hr Room # _____ mrem/hr

Date	Time	Bedside	1 m from bed	Visitor Line	Other
_____	_____ am/pm	_____ mrem/hr	_____ mrem/hr	_____ mrem/hr	_____ mrem/hr
_____	_____ am/pm	_____ mrem/hr	_____ mrem/hr	_____ mrem/hr	_____ mrem/hr
_____	_____ am/pm	_____ mrem/hr	_____ mrem/hr	_____ mrem/hr	_____ mrem/hr
_____	_____ am/pm	_____ mrem/hr	_____ mrem/hr	_____ mrem/hr	_____ mrem/hr
_____	_____ am/pm	_____ mrem/hr	_____ mrem/hr	_____ mrem/hr	_____ mrem/hr

Instructions

Visitor Restrictions
_____ No visitors allowed
_____ No visitors under 18 years of age, and no pregnant visitors
_____ Minutes each day maximum for each visitor
_____ Visitors must stay behind the line on the floor at all times

Nursing Restrictions
_____ Patient is restricted to room
_____ No pregnant nurses may render care
_____ Minutes each day per nurse in the room

Patient Care
_____ Wear disposable gloves. Wash hands after caring for patient.
_____ Meals to be supplied on disposable plates, with disposable utensils and drinking cups
_____ Discard linen, bedclothes, plates, utensils, dressings, etc. in boxes in room
_____ Collect urine in containers provided. Discard feces in toilet.
_____ Discard urine and feces in toilet. Flush 3 times.
_____ Housekeeping staff are not permitted in the room.
_____ Only the Radiation Safety Officer (RSO) may release the room to the admitting office.
_____ Wear your radiation dosimetry when in the patient's room. Leave your dosimetry at the nurses station at the end of your shift. You should use the same dosimeter on your next shift. Do not share dosimeters with others. Call the RSO if additional dosimeters are needed.

In case of emergency, or if you have questions, call:

RSO _____ Work _____ Home _____ Pager _____
AU _____ Work _____ Home _____ Pager _____

XII. RADIATION SAFETY PROCEDURES FOR IMPLANT THERAPY

The following procedures shall be used to reduce worker and public dose during implant therapies.

- A. The patient's room shall be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It shall be a private room.
- B. Post the patient's door with a "Caution: Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room. In addition, any sign shall indicate that women who think they are pregnant should contact the hospital staff prior to entering the room.
- C. Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer.
- D. Supply the nurses with film badges, TLD's, or pocket ionization chambers.
- E. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated With Implant Sources." Allow time for questions and answers during the briefing.
- F. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable, consistent with good medical care.
- G. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.
- H. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.
- I. Following the implant, measure the exposure in mrem/hr (uSv/hr) at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last exposures must conform to requirements in Rule 420-3-26-.03(14). Record this and any other necessary information on the nursing instructions form.
- J. Certain sealed source implant therapy patients may be released if the requirements of Rule 420-3-26-.07(41) are met. Documentation of the basis for authorizing the release of the patient shall be recorded. Instructions to assist in determining if a patient can be released are found in Appendix ?
- K. Before authorizing their release, provide the patient, or the patient's parent or guardian, with oral and written instructions on actions recommended to maintain radiation doses to other individuals as low as reasonably achievable.
- L. When removing temporary implants, do not release any patient 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 on the implant source running inventory form. For low-activity seeds (less than 1 mCi) 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.

- M. Copies of completed forms required by I., J. and L. above shall be maintained by the Radiation Safety Officer.

Nursing Instructions for Patients Treated With Implant Sources

Patient Name _____ Patient ID _____ Room Number _____
Authorized User Physician (AU) _____ Phone _____ Pager _____
Dose _____ mCi (MBq) of _____ as _____ individual sources was loaded on ___/___/___
Sources will be removed at approximately ___:___ (AM/PM) on ___/___/___

Radiation Exposure Rates

Unrestricted areas: Patient Door _____ mrem/hr Hallway Outside Patient Room _____ mrem/hr
Adjacent Rooms: Room # _____ mrem/hr Room # _____ mrem/hr
Patient supine in bed or _____
Date _____ Time _____ am/pm Bedside _____ mrem/hr 1 m from bed _____ mrem/hr
Visitor Line _____ mrem/hr Other _____ mrem/hr

Release Certification: Patient may not be released from the facility until the following certification is signed and dated by the RSO or an authorized user physician.

I have removed and counted _____ individual sources from this patient. A radiation survey of the patient indicated that all radiation sources have been removed from the patient.

Signature _____ Date _____

Instructions

Visitor Restrictions:

- ___ No visitors who are under 18, or pregnant
- ___ _____ Minutes each day maximum for each visitor
- ___ Visitor must remain behind the line on the floor at all times

Nursing Restrictions:

- ___ Patient is restricted to room
- ___ Patient is restricted to bed
- ___ Patient must not move
- ___ No nurses who are pregnant may render care
- ___ _____ Minutes each day per nurse in the room

Patient Care:

- ___ Wear your radiation monitor when caring for the patient. Leave the monitor at the nurses station at the end of your shift. You may use the same monitor during your next shift. Do not share monitors. Call the RSO if additional monitors are needed.
- ___ If a source appears dislodged, call the authorized user and the RSO immediately
- ___ Omit bed bath
- ___ No perineal care. Pad may be changed as necessary
- ___ Save surgical dressings for disposal by the authorized user or the RSO
- ___ See special hygiene care instructions

In case of emergency, or if you have questions, call:

RSO _____ Work _____ Home _____ Pager _____
AU _____ Work _____ Home _____ Pager _____

XIII. REQUIRED SURVEY INSTRUMENTS AND METHODS OF CALIBRATION

- A. A program which performs only uptake, dilution or excretion studies for which a written directive is not required, shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 mrem (1.0 uSv) per hour to 50 mrem (500 uSv) per hour.
- B. A program which performs imaging and localization studies for which a written directive is not required and/or uses radiopharmaceuticals for which a written directive is required and/or uses sealed sources for therapy, shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 mrem (1 uSv) per hour to 50 mrem (500 uSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 mrem (10 uSv) per hour to 1000 mrem (10 mSv) per hour.
- C. Survey meters must be calibrated at least once each year and/or following repair.
- D. The Radiation Safety Officer shall be responsible for assuring that all portable survey meters are calibrated by persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- E. The Radiation Safety Officer shall check each portable survey meter at least quarterly to assure that each meter is operating properly. A record of this check shall be maintained.
- F. Prior to each use of portable survey meters, each user shall verify that the meter is functioning properly. This check can be made by verifying adequate battery power and response to radiation by use of built-in check sources or other sources within the department.
- G. Instruments that are not functioning properly shall be brought to the attention of the Radiation Safety Officer who shall cause meters to be repaired or replaced.

XIV. DOSAGE DETERMINATION AND QUALITY CONTROL TEST AND CHECKS OF DOSE CALIBRATOR

A. Requirements

The activity of all radiopharmaceutical dosages shall be determined and documented. For photon-emitting radioactive material, this determination will be made within thirty (30) minutes prior to medical use. For all other radioactive material, the determination shall be made within the period before medical use that is no greater than ten percent (10%) of the physical half life of the radioactive material.

For photon-emitting radioactive material, the activity will be determined using a properly functioning dose calibrator. For non-photon-emitting radioactive material, activity determinations will be made by a combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 420-3-26-.02 of Rules of the State Board of Health, Radiation Control, or equivalent rules of an Agreement State or the US Nuclear Regulatory Commission.

Unless approved, in writing, by an authorized user, no dosage will be used if it differs from the prescribed dosage by more than 20%.

A record of each dosage determination will be maintained for 3 years. The record will include the radioactive drug, the patient's name or identification number, if one has been assigned, the prescribed dosage, the determined dosage, or a notation that the total activity is less than 30 microcuries (1.1 megabecquerel), the date and time of the dosage determination, and the name of the individual who determined the dosage.

The periodic test and check requirements for dose calibrators are summarized as follows:

1. Instrument calibration (at installation and at intervals not to exceed 12 months thereafter).
2. Instrument linearity (at installation and at intervals not to exceed 3 months thereafter).
3. Geometrical variation (at installation).
4. Instrument constancy (daily).

After repairs or adjustments of the dose calibrator, repeat all of the appropriate requirements listed above.

B. Methods

Radioactive sources used for quality control of the dose calibrator must meet certain requirements. There should be an isotope appropriate to the particular test. It should be contained in a "Type E" vial and, if used for instrument calibration, have activities traceable to the National Institutes of Standards and Technology (NIST). The table below summarizes the more commonly used sources for nuclear medicine quality control.

Table of Reference Sources

Source	Activity	Principle Energies	Simulated Radionuclides
Co-57	3-5 mCi	122, 136 keV	Tc-99m
Cs-137	100-200 μ Ci	662 keV	Mo-99
Ba-133	50-100 μ Ci	80, 356, 392 keV	I-131
Co-60	50 μ Ci	1.17, 1.33 MeV	-----

C. Test for Instrument Calibration

Check the accuracy of the dose calibrator by assaying at least 2 sealed sources containing different radionuclides with minimum activity of 100 μ Ci (3700 kBq) for any photon-emitting radionuclide, and at least one of which has a principle photon energy between 100 and 500 keV.

1. Assay the reference standard in the dose calibrator at the appropriate setting and subtract the background level to obtain the net activity.
2. Repeat Step 1 for a total of 3 determinations and average the results.
3. The average activity determined in Step 2 should agree with the certified activity of the reference source within $\pm 5\%$ after decay corrections.
4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.
5. Keep a log of these calibration checks including the determination of the percent accuracy attained.
6. Calibration checks which do not agree within $\pm 5\%$ indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of the radionuclides. Under no circumstances should a dose calibrator with an accuracy error greater than $\pm 10\%$ be used to assay doses.
7. At the same time the instrument is being initially calibrated with the NIST traceable standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.) and record the readings. These values may later be used to check instrument constancy at each setting (after correcting for decay of the long-lived source), without requiring more NIST traceable standards. Keep a log of these readings for later use in the daily constancy check.

D. Test of Instrument Linearity

The linearity of the dose calibrator shall be determined over the entire range of activities assayed. This test will utilize a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (perhaps up to several hundred millicuries).

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 time intervals of 6, 24, 30, and 48 hours after the initial assay, and enter these measured values beside the appropriate assay time in column 4 of the table below.
3. Using the 30-hour activity measurement as a starting point, calculate the decay predicted activities at 0, 6, 24, and 48 hours (see sample) and enter these values in column 3 of the table below.
4. Subtract the activity measured activity from the decay predicted activity (col. 3 - col. 4) and divide by the decay predicted activity.
5. Multiply this number by 100 to convert to percent error and place beside appropriate assay time in column 5.
6. If one or more of the percent errors in column 5 is greater than $\pm 5\%$, repeat the linearity check. Consistent measurement errors- greater than $\pm 5\%$ indicate the need for repair or adjustment of the instruments.
7. A dose calibrator with a consistent measurement error in excess of $\pm 10\%$ cannot be used for assay of radiopharmaceutical doses.

TABLE I

1 ASSAY TIME(HRS)	2 CORRECTION FACTOR (Tc-99m)	3 DECAY PREDICTED ACTIVITIES	4 MEASURED ACTIVITIES	5 PERCENT ERROR

Example: Assume that at 30 hours the measured activity is 6.50 mCi. Then in column 3 at time 0 enter 208 mCi (32×6.50), at time 6 hours, enter 104 mCi (16×6.50), at time 24 hours, enter 13.0 mCi (2×6.50), at time 30 hours, enter 6.5 mCi (1×6.50) and at time 48 hours, enter 0.812 mCi, (0.125×6.5 mCi).

Note: (Linearity Checks may also be made using an approved absorption tube linearity test kit following directions supplied with the kit.)

E. Test for Geometrical Variation

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 30 cc vial containing 2 mCi of Co-57, 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 2 ml, 4 ml, 8 ml, 10 ml, 20 ml, and 25 ml by adding the amount of water or saline.

After each addition, gently shake vial to mix contents and assay as in step 1. (Follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

3. Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy) and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF). Example: If activities of 2.04 mCi, 2.02 mCi, and 2.00 mCi are measured for 4 ml, 8 ml, and 10 ml volumes and 10 ml is the reference volume selected, then: 4 ml Volume CF = $2.00/2.04 = 0.98$.
4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.
5. The true activity of a sample is calculated as follows: True Activity = Measured Activity x CF, where the CF used is for the same volume and geometrical configuration as the sample measured.
6. Similarly the same activity of Co-57 in a syringe may be compared with that in 10 ml in a 30 cc vial and a correction factor may be calculated.
7. It should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Glass tubes and syringes may also vary enough in thickness to cause significant errors in assaying I-125. Hence, adequate correction factors must be established. An alternate to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

F. Test for Instrument Constancy

Instrument constancy means that there is a reproducibility, within a stated acceptable degree of precision, in measuring a constant activity over time. Use a long-lived source such as Cs-137 or Co-60 of suitable activity (see table of reference sources) at the beginning of each day the dose calibrator is used.

1. Assay the reference source using the appropriate instrument setting, (i.e., Cs-137 setting for Cs-137).
2. Measure background level at the same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.
3. Calculate net activity by subtracting out background level.
4. Enter the net activity on tabular form beside the date the test was performed. At the top of the column for entry for the source and setting used, enter the limits this source may vary (i.e., reading of long-lived source measured at time of annual calibration minus 5% to reading at time of annual calibration plus 5%. See sample table that follows.)
5. Daily entries out of the $\pm 5\%$ values, at the top of the column, indicate the need for repair. Daily entries out by more than $\pm 10\%$ shall require that the dose calibrator be taken out of service immediately.
6. Repeat steps 1 thru 5 for all the commonly used radionuclide settings using the same source as above.
7. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

TABLE 2
Daily Constancy Check

Date	Cs-137 Setting	Tc-99m Setting	I-131 Setting	Etc.
Annual Calibration	190 μ Ci - 210 μ Ci	6.3 μ Ci - 70.4 μ Ci	77 μ Ci - 85 μ Ci	
5/1/07	200 μ Ci	67 μ Ci	81 μ Ci	
5/7/07	205 μ Ci	69 μ Ci	83 μ Ci	
5/8/07	204 μ Ci	68 μ Ci	82 μ Ci	
5/9/07	202 μ Ci	67.5 μ Ci	81 μ Ci	
5/10/07	200 μ Ci	67 μ Ci	80 μ Ci	
5/14/07	198 μ Ci	66 μ Ci	79 μ Ci	
5/15/07	195 μ Ci	64 μ Ci	78 μ Ci	

Operator initials indicating that check was performed, recorded, and evaluated should be included for each day.

XV. QUALITY CONTROL FOR SCINTILLATION CAMERAS

The production of high quality images on a long-term basis can only be accomplished by monitoring the operational status of the scintillation camera(s) at appropriate intervals.

Quality control of the scintillation camera(s) will follow the manufacturer's written recommendations.

(Insert a copy of each camera manufacturer's written quality control procedures here)

In the absence of a manufacturer's written quality control recommendations, the following program will be used.

- A. The minimum daily quality control program for scintillation cameras shall consist of the following:
1. Photopeak position and window width settings are checked and adjusted if needed for the radionuclide being used.
 2. Field-flood image as a qualitative check for uniformity. Plane radiation sources may be used in either solid form as a disc (flood source) or in liquid form contained in a large flat plastic container (flood phantom). either form may be used with the collimator on or off, provided that the activity is adjusted so that the count rate does not exceed 10,000 cps in order to minimize distortion from counting losses and pulse pile-up. As an alternative, a small volume source of radioactive material in a small serum vial may also be used, but only with the collimator off and at a minimum distance of 150 cm from the detector (about 5 feet) to ensure a uniform exposure.
 3. Bar-phantom image as a check for spatial distortion and resolving power. A commercial type bar phantom shall be used to evaluate spatial distortion and resolving power. These are evaluated by interposing a bar phantom between the radiation source and detector with the phantom placed directly against the collimator or detector face and the bars diagonal to the X-Y axis. At least 1×10^6 (1,000,000) counts should be collected.

Spatial distortion is assessed by examining the straightness of the bar pattern image. The interpretation of this parameter is facilitated by the use of a bar phantom which uniformly traverses the entire field of view. Packing of the bar-pattern at the edge of the field of view (edgepacking) and curving of the bar-pattern image at the field edge (barrelling) may then be observed. These effects are not considered significant, however unless they extend into the central 90 percent of the image area.

Resolving power is best evaluated by the use of a bar pattern or pattern segment which best matches the optimum spatial resolution of the particular scintillation camera. A loss of resolving power is noticed by a decrease in sharpness of the bar-pattern image. The resolving power frequently appears reduced at the periphery of the field of view.

A field nonuniformity will result in a mottled appearance for the bar-pattern. Localized disturbances or occasional random breaks of the bar-pattern image may not be serious in nature.

Sharp repetitive breaks or a complete loss of bar-image lines occurring in a repeating pattern over the field of view may arise from a Moire' interaction between the bar width and the diameter of the collimator holes. In such cases the test should be repeated after a slight rotation of the bar phantom. The mottled appearance or Moire' pattern should either shift or disappear.

- B. The field flood and bar-phantom images shall be carefully scrutinized and compared with those obtained previously under similar conditions. The best images for comparison are those obtained at the time the device was set at optimum performance, i.e., when previously serviced. Any slight change that is noticed may be an indication of the slow deterioration or maladjustment of a camera component. If this change continues with time, preventive maintenance is indicated even though the camera may still be clinically usable. Major changes in camera performance require immediate instrument service.
- C. All test images shall be properly labeled and retained for immediate reference. On a day-to-day basis a change may not be noticeable, but by comparing test images over longer time spans, subtle deterioration may be detected.
- D. A review of these images shall be made on a weekly basis to detect long-term deterioration which may not be apparent on the basis of daily inspections.

XVI. CURRENT LIST OF ALL RADIATION MONITORING OR MEASURING INSTRUMENTS

Manufacturer	Model No.	No. of Each	Radiation Detected	To be Used for

Comments:

XVII. PERSONNEL MONITORING REQUIREMENTS

A. External Monitoring

This institution has established personnel monitoring procedures to comply with Rule 420-3-26-.03(18). Each individual working in a restricted area shall wear a film badge or thermoluminescence dosimeter (TLD). The device shall be worn either at the waist level or pocket level of the individual.

In addition to wearing the device described above, any person who elutes generators, prepare doses, prepares radiopharmaceuticals, administers radiopharmaceuticals, prepares sealed source applicators, inserts sealed sources, removes sealed sources, and cleans sealed sources must wear either a ring or wrist film badge or TLD. The device shall be worn on the hand or finger most likely to receive the greatest radiation dose.

Personnel monitoring devices shall be exchanged with the supplier at intervals not to exceed one (1) month. On the expiration date of the film badge, the Radiation Safety Officer shall collect all badges for processing and issue new badges. Records shall be made and kept of lost or damaged badges.

Upon receipt of the exposure reports from the film badge or TLD supplier, the Radiation Safety Officer shall review the reports. Appropriate actions will be taken if exposures exceed the levels specified in Table I of Section I of this manual. Additional emphasis should be placed on all overexposures and trends toward higher exposures. Reporting requirements are specified in Rule 420-3-26-.03(52) and (53) and Rule 420-3-26-.10(4). Exposure reports shall be reviewed by the Radiation Safety Committee at each quarterly meeting. Copies of each exposure report shall be posted in the appropriate department so that each individual can observe his/her exposure record.

NOTE!! No individual will be allowed to work with radiation unless all required personnel monitoring devices are worn. If a badge or TLD is lost or misplaced, a replacement must be obtained prior to continuing work.

B. Internal Monitoring

New personnel who will be working with sodium iodine I-131 should have a thyroid bioassay performed to set their baseline. Twenty-four to seventy-two hours after the administration of oral I-131 (>8 mCi liquid or >15 mCi in capsule form) thyroid bioassays will be performed on all personnel who were present during the administration.

Thyroid bioassays will be performed in the following manner:

1. Obtain a one minute background count of the empty thyroid phantom with the thyroid uptake probe using the I-131 setting.
2. Obtain a one minute count of a NIST traceable I-131 standard (or a mock I-131 standard, such as Ba-133) in the thyroid phantom.
3. Obtain a one minute count of the individual's thyroid.
4. Determine the minimum detectable activity (MDA) for the thyroid uptake probe using the following equations:

$$\text{MDA}(\text{cpm}) = 3 \frac{\text{background (cpm)}}{\text{count} \cdot \text{time}(\text{minutes})}$$

$$\text{MDA}(\mu\text{Ci}) = \frac{\text{MDA}(\text{cpm})}{\text{I-131 standard}(\text{cpm}/\mu\text{Ci})}$$

Note: If the MDA is not lower than the action levels, repeat 1., 2. And 3. using longer count times (ex: 5 minutes)

5. Determine the activity of I-131 in the individual's thyroid using the following equation:

$$\text{Thyroid burden}(\mu\text{Ci}) = \frac{\text{Net thyroid}(\text{cpm})}{\text{I-131 standard}(\text{cpm}/\mu\text{Ci})}$$

Review Level

If the thyroid burden exceeds 2% of the annual limit of intake (ALI) as found in Appendix II of 420-3-26-.03, a program review will be performed to determine the cause(s) of the uptake and evaluate what actions can be taken to minimize the chance of a recurrence. A repeat bioassay will be performed one week after the previous measurement to help determine the effective half life for use in estimating dose commitment.

Investigational Level

If the thyroid burden exceeds 10% of the ALI, an investigation will be performed. All steps from the Review Level will be performed. An appropriate medical consultant will be asked for recommendations regarding procedures that can be followed to accelerate the removal of radioactive iodine from the body. Continue weekly bioassays until the thyroid burden has dropped to less than 2% of the ALI. The RSO will perform an investigation of the causes of any uptakes which exceed the Investigational Level. The RSO and the Radiation Safety Committee shall determine what corrective actions are to be taken to minimize a recurrence. Documentation of investigations and corrective actions shall be maintained.

Records of all thyroid bioassays shall be maintained. Records will include the date of the bioassay, the name of the individual, the thyroid burden measurement, the MDA, and the initials of the individual who made the measurement.

XVIII. AMENDMENTS TO LICENSES

The application to amend a license may be made by letter or by using Agency Form RM, and must be completed and signed in the same manner as an initial application. In applying for an amendment, we should state which item(s) of the radioactive material license are to be amended and what changes need to be made in each item.

To add new physicians to the license, the appropriate Agency Form RM-HU should be obtained from the Alabama Office of Radiation Control web site (www.adph.org/radiation) and completed. Form RM-HU documents physician qualifications and must be submitted to the State Health Department for approval. For adding diagnostic use authorized user physicians, use Form RM-HU(aud). For adding unsealed source, therapeutic radiopharmaceutical authorized user physicians, use Form RM-HU(aut). For adding sealed source, therapeutic radioactive material authorized user physicians, use Form RM-HU(aus).

All amendment requests must be reviewed by the Radiation Safety Committee and signed by a designated representative of this institution's Administrative Staff prior to submittal.

XIX. RENEWAL OF A LICENSE

A radioactive material license is normally issued for a period of five (5) years. A complete application (Form RM appropriately supplemented) should be submitted at least thirty (30) days prior to the expiration date of the license. A renewal application should include all information specified in the Health Department's Guide since changes may have occurred in personnel, procedures, facilities, and equipment. On the items for which there have been no changes, the information shall be restated.

NOTE!! Keeping this manual current will greatly simplify renewal procedures as a current copy may be submitted at renewal in lieu of re-writing this entire manual. However, this manual must be reviewed at renewal by the Radiation Safety Committee. Additions and deletions must be made, if needed, prior to submittal with the renewal application. Any changes must be referenced by item and page number with the renewal application.

Renewal applications and amendment requests should be sent to:

Alabama Office of Radiation Control
P.O. Box 303017
Montgomery, AL 36130-3017

XX. INFORMATION AND ASSISTANCE

Additional information regarding radiation safety, regulation interpretations, license condition interpretations, or assistance in either routine matters or emergency incidents may be obtained by writing the Office of Radiation Control, or by calling (334) 206-5391, or our in-state toll free number, 800-582-1866. If you have questions or need assistance, do not hesitate to contact:

Alabama Office of Radiation Control
Post Office Box 303017
Montgomery, Alabama 36130-3017

APPENDIX A

REFERENCES

1. "Alabama Rules for Control of Radiation," available on the Agency's web site (www.adph.org/radiation) or from the Alabama Office of Radiation Control, P.O. Box 303017, Montgomery, Alabama 36130, at a cost of \$6.50/per copy.
2. NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," LCCCN 76-125343, available from NCRP Publications, Post Office Box 30175, Washington, D.C. 20014.
3. NCRP Report No. 40, "Protection Against Radiation from Brachytherapy Sources," LCCCN 76-190610, available from NCRP Publications, Post Office Box 30175, Washington, D.C. 20014.
4. "Workshop Manual, Documents, Manual for Quality Control of Scintillation Camera in Nuclear BRR, FDA, 76-8039, 1976, available from Superintendent of U.S. Government Printing Office, Washington, D.C. 20401.
5. "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions as Low as Reasonably Achievable," NUREG-0267, U.S. Nuclear Regulatory Commission, Office of Standards Development, Washington, D.C. 20555.
6. Regulatory Guide 8.18, U.S. Nuclear Regulatory Commission, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will be as Low as Reasonably Achievable," USNRC, Office of Standards Development, Washington, D.C. 20555.
7. "A Training Manual for Nuclear Medicine Technologists," U.S. Department of HEW, BRH/DMRE 70-3, October 1970, available from U.S. Department of HEW, Public Health Service, Bureau of Radiological Health, Rockville, Maryland 20852.
8. NCRP Report No. 48, "Radiation Protection for Medical and Allied Health Personnel," LCCCN 76-19728, available from NCRP Publication, Post Office Box 30175, Washington, D.C. 20014.
9. "American National Standard Calibration and Usage of 'Dose Calibrator' Ionization Chambers for the Assay of Radionuclides," ANSI N42.13-1978, American National Standards Institute, Inc., New York.
10. "Radiation Safety in Nuclear Medicine: A Practical Guide," FDA 82-8180, Public Health Service, Bureau of Radiological Health, FDA, 5600 Fishers Lane, Rockville, Maryland 20857.
11. Regulatory Guide 10.8, U.S. Nuclear Regulatory Commission, "Guide for the Preparation of Applications for Medical Programs," Revision 2, August 1987, USNRC, Office of Standards Development, Washington, D.C. 20555.

APPENDIX B

MODEL PROCEDURE FOR RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS ADMINISTERED RADIOACTIVE MATERIALS

Rule 420-3-26-.07(41), "Release of Individuals Containing Radioactive Drugs or Implants," permits a licensee to "authorize the release from its control any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem)."

In this appendix, the individual or human research subject to whom the radioactive material has been administered is called the "patient."

Release Equation

The activities at which patients could be released were calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides."

NCRP Report No. 37 uses the following equation to calculate the exposure until time t at a distance r from the patient:

Equation B.1:

$$D(t) = \frac{34.6 \Gamma Q_0 T_p (1 - e^{-0.693t/T_p})}{r^2}$$

Where:

- D(t) = Accumulated exposure at time t , in roentgens
- 34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44)
- Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm
- Q_0 = Initial activity of the point source in millicuries, at the time of the release
- T_p = Physical half-life in days
- r = Distance from the point source to the point of interest, in centimeters
- t = Exposure time in days.

This appendix uses the NCRP equation (Equation B.1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $(1 - e^{-0.693t/T_p})$ is set equal to 1.
- It is assumed that 1 roentgen is equal to 10 millisieverts (1 rem).
- The exposure-rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Supplement A to this appendix.
- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the

radionuclides.

- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation B.1 is modified to account for the uptake and retention of the radionuclide by the patient, as discussed in Supplement B.2.
- For radionuclides with a physical half-life greater than 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25% of the dose to total decay (0.25 in Equation B.2), at a distance of 1 meter. Selection of 25% of the dose to total decay at 1 meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis that indicate the dose calculated using an occupancy factor, E , of 25% at 1 meter is conservative in most normal situations.
- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25, because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life greater than 1 day:

Equation B.2:

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p (0.25)}{(100 \text{ cm})^2}$$

For radionuclides with a physical half-life less than or equal to 1 day, and if an occupancy factor of 1.0 is used:

Equation B.3:

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p (1)}{(100 \text{ cm})^2}$$

Equations B.2 and B.3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public, because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent), relative to the external gamma dose (see “Internal Dose,” of Supplement B). Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child must be considered separately, as discussed in Item B.1.1, “Release of Patients Based on Administered Activity.”

B.1 Release Criteria

Licensees should use one of the following options to release a patient to whom unsealed byproduct material or implants containing byproduct material have been administered in accordance with regulatory requirements.

B.1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in 420-3-26-.07(41)(a), licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table B.1. The activities in Table B.1 are based on a total effective dose equivalent of 5 millisieverts (0.5 rem) to an individual using the following conservative assumptions:

- Administered activity;
- Physical half-life;
- Occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day and an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day; and
- No shielding by tissue.

The total effective dose equivalent is often approximately equal to the external dose because the internal dose generally is a small fraction of the external dose (see Section B.3, “Internal Dose,” of Supplement B). The activities in Column 1 of Table B.1 were calculated using either Equation B.2 or B.3, depending on the physical half-life of the radionuclide.

Rule 420-3-26-.07(41)(d) requires a record because the patient’s release is based on the retained activity rather than the administered activity. In this case, reference to activities listed in Table B.1 may be recorded as the basis for the release.

If the activity administered exceeds the activity in Column 1 of Table B.1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table B.1.

If a radionuclide that is not listed in Table B.1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for Agency inspection, calculation of the release activity that corresponds to the dose limit of 5 millisievert (0.5 rem). Equation B.2 or B.3 may be used, as appropriate, to calculate the activity Q corresponding to 5 millisieverts (0.5 rem).

The release activities in Column 1 of Table B.1 do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in the patient’s breast milk. **When the patient is breast-feeding an infant or child, the activities in Column 1 of Table B.1 are not applicable to the infant or child.**

B.1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table B.1, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table B.1 for that radionuclide. In this case, the record required by Rule 420-3-26-.07(41)(d) may reference the measured dose rate as listed in Table B.1.

If a radionuclide not listed in Table B.1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5 millisieverts (0.5 rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by 420-3-26-.07(41)(d). The dose rate at 1 meter may be calculated from Equation B.2 or B.3, as appropriate, because the dose rate at 1 meter is equal to $\Gamma Q / 10,000 \text{ cm}^2$.

B.1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, based on 420-3-26-.07(41)(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 millisievert (0.5 rem), the patient may be released. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table B.1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. Again, a record of the release is required by 420-3-26-.07(41)(d).

Supplement B contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

Table B.1 Activities and Dose Rates for Authorizing Patient Release[†]

Radionuclide	COLUMN 1		COLUMN 2	
	Activity at or Below Which Patients May Be Released (GBq)	(mCi)	Dose Rate at 1 Meter, at or Below Which Patients May Be Released (mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	*	*	*	*
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.2	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89	*	*	*	*
Tc-99m	28	760	0.58	58
Tl-201	1	430	0.19	19
Y-90	*	*	*	*
Yb-169	0.37	10	0.02	2

[†] The activity values were computed based on 5 millisieverts (0.5 rem) total effective dose equivalent.

*

Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Notes: The millicurie values were calculated using Equations B.2 or B.3 and the physical half-life. The gigabecquerel values were calculated using the millicurie values and the conversion factor from millicurie to gigabecquerels. The dose rate values are calculated using the millicurie values and the exposure rate constants.

In general, the values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

B.2 Instructions

This Section provides acceptable instructions for release of patients administered radioactive materials. You may either adopt these model instructions or develop your own instructions to meet the requirements of 420-3-26-.07(41).

B.2.1 Additional Instructions for Release of Patients Who Could Be Breast-Feeding After Release

Rule 420-3-26-.07(41)(b) requires that a licensee provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation, and presumes that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient. The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breast-feeding an infant or child when the dose to the infant or child could exceed 5 millisieverts (0.5 rem) if there is no interruption of breast-feeding.

If the patient could be breast-feeding an infant or child after release, the licensee must give the patient instructions on the discontinuation or interruption period for breast-feeding and the consequences of failing to follow the recommendation. The patient should also be informed if there would be no consequences to the breast-feeding infant or child.

Table B.2 Column 1, provides a list of activities for various radioisotopes which, if the patient does not interrupt breast-feeding, will likely result in the breast-feeding infant or child receiving greater than 1 millisievert (0.1 rem).

Table B.2., Column 2, provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 1 millisievert (0.1 rem).

The radiopharmaceuticals listed in Table B.2 are commonly used in medical diagnosis and treatment. If a radiopharmaceutical not listed in Table B.2 is administered to a patient who could be breast-feeding, and if information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50% of the administered activity is excreted in the breast milk. The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant by Stabin.

B.2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations; however, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable contact person and that person's telephone number, in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided (refer to B.2.3.1 and B.2.3.2).

Table B.2. Activities of Radiopharmaceuticals that Likely Result in a Breast-Feeding Infant or Child Receiving 1 Millisievert (0.1rem) and Recommended Duration of Interruption of Breast-Feeding

Radionuclide	COLUMN 1		COLUMN 2 Examples of Recommended Duration of Interruption of Breast-Feeding
	Activity to Receive 1 Millisievert (0.1rem) (MBq)	(mCi)	
I-131 NaI	0.01	0.0004	Complete cessation (for this infant or child)
I-123 NaI	20	0.5	
I-123 OIH	100	4	
I-123 MIBG	70	2	24 hours for 370 MBq (10 mCi) 12 hours for 150 MBq (4 mCi)
I-125 OIH	3	0.08	
I-131 OIH	10	0.3	
Tc-99m DTPA	1000	30	
Tc-99m MAA	50	1.3	12.6 hours for 150 MBq (4 mCi)
Tc-99m	100	3	24 hours for 1,100 MBq (30 mCi)
Pertechnetate			12 hours for 440 MBq (12 mCi)
Tc-99m DISIDA	1000	30	
Tc-99m			
Glucoheptonate	1000	30	
Tc-99m MIBI	1000	30	
Tc-99m MDP	1000	30	
Tc-99m PYP	900	25	
Tc-99m Red Blood Cell <i>In Vivo</i> Labeling	400	10	6 hours for 740 MBq (20 mCi)
Tc-99m Red Blood Cell <i>In Vitro</i> Labeling	1000	30	
Tc-99m Sulphur Colloid	300	7	6 hours for 440 MBq (12 mCi)
Tc-99m DTPA Aerosol	1000	30	
Tc-99m MAG3	1000	30	
Tc-99m White Blood Cells	100	4	24 hours for 1,100 MBq (30 mCi) 12 hours for 440 MBq (12 mCi)
Ga-67 Citrate	1	0.04	1 month for 150 MBq (4 mCi) 2 weeks for 50 MBq (1.3 mCi) 1 week for 7 MBq (0.2 mCi)
Cr-51 EDTA	60	1.6	
In-111 White Blood Cells	10	0.2	1 week for 20 MBq (0.5 mCi)
Tl-201 Chloride	40	1	2 weeks for 110 MBq (3 mCi)

Footnotes for Table B.2

* The duration of interruption of breast-feeding is selected to reduce the maximum dose to a newborn infant to less than 1 millisievert (0.1 rem), although the regulatory limit is 5 millisieverts (0.5 rem). The actual doses that would be received by most infants should be far below 1 millisievert (0.1 rem).

Notes: Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG- 1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material."

If there is no recommendation in Column 2 of this table, the maximum activity normally administered is below the activities that would likely result in a breast-feeding infant or child receiving 1 millisievert (0.1rem).

B.2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following:

- Maintaining distance from other persons, including separate sleeping arrangements.
- Minimizing time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Precautions to reduce the spread of radioactive contamination.
- The length of time each of the precautions should be in effect.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine. This pamphlet was prepared jointly by the Society of Nuclear Medicine and NRC. The pamphlet contains blanks for the physician to fill in the length of time that each instruction should be followed. Although this pamphlet was written for the release of patients to whom less than 1,110 megabecquerels (30 millicuries) of iodine-131 had been administered, the Agency still considers the instructions in this pamphlet to be an acceptable method for meeting the requirements of 420-3-26-.07(b), provided the times filled in the blanks are appropriate for the activity and the medical condition.

If additional instructions are required because the patient is breast-feeding, the instructions should include appropriate recommendations on whether to interrupt breast-feeding, the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breast-feeding. The consequences should be explained so that the patient will understand that, in some cases, breast-feeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving iodine-131 is that continued breast-feeding could harm the infant's or child's thyroid. Most diagnostic procedures involve radionuclides other than radioiodine and there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the infant or child from breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding an infant or child, the pamphlet should be supplemented with information specified in 420-3-26-.07(41)(b)(1) and (2).

B.2.3.2 Instructions Regarding Implants

For patients who have received implants, additional instructions may include the following:

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for ____ days.

- Stay at a distance of ____ feet from _____.
- Maintain separate sleeping arrangements.
- Minimize time with children and pregnant women.
- Do not hold or cuddle children.
- Avoid public transportation.
- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.

If you find a seed or pellet that falls out:

- do not handle it with your fingers (instead, use something like a spoon or tweezers to handle it), and follow the instructions given to you by your physician.
- Notify _____ at telephone number _____.

B.3 Records

B.3.1 Records of Release

A record of the basis for the release is required by 420-3-26-.07(d). This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information:

- **For Immediate Release of a Patient Based on a Patient-Specific Calculation:** The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Supplement B of this appendix) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.
- **For Immediate Release of a Patient Based on Radionuclide Activity:** The activity administered and the date and time of release.
- **For Immediate Release of a Patient Based on Measured Dose Rate:** The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.

- **For Delayed Release of a Patient Based on Radioactive Decay Calculation:** The time of the administration, date and time of release, and the results of the decay calculation.
- **For Delayed Release of a Patient Based on Measured Dose Rate:** The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

Records, as required by 420-3-26-.07(d), should be kept in a manner that ensures the patient's confidentiality. That is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These recordkeeping requirements may also be used to verify that licensees have proper procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients who were administered radioactive material.

B.3.2 Records of Instructions for Breast-Feeding Patients

A record that instructions were provided to interrupt or discontinue breast-feeding is required by 420-3-26-.07(e). The record should include the patient's identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radiopharmaceutical administered, the administered activity, the date of the administration, and whether instructions were provided to the patient who could be breast-feeding an infant or child.

Implementation

The purpose of this section is to provide information to licensees and applicants regarding the Agency staff's plans for using this appendix. Except in those cases in which a licensee proposes an acceptable alternative method for complying with Rule 420-3-26-.07(41), the methods described in this appendix will be used in the evaluation of a licensee's compliance with 420-3-26-.07(41).

References

US Nuclear Regulatory Commission NUREG 1556, Vol. 9, Rev. 1 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," May, 2005.

National Council on Radiation Protection and Measurements (NCRP), "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," NCRP Report No. 37, October 1, 1970. (Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3095.)

S. Schneider and S. A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492 (Final Report), NRC, February 1997.

M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine," in *Pediatric Nuclear Medicine*, edited by S. Treves, Springer Verlag, New York, 1995.

"Guidelines for Patients Receiving Radioiodine Treatment," *Society of Nuclear Medicine*, 1987. This pamphlet may be obtained from the Society of Nuclear Medicine, 1850 Samuel Morse Drive, Reston, VA 20190-5316.

Supplement A

Table B.3 Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine

Radionuclide	Physical Half-Life (days) ¹	Exposure Rate Constant ² (R/mCi-h at 1 cm)
Ag-111	7.45	0.15
Au-198	2.696	2.3
Cr-51	27.704	0.16
Cu-64	0.529	1.2
Cu-67	2.578	0.58
Ga-67	3.261	0.753
I-123	0.55	1.61
I-125	60.14	1.42
I-125 implant	60.14	1.11 ³
I-131	8.04	2.2
In-111	2.83	3.21
Ir-192 implant	74.02	4.59 ³
P-32	14.29	N/A ⁵
Pd-103 implant	16.96	0.86 ⁴
Re-186	3.777	0.2
Re-188	0.708	0.26
Sc-47	3.351	0.56
Se-75	119.8	2
Sm-153	1.946	0.425
Sn-117m	13.61	1.48
Sr-89	50.5	N/A ⁵
Tc-99m	0.251	0.756
Tl-201	3.044	0.447
Y-90	2.67	N/A ⁵
Yb-169	32.01	1.83

Footnotes for Table B.3

¹ K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.

² Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, pp. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D.E. Barber, J.W. Baum, and C.B. Meinhold, "Radiation Safety Issues Related to Radiolabeled Antibodies," NUREG/CR-4444, U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," U.S. NRC, February 1997.

³ R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of ¹²⁵I and ¹⁹²Ir Interstitial Brachytherapy Sources," *Medical Physics*, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.

⁴ A.S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an "apparent" value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant capsule itself.

⁵ Not applicable (N/A) because the release activity is not based on beta emissions.

Supplement B

Procedures for Calculating Doses Based on Patient-Specific Factors

A licensee may release a patient to whom an activity with a value higher than the values listed in Column 1 of Table B.1 of this Appendix has been administered, if dose calculations using patient-specific parameters show that the potential total effective dose equivalent to any individual would be no greater than 5 millisieverts (0.5 rem).

If the release of a patient is based on a patient-specific calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, biological or effective half-life, or shielding by tissue, the following equation can be used to calculate doses:

Equation B-1:

$$D_{(t)} = \frac{34.6 \Gamma Q_0 T_p E (1 - e^{-0.693t/T_p})}{r^2}$$

Where:

- $D_{(t)}$ = Accumulated dose to time t, in rem;
- 34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44);
- Γ = Exposure rate constant for a point source, R/mCi x hr at 1 cm;
- Q_0 = Initial activity at the start of the time interval;
- T_p = Physical half-life, in days;
- E = Occupancy factor that accounts for different occupancy times and distances when an individual is around a patient;
- r = Distance in centimeters. This value is typically 100 cm; and
- t = Exposure time in days.

B.1 Occupancy Factor

B.1.1 Rationale for Occupancy Factors Used to Derive Table B.1

In Table B.1 of this Appendix, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members, as well as considerations of normal human behavior, suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will generally produce a conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

An occupancy factor of 0.25 at 1 meter may not be appropriate when the physical half-life is less than or equal to 1 day, and hence, the dose is delivered over a short time. Specifically, the assumptions regarding patient behavior that led to an occupancy factor of 0.25 at 1 meter include

the assumption that the patient will not be in close proximity to other individuals for several days; however, when the dose is from a short-lived radionuclide, the time that individuals spend in close proximity to the patient immediately following release will be most significant because the dose to other individuals could be a large fraction of the total dose from the short-lived radionuclide. Thus, to be conservative when providing generally applicable release quantities that may be used with little consideration of the specific details of a particular patient's release, the values calculated in Table B.1 were based on an occupancy factor of 1 at 1 meter when the half-life is less than or equal to 1 day. If information about a particular patient implies the assumptions were too conservative, licensees may consider case-specific conditions. Conversely, if young children are present in the household of the patient who is to be discharged, conservative assumptions about occupancy may be appropriate.

B.1.2 Occupancy Factors to Consider for Patient-Specific Calculations

The selection of an occupancy factor for patient-specific calculations will depend on whether the physical or effective half-life of the radionuclide is used. The following occupancy factors, E, at 1 meter, may be useful for patient-specific calculations:

- E = 0.75 when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day.
- E = 0.25 when an effective half-life is greater than 1 day, and the patient has been given instructions, such as:
 - Maintain a prudent distance from others for at least the first 2 days;
 - Sleep alone in a room for at least the first night;
 - Do not travel by airplane or mass transportation for at least the first day;
 - Do not travel on a prolonged automobile trip with others for at least the first 2 days;
 - Have sole use of a bathroom for at least the first 2 days; and
 - Drink plenty of fluids for at least the first 2 days.
- E = 0.125 when an effective half-life is greater than 1 day if the patient has been given instructions, such as:
 - Follow the instructions for E = 0.25 above;
 - Live alone for at least the first 2 days; and
 - Have few visits by family or friends for at least the first 2 days.

In a two-component model (e.g., uptake of iodine-131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to one day but is greater than one day for the other component, it is more justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1: Calculate the maximum likely dose to an individual exposed to a patient who has received 2,220 megabecquerels (60 millicuries) of oral sodium iodine-131. The patient received instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

Solution: The dose to total decay ($t = 4$) is calculated based on the physical half-life using Equation B-1. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p E}{r^2}$$

Because the patient has received extensive instructions for reducing exposure as recommended

for an occupancy factor of $E = 0.125$, the occupancy factor of 0.125 at 1 meter may be used.

$$D(\infty) = \frac{34.6 (2.2 \text{ R}\cdot\text{cm}^2/\text{mCi}\cdot\text{hr})(60\text{mCi})(8.04 \text{ d})(0.125)}{(100 \text{ cm})^2}$$

$$D(\infty) = 4.59 \text{ millisieverts (0.459 rem)}$$

Since the dose is less than 5 millisievert (0.5 rem), the patient may be released. A record of the calculation must be maintained, pursuant to 420-3-26-.07(41)(d).

B.2 Effective Half-Life

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits for individuals exposed to the patient that are stated in 420-3-26-.07(41). The effective half-life is defined as:

Equation B-2:

$$T_{eff} = \frac{T_b \times T_p}{T_b + T_p}$$

Where:

T_b = Biological half-life of the radionuclide and
 T_p = Physical half-life of the radionuclide.

The behavior of oral sodium iodine-131 can be modeled using two components: extrathyroidal iodide (i.e., existing outside of the thyroid) and thyroidal iodide following uptake by the thyroid. The effective half-lives for the extrathyroidal and thyroidal fractions (i.e., F_1 and F_2 , respectively) can be calculated with the following equations.

Equation B-3:

$$T_{1eff} = \frac{T_{b1} \times T_p}{T_{b1} + T_p}$$

Equation B-4:

$$T_{2eff} = \frac{T_{b2} \times T_p}{T_{b2} + T_p}$$

Where:

T_{b1} = Biological half-life for extrathyroidal iodide;
 T_{b2} = Biological half-life of iodide following uptake by the thyroid; and
 T_p = Physical half-life of iodine-131.

However, simple exponential excretion models do not account for: (a) the time for the iodine-131 to be absorbed from the stomach to the blood; and (b) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this Supplement makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80% of the iodine administered is removed from the body at a rate determined only by the physical half-life of iodine-131.

Thus, an equation to calculate the dose from a patient administered oral sodium iodine-131 may have three components. First is the dose for the first 8 hours (0.33 day) after administration. This component comes directly from Equation B-1, using the physical half-life and a factor of 80%. Second is the dose from the extrathyroidal component from 8 hours to total decay. In this component, the first exponential factor represents the activity at $t = 8$ hours based on the physical half-life of iodine-131. The second exponential factor represents the activity from $t = 8$ hours to total decay based on the effective half-life of the extrathyroidal component. The third component, the dose from the thyroidal component for 8 hours to total decay, is calculated in the same manner as the second component. The full equation is shown as Equation B-5.

Equation B-5:

$$D(\infty) = \frac{34.6 \Gamma Q_0}{(100\text{cm})^2} \left\{ E_1 T_p (0.8)(1 - e^{-0.693(0.33)/T_p}) + e^{-0.693(0.33)/T_p} E_2 F_1 T_{1\text{eff}} + e^{-0.693(0.33)/T_p} E_2 F_2 T_{2\text{eff}} \right\}$$

Where:

- F_1 = Extrathyroidal uptake fraction;
- F_2 = Thyroidal uptake fraction;
- E_1 = Occupancy factor for the first 8 hours; and
- E_2 = Occupancy factor from 8 hours to total decay.

All the other parameters are as defined in Equations B-1, B-3, and B-4. Acceptable values for F_1 , $T_{1\text{eff}}$, F_2 , and $T_{2\text{eff}}$ are shown in Table B.4 for thyroid ablation and treatment of thyroid remnants after surgical removal of the thyroid for thyroid cancer. If these values have been measured for a specific individual, the measured values may be used.

The record of the patient's release required by 420-3-26-.07(41)(d) or (e) is described in Item B.3.1 of this Appendix.

Example 2, Thyroid Cancer: Calculate the maximum likely dose to an individual exposed to a patient to whom 5550 megabecquerel (150 millicurie) of iodine-131 has been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, we will calculate the dose by using Equation B-5 to account for the elimination of iodine-131 from the body, based on the effective half-lives appropriate for thyroid cancer. The physical half-life and the exposure rate constant are from Table B.3. The uptake fractions and effective half-lives are from Table B.4. An occupancy factor, E , of 0.75 at 1 meter, will be used for the first component because the time period under consideration is less than 1 day; however, for the second and third components, an occupancy factor of 0.25 will be used, because: (1) the effective half-life associated with the dominant component is greater than 1 day; and (2) patient-specific questions were provided to the patient to justify the occupancy factor (see Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations," of this Supplement).

Table B.4. Uptake Fractions and Effective Half-Lives for Iodine-131 Treatments

Medical Condition	Extrathyroidal Component		Thyroidal Component	
	Uptake Fraction F_1	Effective Half-Life $T_{1\text{eff}}$ (day)	Uptake Fraction F_2	Effective Half-Life $T_{2\text{eff}}$ (day)
Hyperthyroidism	0.20 ¹	0.32 ²	0.80 ¹	5.2 ¹
Post Thyroidectomy for Thyroid Cancer	0.95 ³	0.32 ²	0.05 ³	7.3 ²

Footnotes for Table B.4.

¹ M.G. Stabin et al., “Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism,” *Journal of Nuclear Medicine*, Volume 32, Number 5, May 1991. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this referenced document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight-line fit that accounts for about 75% of the data points shown in Figure 1 of the *Journal of Nuclear Medicine* document.

² International Commission on Radiological Protection (ICRP), “Radiation Dose to Patients from Radiopharmaceuticals,” ICRP Publication No. 53, March 1987. (Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.) The data in that document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid and thyroid cancer patients. For thyroid cancer, the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid), as suggested in the ICRP document.

³ The thyroidal uptake fraction of 0.05 was recommended by Dr. M. Pollycove, M.D., NRC medical visiting fellow, as an upper-limit post-thyroidectomy for thyroid cancer.

Substituting the appropriate values into Equation B-5, the dose to total decay is:

$$D(\infty) = \frac{(34.6)(2.2)(150)}{(100\text{cm})^2} \left\{ (0.75)(8.04)(0.8)(1 - e^{-0.693(0.33)/8.04}) + e^{-0.693(0.33)/8.04} (0.25)(0.95)(0.32) + e^{-0.693(0.33)/8.04} (0.25)(0.05)(7.3) \right\}$$

$$D(\infty) = 3.40 \text{ mSv (0.340 rem)}$$

Therefore, thyroid cancer patients to whom 5550 megabecquerel (150 millicurie) of iodine-131 or less has been administered would not have to remain under licensee control, and could be released under 420-3-26-.07(41), **assuming that the foregoing assumptions can be justified for the individual patient’s case and that the patient is given adequate instructions.**

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3, Hyperthyroidism: Calculate the maximum likely dose to an individual exposed to a

patient to whom 2035 megabecquerels (55 millicuries) of iodine-131 has been administered for the treatment of hyperthyroidism.

Solution: In this example, we will again calculate the dose using Equation B-5, Table B.3, and Table B.4, to account for the elimination of iodine-131 from the body by using the effective half-lives appropriate for hyperthyroidism. An occupancy factor, E , of 0.25 at 1 meter will be used for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor (see Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations").

Substituting the appropriate values into Equation B-5, the dose to total decay is:

$$D(\infty) = \frac{(34.6)(2.2)(55)}{(100\text{cm})^2} \left\{ (0.75)(8.04)(0.8)(1 - e^{-0.693(0.33)/8.04}) \right. \\ \left. + e^{-0.693(0.33)/8.04}(0.25)(0.20)(0.32) + e^{-0.693(0.33)/8.04}(0.25)(0.80)(5.2) \right\}$$

$$D(\infty) = 4.86 \text{ mSv (0.486 rem)}$$

Therefore, hyperthyroid patients to whom 2035 megabecquerels (55 millicuries) of iodine-131 has been administered would not have to remain under licensee control and could be released under 420-3-26-.07(41), **assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given adequate instructions.**

In the example above, the thyroidal fraction $F_2 = 0.8$ is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B.3 Internal Dose

For some radionuclides, such as iodine-131, there may be concerns that the internal dose of an individual from exposure to a released patient could be significant. A rough estimate of the maximum likely committed effective dose equivalent from internal exposure can be calculated from Equation B-6.

Equation B-6:

$$D_i = Q (10^{-5})(DCF)$$

Where:

- D_i = Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rem;
- Q = Activity administered to the patient in millicuries;
- 10^{-5} = Assumed fractional intake; and
- DCF = Dose conversion factor to convert an intake in millicurie to an internal committed effective dose equivalent (such as tabulated in Reference B-2).

Equation B-6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb was developed in reference B-3 for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility, but it does not specifically apply to cases of intake by an individual exposed to a patient. However, two studies (Refs. B-4 and B-5) regarding the intakes of individuals exposed to patients administered iodine-131, indicated that intakes were generally of the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of 10^{-5} has been assumed.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient to whom 1221 megabecquerels (33 millicuries) of iodine-131 has been administered. The ingestion pathway was selected because it is likely that most of the intake would be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

Solution: This is an example of the use of Equation B-6. The dose conversion factor DCF for the ingestion pathway is 53 rem/millicurie from Table 2.2 of Reference B-2.

Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.17 \text{ mSv (0.017 rem)}$$

Using Equation B-1 and assuming the patient has received instructions for reducing exposure as recommended for an occupancy factor of 0.25, the external dose is approximately 5 mSv (0.5 rem). Thus, the internal dose is about 3% of the external dose due to gamma rays. Internal doses may be ignored in calculations of total dose if they are likely to be less than 10% of the external dose because the internal dose due to this source is small in comparison to the magnitude of uncertainty in the external dose.

The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP. The NCRP addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients" (Ref. B-6). The NCRP concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely." For additional discussion on the subject, see Reference B-1.

Example 5, Internal Dose: Calculate the maximum internal dose to a person exposed to a patient to whom 5550 megabecquerels (150 millicuries) of iodine-131 has been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, we will again calculate the dose using Equation B-6 and selecting the ingestion pathway. Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (150 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.80 \text{ mSv (0.08 rem)}$$

In this case, the external dose to the other person from Example 2, Thyroid Cancer, was approximately 3.4 millisieverts (0.34 rem), while the internal dose would be about 0.80 millisievert (0.08 rem). Thus, the internal dose is about 24% of the external gamma dose. The summation of the internal and external doses determines the total dose; 4.2 millisieverts (0.42 rem).

References for Supplement B

- B-1. S. Schneider and S.A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," U.S. NRC, NUREG-1492, February 1997.
- B-2. K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Federal Guidance Report No.11, U. S. Environmental Protection Agency, Washington, DC, 1988.
- B-3. A. Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10^{-6} a Magic Number in Health Physics?)," *Health Physics*, Volume 39, Number 6, 1980.
- B-4. R.C.T. Buchanan and J.M. Brindle, "Radioiodine Therapy to Out-patients – The Contamination Hazard," *British Journal of Radiology*, Volume 43, 1970.
- B-5. A.P. Jacobson, P.A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," *American Journal of Public Health*, Volume 68, Number 3, 1978.
- B-6. National Council on Radiation Protection and Measurements, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," Commentary No. 11, February 28, 1995.

APPENDIX C

ACCEPTABLE TRAINING AND EXPERIENCE FOR MEDICAL USES OF RADIOACTIVE MATERIAL

- I. Diagnostic uses authorized in 420-3-26-.07(45), Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for which a Written Directive is Not Required. A licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 420-3-26-.07(45) to be a physician who:**
- (a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph 420-3-26-.07(47)(c)(2). To have its certification process recognized, a specialty board shall require all candidates for certification to:
1. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs 420-3-26-.07(47)(c)(1)(i) and (c)(1)(ii); and
 2. Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or
- (b) Is an authorized user under 420-3-26-.07(51) or (56), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
- (c) 1. Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:
- (i) Classroom and laboratory training in the following areas:
 - (I) Radiation physics and instrumentation;
 - (II) Radiation protection;
 - (III) Mathematics pertaining to the use and measurement of radioactivity;
 - (IV) Chemistry of radioactive material for medical use; and
 - (V) Radiation biology; and
 - (ii) Work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(47), (51) (56), or equivalent Nuclear Regulatory Commission or Agreement State requirements, involving:

- (I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (III) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
- (V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (VI) Administering dosages of radioactive drugs to patients or human research subjects; and

2. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(47), (51) (56), or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph 420-3-26-.07(47)(a)(1) or (c)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 420-3-26-.07(45).

II. Diagnostic uses authorized in 420-3-26-.07(48), Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required. A licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 420-3-26-.07(48) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and

2. Pass an examination, administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under 420-3-26-.07(56) and meets the requirements in 420-3-26-.07(51)(c)(1)(ii)(VII), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(c) 1. Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use;

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in 420-3-26-.07(51), or 420-3-26-.07(51)(c)(1)(ii)(VII) and 420-3-26-.07(56), or equivalent Nuclear Regulatory Commission or Agreement State requirements, involving

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(V) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(VI) Administering dosages of radioactive drugs to patients or human research subjects; and

(VII) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

2. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(51) or 420-3-26-.07(56) and 420-3-26-.07(51)(c)(1)(ii)(VII), or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has

achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 420-3-26-.07(45) and (48).

III. Diagnostic and therapeutic uses authorized in 420-3-26-.07(52), Use of Unsealed Radioactive Material for Which a Written Directive is Required. A licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 420-3-26-.07(52) to be a physician who:

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 420-3-26-.07(52) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs 420-3-26-.07(56)(b)1.(ii)(VII) and (b)2. To be recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs 420-3-26-.07(56)(b)1.(i) through (b)1.(ii)(V). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(b) 1. Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

(i) Classroom and laboratory training in the following areas

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(56), or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in 420-3-26-.07(56)(b) must also have experience in administering dosages in the same dosage category or categories (i.e., 420-3-26-.07(56)(b)1.(ii)(VII)) as the individual requesting authorized user status. The work experience must involve:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(VI) [Reserved]

(VII) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status

(A) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

(B) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

(C) Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

(D) Parenteral administration of any other radionuclide, for which a written directive is required; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(56)(a)1. and (b)1.(ii)(VII) or (b)1., and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 420-3-26-.07(52). The written attestation must be signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(56), or equivalent Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user, who meets the

requirements in 420-3-26-.07(56)(b) must have experience in administering dosages in the same dosage category or categories (i.e., 420-3-26-.07(56)(b)1.(ii)(VII)) as the individual requesting authorized user status.

IV. Rule 420-3-26-.07(57), Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less than or Equal to 1.22 Gigabecquerels (33 millicuries) for which a Written Directive is Required.

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 420-3-26-.07(57)(c)1. and (c)2. and whose certification process has been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph 420-3-26-.07(57)(c)3. of this section; or

(b) Is an authorized user under 420-3-26-.07(56)(a), 420-3-26-.07(56)(b) for uses listed in 420-3-26-.07(56)(b)1.(ii)(VII)(A) or (B), 420-3-26-.07(58) or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(c) 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Chemistry of radioactive material for medical use; and
- (v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(56)(a), 420-3-26-.07(56)(b), 420-3-26-.07(57), 420-3-26-.07(58) or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements in 420-3-26-.07(56)(b), must also have experience in administering dosages as specified in 420-3-26-.07(56)(b)1.(ii)(VII)(A) or (B). The work experience must involve:

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;
 - (v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerel (33 millicuries) of sodium iodide I-131; and
- (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(57)(c)1. and (c)2., and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 420-3-26-.07(52). The written attestation must be signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(56), 420-3-26-.07(57) or 420-3-26-.07(58) or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirement in 420-3-26-.07(56)(b), must also have experience in administering dosages as specified in 420-3-26-.07(56)(b)1.(ii)(VII)(A) or (B).

V. Rule 420-3-26-.07(58), Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabecquerels (33 millicuries) for which a Written Directive is Required.

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who:

- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 420-3-26-.07(58)(c)1. and (c)2., and whose certification has been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State, and who meets the requirements in paragraph 420-3-26-.07(58)(c)3.; or
- (b) Is an authorized user under 420-3-26-.07(56)(a), 420-3-26-.07(56)(b) for uses listed in 420-3-26-.07(56)(b)1.(ii)(VII)(B), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
- (c) 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Chemistry of radioactive material for medical use; and
- (v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(56)(a), 420-3-26-.07(56)(b), 420-3-26-.07(58), or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in 420-3-26-.07(56)(b), must also have experience in administering dosages as specified in 420-3-26-.07(56)(b)(1)(ii)(VII)(B). The work experience must involve:

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;
- (v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(58)(c)1. and (c)2., and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 420-3-26-.07(52). The written attestation must be signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(56) or 420-3-26-.07(58), or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirements in 420-3-26-.07(56)(b), must also have experience in administering dosages as specified in 420-3-26-.07(56)(b)(1)(ii)(VII)(B).

VI. Rule 420-3-26-.07(59), Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

(a) Is an authorized user under 420-3-26-.07(56) for uses listed in 420-3-26-.07(56)(b)1.(ii)(VII)(C) or 420-3-26-.07(56)(b)1.(ii)(VII)(D), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(b) Is an authorized user under 420-3-26-.07(68) or 420-3-26-.07(89), or equivalent Nuclear Regulatory Commission or Agreement State requirements and who meets the requirements in paragraph 420-3-26-.07(59)(d) of this section; or

(c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under 420-3-26-.07(68) or 420-3-26-.07(89) and who meets the requirements in paragraph 420-3-26-.07(59)(d) of this section.

(d) 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(56) or 420-3-26-.07(59), or equivalent Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 420-3-26-.07(56) must have experience in administering dosages as specified in 420-3-26-.07(56)(b)1.(ii)(VII)(C) and/or 420-3-26-.07(56)(b)1.(ii)(VII)(D). The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

- (ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
 - (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (iv) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
 - (v) Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and
 - (vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and
- (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 420-3-26-.07(59)(b) or (c), and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(56), 420-3-26-.07(59), or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirements in 420-3-26-.07(56) must have experience in administering dosages as specified in 420-3-26-.07(56)(b)1.(ii)(VII)(C) and/or 420-3-26-.07(56)(b)1.(ii)(VII)(D).

VII. Therapeutic uses authorized in 420-3-26-.07(60), Use of Sealed Sources for Manual Brachytherapy. A licensee shall require an authorized user of sealed sources for manual brachytherapy authorized under 420-3-26-.07(60) to be a physician who:

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 420-3-26-.07(60) to be a physician who:

- (a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State, and who meets the requirements in paragraph 420-3-26-.07(68)(b)3. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(b) 1. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(68), or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Checking survey meters for proper operation;

(III) Preparing, implanting, and removing brachytherapy sources;

(IV) Maintaining running inventories of radioactive material on hand;

(V) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(VI) Using emergency procedures to control radioactive material; and

2. Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 420-3-26-.07(68), or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph 420-3-26-.07(68)(b)1.(ii); and

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(68), or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(68)(a)1., or 420-3-26-.07(68)(b)1. and (b)2. of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 420-3-26-.07(60).

VIII. Rule 420-3-26-.07(69), Training for Ophthalmic Use of Strontium-90.

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under 420-3-26-.07(60) to be a physician who:

(a) Is an authorized user under 420-3-26-.07(68), or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

(b) 1. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(68) or 420-3-26-.07(69), or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

IX. Diagnostic uses authorized in 420-3-26-.07(70), Use of Sealed Sources for Diagnosis. A licensee shall require an authorized user of sealed sources for diagnosis authorized under 420-3-26-.07(60) to be a physician who:

Except as provided in 420-3-26-.07(29), the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under 420-3-26-.07(70) to be a physician, dentist, or podiatrist who:

- (a) Is certified by a specialty board whose certification process includes all of the requirements in 420-3-26-.07(71)(b) and (c) and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission; or
- (b) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes:
 - 1. Radiation physics and instrumentation;
 - 2. Radiation protection;
 - 3. Mathematics pertaining to the use and measurement of radioactivity;
 - 4. Radiation biology; and
- (c) Has completed training in the use of the device for the uses requested.

X. Therapeutic uses authorized in 420-3-26-.07(27), Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit. A licensee shall require an authorized user of sealed sources authorized under 420-3-26-.07(72) to be a physician who:

Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of a sealed source for a use authorized under 420-3-26-.07(72) to be a physician who:

- (a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs 420-3-26-.07(89)(b)3. and (c) of this section. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - 1. Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and
 - 2. Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality

assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(b) 1. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(89), or equivalent Nuclear Regulatory Commission or Agreement State requirements at a medical institution, involving:

(I) Reviewing full calibration measurements and periodic spot-checks;

(II) Preparing treatment plans and calculating treatment doses and times;

(III) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(IV) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(V) Checking and using survey meters; and

(VI) Selecting the proper dose and how it is to be administered; and

2. Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in 420-3-26-.07(89), or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph 420-3-26-.07(89)(b)1.(ii); and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(89)(a)1. or (b)1. and (b)2., and (c), and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written

attestation must be signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(89), or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

APPENDIX D

QUICK REFERENCE TO REGULATIONS

- (1) Definitions - 420-3-26-.01(2)(a)
 5. Act
 8. Agency
 10. Airborne radioactive material
 11. Airborne radioactivity area
 12. As low as reasonably achievable
 18. Calender quarter
 19. Calibration
 25. Controlled Area
 47. High radiation area
 51. Individual monitoring devices
 62. Member of the public
 68. Occupational dose
 81. Radiation area
 93. Restricted area
 95. Sealed source
 106. Survey
 113. Unrestricted area
 118. Worker
- (2) Records - 420-3-26-.01(4), 420-3-26-.07(91) through (119)
- (3) License Requirement - 420-3-26-.02(2)
- (4) Types of Licenses - 420-3-26-.02(5)
- (5) General License (in vitro) - 420-3-26-.02(7)(h)
- (6) Licenses for Human Use of Radioactive Materials - 420-3-26-.02(10)(a)
- (7) Physician Licensing Requirements - 420-3-26-.02(10)(b)
- (8) Expiration and Termination of Licenses - 420-3-26-.02(13)
- (9) Renewal of Licenses - 420-3-26-.02(14)
- (10) Amendment Requests - 420-3-26-.02(15)
- (11) Transfer of Material - 420-3-26-.02(18)
- (12) Transportation of Radioactive Material - 420-3-26-.02(21),(22),(23), and (24)

- (13) ALARA - 420-3-26-.03(5)(b) and 420-3-26-.07(18)
- (14) Occupational Dose Limits - 420-3-26-.03(6)
- (15) Occupational Dose Limits to Minors - 420-3-26-.03(12)
- (16) Public Dose Limits - 420-3-26-.03(14)
- (17) Surveys and Monitoring - 420-3-26-.03(17) and (18)
- (18) Security of Stored Radioactive Material - 420-3-26-.03(25)
- (19) Control of radioactive Material not in Storage - 420-3-26-.03(26)
- (20) Posting Requirements - 420-3-26-.03(28)
- (21) Container Labeling Requirements - 420-3-26-.03(30) and 420-3-26-.07(39)
- (22) Receiving and Opening Packages - 420-3-26-.03(32)
- (23) Waste Disposal - 420-3-26-.03(33)
- (23) Disposal Into Sanitary Sewerage - 420-3-26-.03(35)
- (24) Records of Surveys - 420-3-26-.03(42) and 420-3-26-.07(100)
- (25) Records of Radiation Monitoring - 420-3-26-.03(46)
- (26) Records of Waste Disposal - 420-3-26-.03(48) and 420-3-26-.07(103)
- (27) Reports of Theft or Loss of Radioactive Material - 420-3-26-.03(51)
- (28) Notification of Incidents - 420-3-26-.03(52)
- (29) Reports of Exposures - 420-3-26-.03(53)
- (30) License Termination - 420-3-26-.03(59)
- (31) Definitions - 420-3-27-.07(2)
 - (a) Address of use
 - (b) Area of use
 - (d) Authorized medical physicist
 - (e) Authorized nuclear pharmacist
 - (f) Authorized user
 - (g) Brachytherapy
 - (h) Dedicated check source

- (l) Diagnostic clinical procedures manual
 - (o) Management
 - (r) Medical use
 - (bb) Prescribed dosage
 - (cc) Prescribed dose
 - (rr) Written directive
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- (32) Visiting Authorized User - 420-3-26-.07(12)
 - (33) Visiting Authorized Medical Physicist - 420-3-26-.07(13)
 - (34) Visiting Authorized Nuclear Pharmacist - 420-3-26-.07(14)
 - (35) Misadministrations - 420-3-26-.07(120)
 - (36) Report of Doses to Embryo/Fetus or Nursing Child - 420-3-26-.07(121)
 - (37) Posting of Notices to Workers - 420-3-26-.10(2)
 - (38) Instructions to Workers - 420-3-26-.10(3)
 - (39) Reports to Individuals - 420-3-26-.10(4)