



RHF-1M
APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
MEDICAL

INSTRUCTIONS – Complete all items in this application to apply for a new license or the renewal of an existing license. Use supplemental sheets where necessary. **Item 30 must be completed on all applications.** **US Mail to:** DOH - ORP Radioactive Materials, PO Box 47827, Olympia, Washington 98504-7827 or **Expedite to:** DOH - ORP Radioactive Materials, 111 Israel Rd SE, TC-2, Tumwater, WA 98501. Retain a copy of entire application, including attachments for your records. Upon approval of this application, a State of Washington Radioactive Material License will be issued in accordance with the general requirements contained in Washington State Department of Health, Radiation Protection Regulations, and the Washington Energy and Radiation Control Act, Chapter 70.98 RCW.

1a. NAME AND MAILING ADDRESS OF APPLICANT (Institution, Firm, Clinic, Physician, etc.) INCLUDE ZIP CODE	1b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED if different than 1a. INCLUDE ZIP CODE
2. PERSON TO CONTACT REGARDING THIS APPLICATION	TELEPHONE NO. () _____ - _____ FAX NUMBER () _____ - _____ EMAIL ADDRESS _____ WEBSITE ADDRESS _____
3. THIS IS AN APPLICATION FOR: (check Appropriate item) A. NEW LICENSE B. AMENDMENT TO LICENSE NO. WN-M _____ C. RENEWAL OF LICENSE NO. WN-M _____	
4. INDIVIDUAL USERS (If more than one will be named, complete "Authorized Use" Form)	5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as Radiation Safety Officer).

6a. RADIOACTIVE MATERIAL FOR MEDICAL USE

Radioactive Material authorized by	ITEMS DESIRED MARK "X"	MAXIMUM POSSESSION LIMIT REQUESTED (in curies)	Single procedure desired.	ITEMS DESIRED MARK "X"	MAXIMUM POSSESSION LIMIT REQUESTED (in curies)
WAC 246-240-151		As Needed	IODINE-131 as iodide for treatment of hyperthyroidism		
WAC 246-240-157		As Needed	PHOSPHORUS-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases		
WAC 246-240-201		As Needed	PHOSPHORUS-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions		
WAC 246-240-251		As Needed (Subject to Limitations)	IODINE-131 as iodide for treatment of thyroid carcinoma or hyperthyroidism.		
WAC 246-240-301		As Needed	STRONTIUM-89 as chloride for treatment of pain from cancer metastases		
WAC 246-240-351			SAMARIUM-153 for treatment of pain from cancer.		
WAC 246-240-501					
Gd-153 Sealed QA Sources					

6b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6A. (Sealed sources used for calibration and reference standards are authorized under WAC 246-240-110 and **NEED NOT BE LISTED**).

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OR BECQUERELS OF EACH FORM	DESCRIBE PURPOSE OF USE

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 29

For Items 7 through 29, check the appropriate box(es) and submit a detailed description of all the requested information. Submit signed and dated "ready made" attachments or your equivalent procedures. Begin each item on a separate sheet. ***Any electronic modifications to this "ready made" application and/or Attachments (other than in format, typographical corrections or minor editing) must be made clearly evident to the reviewer.***

- | | | |
|---|--|--|
| <p>7. RADIATION SAFETY COMMITTEE
(check one or more)
Names and Specialties Attached; and Duties in Attachment "A" or Equivalent Duties Attached</p> <p>8. RADIATION SAFETY OFFICER
(check one)
Duties in Attachment "B" or RSO C & D of Authority Attached Equivalent Duties Attached</p> <p>9. TRAINING AND EXPERIENCE
(check one or more)
Form RHF-2M completed for each individual user and/or RSO Accepted Certification Attached for each individual user and/or RSO Individual user and/or RSO named in another license (license and license number attached)</p> <p>10. INSTRUMENTATION
(check one)
Attachment "C" attached, or Equivalent list attached (list by name & model number)</p> <p>11. CALIBRATION OF INSTRUMENTS
(check two)
Attachment "D" Procedures Attached for survey instruments, or Equivalent Procedures Attached; and (check one)
Attachment "D" Procedures Attached for Dose calibrator; or Equivalent Procedures Attached</p> <p>12. FACILITIES AND EQUIPMENT
Description Attached
Diagram Attached</p> <p>13. PERSONNEL TRAINING PROGRAM
(check one)
Attachment "E" Procedures Attached for Training, or Equivalent Procedures Attached</p> <p>14. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL
(check one)
Attachment "F" Procedures Attached, or Equivalent Procedures Attached</p> | <p>15. PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL
(check one)
Attachment "G" Procedures Attached,
or
Equivalent Procedures Attached</p> <p>16. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL
(check one)
Attachment "H" Procedures Attached,
or
Equivalent Procedures Attached</p> <p>17. EMERGENCY PROCEDURES
(check one)
Attachment "I" Procedures Attached
or
Equivalent Procedures Attached</p> <p>18. AREA SURVEY PROCEDURES
(check one)
Attachment "J" Procedures Attached
or
Equivalent Procedures Attached</p> <p>19. WASTE DISPOSAL/STORAGE
(check one)
Attachment "K" Procedures Attached
or
Equivalent Procedures Attached</p> <p>20. THERAPEUTIC USE OF RADIOPHARMACEUTICALS
(check one)
Attachment "L" Procedures Attached
or
Equivalent Procedures Attached
No therapeutic use of radiopharmaceuticals
Therapy Patient Release per Regulatory Guide 8.39</p> <p>21. THERAPEUTIC USE OF SEALED SOURCES
(check one or more)
Detailed Information Attached, and (check one)
Attachment "M" Procedures Attached
or
Equivalent Procedures Attached, or
No therapeutic use of sealed sources
Therapy Patient Release per Regulatory Guide 8.39</p> | <p>22. RADIOACTIVE GAS & AEROSOL
(e.g.,Xe-133) (check one or two)

Attachment "N" Attached, or Equivalent Supporting Information Attached
No Xe-133 use
No aerosol use</p> <p>23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS
(check one)
Detailed Information Attached
No radioactive materials used in animals.</p> <p>24. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6b.
Detailed Information Attached</p> <p>25. PERSONNEL MONITORING, BIOASSAY, AND LEAK TEST PROGRAMS
(check one)
Attachment "O" Procedures Attached,
or
Equivalent Detailed Information Attached.</p> <p>26. PRIVATE PRACTICE APPLICANT PROGRAM
Detailed Information Attached</p> <p>27. "ALARA" PROGRAM (Radiation Levels As Low As Reasonably Achievable)
(check one)
Attachment "P" Procedures Attached
or
Equivalent Program Attached</p> <p>28. WRITTEN DIRECTIVE PLAN
Program Attached
N/A</p> <p>29. LICENSE FEE REQUIRED
(See WAC 246-254-080)
License Fee Category # _____
New Applicant only
License Fee Enclosed:
New Application Fee Enclosed:</p> |
|---|--|--|



**MEDICAL USE TRAINING AND EXPERIENCE
AND PRECEPTOR CERTIFICATION UNDER OATH**

PART I -- TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation specified in chapter 246-240 WAC.

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., WAC 246-240-163, WAC 246-240-210, etc.)

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

3. CERTIFICATION

- a. Provide a copy of the board certification. *(Stop here if applying under WAC 246-240-069, 246-240-072, 246-240-075, 246-240-154, 246-240-163, 246-240-210, 246-240-213, 246-240-216, 246-240-219, 246-240-278, 246-240-281, and 246-210-304, continue if applying under other sections.)*
- b. Provide documentation in where applicable for items 4 through 10, of training or clinical case work required by WAC 246-240.
- c. Provide completed Part II Preceptor Certification, Items 11a through 11d.
Stop here after completing items 3a, 3b, and 3c when using board certification to meet chapter 246-240 WAC training and experience requirements.

4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS

- a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)
- b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in WAC 246-240-069; or AU in WAC 246-240-163 or WAC 246-240-210 or WAC 246-240-278 or WAC 246-240-399; or AMP under WAC 246-240-072.
- c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in WAC 246-240-219.

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity			
Radiation Biology			
Chemistry of Radioactive Material for Medical Use			
OTHER			

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR CERTIFICATION UNDER OATH (continued)

6c. TRAINING FOR WAC 246-240-278, WAC 246-240-072, WAC 246-240-304, or WAC 246-240-399.

Training Element	Type of Training *	Location and Dates

* Types of training may include supervised (complete item 10 for WAC 246-240-069, WAC 246-240-072 and WAC 246-240-399) didactic, or vendor training.

7. FORMAL TRAINING: Physicians (for uses under WAC 246-240-251 and WAC 246-240-351) and Medical Physicists

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Numbers	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education)

8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE

YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision of _____ the RSO for License No. _____.

N/A

9. MEDICAL PHYSICIST -- ONE YEAR FULL-TIME TRAINING/WORK EXPERIENCE

YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics or medical physics (WAC 246-240-072) under the supervision of _____ who is a medical; physicist or meets the requirements for Authorized Medical Physicist (WAC 246-240-072)

N/A

and

YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) _____ under the supervision of _____ who is a medical physicist or meets requirements for Authorized Medical Physicists (WAC 246-240-072) (specify use or device)

N/A

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR CERTIFICATION UNDER OATH (continued)

10. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in chapter 246-240 WAC, provide the following information for each):

A. Name of Supervisor

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of chapter 246-240 WAC, section(s) _____

for medical uses in chapter 246-240 WAC, section(s) _____

D. Address

E. Materials License Number

PART II -- PRECEPTOR CERTIFICATION UNDER OATH

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in WAC 246-240-304.

I certify under oath that the individual named in Item 1:

11a. has satisfactorily completed the requirements in chapter 246-240 WAC, section(s) _____ as documented in section(s) _____ of this form.

11b. Select one

meets the requirements in WAC 246-240-069 WAC 246-240-072, WAC 246-240-210,

N/A WAC 246-240-399 for _____ types of use, as documented in section(s) _____ of this form.

11c.

has achieved a level of competency sufficient to operate a nuclear pharmacy (for WAC 246-240-484); **or**

has achieved a level of competency sufficient to function independently as an authorized _____ for _____ uses (or units); **or**

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation

N/A Safety Officer for a medical use licensee ; **or**

11d.

I am an Authorized Nuclear Pharmacist; **or**

I am a Radiation Safety Officer; **or**

I meet the requirements of _____ section(s) of chapter 246-240 WAC or equivalent Agreement State or U.S. NRC requirements to be a preceptor AU or AMP for the following radioactive material uses: _____

A. Address

B. Materials License Number

C. NAME OF PRECEPTOR (print clearly)

D. SIGNATURE -- PRECEPTOR

E. DATE

**Office of Radiation Protection
Washington State Department of Health**

Medical Radioactive Materials License Application

Application Index

The following documents are contained in this radioactive materials license application. The first section forms the actual license application and that original must be returned to the Office of Radiation Protection in the same order it appears here, while retaining a copy for your records.

I. RETURN THE FOLLOWING

Form RHF-1M – Application for Radioactive Material License – Medical

Form RHF-2M – Training and Experience, Authorized User or Radiation Safety Officer –
Preceptor Statement (separately, for each one proposed) - Item 9.

<u>ATTACHMENT</u>	<u>Corresponding Item Number on RHF-1M</u>
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II. RETAIN THE FOLLOWING FOR YOUR RECORDS

- A. Reg. Guide 10.8 – Instructions for the Preparation of Applications for Medical Programs
- B. Reg. Guide 8.20 – Bioassay Criteria for I-125 and I-131, as applicable.
- C. At least one copy of this completed application, including all attachments.

ATTACHMENT A

RADIATION SAFETY COMMITTEE

Responsibility

The Committee is responsible for:

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with state rules and regulations and conditions of license.
2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with state rules and regulations and conditions of the license.

Duties

The Committee shall:

1. Be familiar with all pertinent regulations, the terms of the license, and information submitted in support of the request for the license and subsequent amendments.
2. Review the training and experience of all individuals who use radioactive materials (including physicians, technologists, physicists, and pharmacists) and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with regulations and conditions of the license.
3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by WAC 246-222-030, WAC 246-240-204, WAC 246-240-263 & WAC 246-240-360, and conditions of the license.
4. Review and approve (subject to Department restrictions) all requests for use of radioactive material within the institution prior to any such use.
5. Prescribe special conditions which will be required during a proposed use of radioactive material; e.g., requirements for bioassay, physical examinations of users, special monitoring procedures, etc.
6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with ALARA concepts, state rules and regulations, and the conditions of the license. The review shall be documented and include an examination of all records, procedures, equipment, reports from the Radiation Safety Officer, results of state inspections, written safety procedures, and the adequacy of the institution's management control system.
7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
8. Maintain written records of all committee meetings, actions, investigations, recommendations, and decisions.
9. Ensure that the radioactive materials license is amended when necessary, **prior** to any changes in facilities, equipment, policies, procedures, and personnel, as specified in the license.

ATTACHMENT A (Continued)
RADIATION SAFETY COMMITTEE

Meeting Frequency

The medical isotopes committee shall meet as often as necessary to conduct its business, but not less than once each calendar quarter.

Current Membership

Name	Specialty
	Radiation Safety Officer
	Nuclear Medicine Physician
	Nuclear Medicine Representative
	Administration Representative
	Nursing Representative
	Radiation Oncology Physician or Rep
	Laboratory Representative

Approved by: _____ Date: _____

ATTACHMENT B

DUTIES OF THE RADIATION SAFETY OFFICER AND RSO CERTIFICATION AND DELEGATION OF AUTHORITY

1. Be familiar with all applicable state and federal regulations and license application guides, and assure that license applications are properly filled out and are submitted on time. Make sure that the institutional radiation use and safety programs adhere to the license and license application conditions as well as the regulations.
2. Establish and maintain record systems for all radiation area surveys, wipe tests, leak tests, calibration of instruments, and personnel dosimetry reports. Perform a documented review of records of radiation level surveys to determine that they are at ALARA levels.
3. Advise individual radiation workers of each high dosimetry report, and conduct an investigation to determine the cause of each overexposure and each high badge reading to preclude recurrence. Perform a documented review of occupational exposure to authorized users and workers to determine that the exposures are within the limits established for the ALARA program. **Annually apprise, in writing, each radiation employee of annual accrued dose.**

Ensure documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided; that documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public.

Ensure, when necessary, that personnel monitoring devices and controls are stored in the requisite low-background area, are used and exchanged at the proper intervals, and that current records of the results of such monitoring are maintained for inspection by the Department.

4. Ensure that individuals working with radiation have appropriate protective devices, including shielding, ventilation, clothing, gloves, remote handling equipment (where necessary), instrumentation, and facilities which aid in keeping exposures As Low As Reasonably Achievable (ALARA). Ensure that up-to-date radiation protection procedures in the daily operation of the licensee's radiation safety program are developed, distributed, and implemented
5. Act as liaison with regulatory authorities, be available for assistance with inspections and audits, and notify the Department:
 - A. In writing **before** making any change which would render the Application for Radioactive Materials License or the Radioactive Materials License itself no longer accurate.
 - B. **Immediately** in the event of any radiation accident or incident (**including high dosimeter reading**).
 - C. Within five days of any positive leak test result of a sealed source.
 - D. Within thirty (30) days in a report stating remedial action taken after accident or incident.
6. Perform, or cause to be performed, documented semi-annual inventories of all sealed sources received or possessed. Make sure all surveys, calibrations, and leak tests are performed on time.

ATTACHMENT B (Continued)

DUTIES OF THE RADIATION SAFETY OFFICER

7. Post conspicuously "Notice to Employees" (Form RHF-3) and notices of items of noncompliance resulting from Department inspections, as required.
8. Supply employers of terminated radiation personnel with radiation exposure records as required by regulation.
9. Establish, and cause to be maintained, inventory control of radionuclides at your institution, making sure inventory never exceeds amount licensed, and that possession, use, and storage of licensed material is consistent with the limitations of the license, the regulations, the manufacturer's recommendations and instructions, and, where applicable, provisions of the Sealed Source & Device Registry for sources possessed. Keep, or cause to be kept, records of receipts of incoming nuclides and survey of incoming and outgoing shipments. Make sure that all incoming and outgoing shipments have received documented required outgoing surveys, and are accompanied by proper shipping papers. Assure that radioactive materials are disposed of properly, and that records are maintained of all radioactive wastes disposed.
10. Perform a documented annual review of the radiation safety program for adherence to ALARA concepts. Make sure the safety program is followed by all workers dealing with radioactive material. Investigate any deviation from the program, and take any remedial action necessary.
11. Schedule briefings and educational sessions to inform workers of radiation safety rules and procedures:
 - A. For all new personnel,
 - B. With each change in license condition or safety program, and
 - C. Annually in a refresher course for all appropriate personnel.

This includes instruction in the ALARA program and philosophy.
12. Take charge in all emergency situations in the event of major or minor spills, or release of radioactive material, to make sure correct emergency decontamination and protection procedures are implemented. Evaluate the situation that led to the emergency, to reduce the chance of further problems. Ensure that proper and timely notification is provided to the Department and others of emergency situations, fire, and/or theft or loss of radioactive material.
13. Ensure that medical events and precursor events are investigated and reported to Washington State Department of Health Office of Radiation Protection, and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
14. Ensure that radioactive material and waste is both properly secured from unauthorized access at all times and properly disposed.
15. Maintain, or cause to be maintained, written records of all Radiation Safety Committee meetings, actions, recommendations, and decisions.

ATTACHMENT B (Continued)

DUTIES OF THE RADIATION SAFETY OFFICER

Delegation of Authority

Memo To: Radiation Safety Officer _____

From: Chief Executive Officer _____

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations and conditions of the radioactive materials license. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by personnel who do not meet the necessary requirements, and terminating operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Washington State Department of Health Office of Radiation Protection at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

I accept the above responsibilities,

Signature of Management Representative

Signature of Radiation Safety Officer

Management Representative Printed Name

Radiation Safety Officer Printed Name

Job Title of Management Representative

Job Title of Radiation Safety Officer

Date

Date

cc: Affected administrators / department heads as appropriate.

Approved by: _____

Date: _____

ATTACHMENT C

INSTRUMENTATION

1. **SURVEY METERS:** (Instruments generally required are a low-level survey meter for contamination surveys in CPM, and a high-level survey meter to measure radiation exposure rates in mR/hr in the vicinity of generators and therapeutic quantities of radioactive material.)

LOW-LEVEL/CONTAMINATION

A. Manufacturer's name _____

Instrument and probe(s) model(s) number(s) _____

Number of instruments available _____

Window thickness _____ mg/cm²

Minimum range _____ CPM to _____ CPM

Maximum range _____ CPM to _____ CPM

HIGH-LEVEL DOSE RATE

B. Manufacturer's name _____

Instrument and probe(s) model(s) number(s): _____

Number of instruments available _____

Wall thickness _____ mg/Cm²

Minimum range _____ mR/hr to _____ mR/hr

Maximum range _____ mR/hr to _____ mR/hr to _____ R/hr

2. **Dose calibrator**

Manufacturer's name & model number _____

Number of instruments available _____

3. **Instruments used for diagnostic procedures** (gamma camera, uptake monitoring equipment, etc.)

<u>Type of Instrument</u>	<u>Manufacturer's Name</u>	<u>Model No.</u>
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_____	_____	_____
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_____	_____	_____
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4. **Other** (e.g., liquid scintillation counter, area monitor, velometer)

Approved by: _____ Date: _____

ATTACHMENT D

Section 1

CALIBRATION OF EXPOSURE RATE AND CONTAMINATION INSTRUMENTS (DOES NOT INCLUDE POCKET DOSIMETERS OR CHIRPERS)

1. Calibration of survey meters shall be performed with radionuclide sources.

- A. The sources shall approximate point sources for dose rate instruments and planchet sources for beta detectors.
- B. The source activities, exposure rates, or beta emission rates at given distances shall be traceable by documented measurements to a standard source certified within five percent accuracy by the National Institute of Standards and Technology (NIST, formerly NBS).
- C. The frequency shall be at least every 12 months and after servicing.
- D. Each scale of the instrument shall be calibrated for at least at two points located at approximately 1/3 and 2/3 of full scale.
- E. The exposure rate (mR/hr) for dose rate instruments measured by the instrument shall differ from the true exposure rate by less than 10 percent at the two points on each scale (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration). Readings within ± 20 percent will be considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret meter readings to within 10 percent accuracy for radiation protection purposes.

Beta efficiency determination shall be used for calibration of contamination survey instruments.

- F. Records of required calibrations shall be maintained for inspection for a period of at least two years from the date of calibration.

NOTE: Sources of Cs-137, Ra-226, or Co-60 * are appropriate for use in dose rate calibrations. Since these sources emit rather high-energy photons, they are not suitable for low-energy or beta efficiency calibrations which may be required under special circumstances (see Item 3 below). The activity of the calibration standard should be sufficient to calibrate the survey meter on each scale to be used for radiation protection purposes. Scales up to 1 R/hr should be calibrated, but higher-range scales above 1 R/hr need not be calibrated when they will not be needed for radiation protection surveys. If there are higher ranges, they should at least be checked for operation and approximately correct response to radiation. Otherwise, a cautionary note that they have not been checked should be placed on the instrument.

2. A reference check source of long half-life, e.g., Cs-137 or Ra-226, shall also be read at the time of the above calibration or as soon as the instrument is received from a calibration vendor. The readings shall be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source shall be taken:

- A. Before each use to ensure that the instrument was operational during the survey.
- B. After each maintenance and/or battery change.
- C. At least every three months.

If any reading using the same geometry is not within ± 20 percent of the reading measured immediately after calibration, the instrument must be recalibrated immediately (see Item 1).

* Minimum activities of typical dose rate sources are 85 mCi of Cs-137, 21 mCi of Co-60, or 3-4 mCi of Ra-226 (to give at least 700 mR/hr at 20 cm).

ATTACHMENT D (Section 1) (Continued)

**CALIBRATION OF EXPOSURE RATE AND CONTAMINATION INSTRUMENTS
(DOES NOT INCLUDE POCKET DOSIMETERS OR CHIRPERS)**

These procedures and standards are not appropriate for instruments used to detect or quantify measurements in the I-125 (approximately 30 KeV) energy range.

3. **Calibration source energies must correspond to energies of radioactive materials to be detected** if instrument response is energy dependent, and if the instrument is to be used for quantitative measurements in the Xe-133 or Tc-99m energy ranges.

The calibration may be done either:

- A. As in Item 1 above, with NIST-traceable calibration standards of radionuclides at or near the desired energies, or
- B. As a relative intercomparison with an energy-independent instrument and unassumed or uncertified radionuclides.

Alternatively, the manufacturer's energy response curve(s) may be used to correct instrument readings appropriately when lower-energy radiation is monitored.

4. Records of the above Items shall be maintained for inspection.

5. **Use of Inverse Square Law and Radioactive Decay Law**

- A. An approved calibration source will have a calibration certificate giving its exposure or beta emission rate at a given distance, or its activity, measured on a specified date by the manufacturer or NIST.

- (1). The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.
- (2). The Radioactive Decay Law may be used to calculate the exposure rates or source activities at times other than the calibration date.

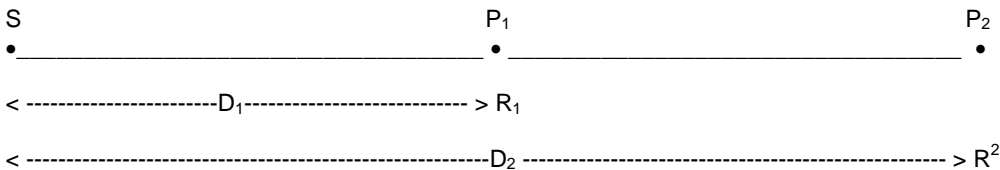
B. **Inverse Square Law For Dose Rate Calibrations**

Consider a "point" * source of radiation at position S, as shown in Figure D-1. Then, the relationship between exposure rates R_1 and R_2 at detector positions P_1 and P_2 , which are at distances D_1 and D_2 and S, respectively is given by the following equation:

$$R_2 = \frac{D_1^2}{D_2^2} \times R_1$$

Where R_1 and R_2 are exposure rates in the same units (e.g., mR/hr, R/hr) and D_1 and D_2 are the distances in Figure D-1 in the same units (e.g., m, cm, ft).

FIGURE D-1



ATTACHMENT D (Section 1) (Continued)

**CALIBRATION OF EXPOSURE RATE AND CONTAMINATION INSTRUMENTS
(DOES NOT INCLUDE POCKET DOSIMETERS OR CHIRPERS)**

C. Radioactive Decay Law

Exposure rate “t” units of time after specified calibration date

$$R_t = R_o \times e - \frac{(0.693)}{T_{1/2}} \times t$$

Where

R_o and R_t are in the same units (e.g., mR/hr or R/hr)

R_o is exposure rate on the specified calibration date.

R_t is exposure rate t units of time later

$T_{1/2}$ and t are in the same units (years, months, days, etc.)

$T_{1/2}$ is the radionuclide half-life.

t is number of units of time elapsed between calibration and present time.

D. **Example** Source output is given by calibration certificates as 100 mR/hr at 1 foot on March 10, 2005. Radionuclide half-life is 5.27 years.

Question What is the output at 3 feet on March 10, 2007 (2.0 years later)?

(1). Output at 1 foot, 2.0 years after calibration date:

$$R = 100 \text{ mR/hr} \times e - \frac{(0.693 \times 2.0)}{5.27}$$

$$= 100 \times 0.77 = 77 \text{ mR/hr at 1 foot on March 10, 2007.}$$

(2). Output at 3 feet, 2.0 years after calibration date:

$$R_3 = \frac{(1 \text{ ft})^2}{(3 \text{ ft})^2} \times 77 \text{ mR/hr}$$

$$= 1/9 \times 77 = 8.6 \text{ mR/hr at 3 feet, 2.0 years after calibration.}$$

* A Source may be considered a “point” source when the source and the radiation detector are small, in any dimension, compared to the distances at which radiation is to be measured. The center of the detector should be at distances D_1 or D_2 as shown in Figure D-1

Approved by: _____

Date: _____

ATTACHMENT D (Section 1) (Continued)

**CALIBRATION OF EXPOSURE RATE AND CONTAMINATION INSTRUMENTS
(DOES NOT INCLUDE POCKET DOSIMETERS OR CHIRPERS)**

CALIBRATION CHECK SHEET

Check appropriate items.

- 1. **Survey instruments will be calibrated at least every 12 months and immediately following repair.**
- 2. **Calibration will be performed at two points on each scale** used for radiation protection purposes; i.e., at least up to 1R/hr for dose rate.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ± 10 percent. When higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated:

A. By the manufacturer

B. By the licensee

(1) Calibration source(s)

Manufacturer's name _____

Model No. _____

Activity in millicuries _____

OR

Exposure rate at a specified distance _____

Accuracy _____

Traceability to primary NIST standard _____

(2) The calibration procedures in Attachment D, Section 1 will be used

OR

(3) The step-by-step procedures, including radiation safety procedures, are attached.

C. By a consultant or outside vendor.

(1) Name & License Number _____

(2) Address _____

(3) Phone Number _____ E-Mail _____

SAMPLE FORM
“CERTIFICATE OF INSTRUMENT CALIBRATION”

Licensee Name _____

Instrument:

Probe (if detachable):

Manufacturer _____

Manufacturer _____

Type _____

Type _____

Model No. _____

Model No. _____

Serial No. _____

Serial No. _____

Calibration Data:

Scale	Actual Exposure or Beta Emission Rate (mR/hr or CPM)	Initial Instrument Reading (mR/hr or CPM)	% Error	Adjusted Instrument Reading (mR/hr or CPM)	Final % Error

Replace Batteries? Yes No

Comments:

Calibration Source:

Manufacturer/Model No. _____ Serial No. _____

Nuclide _____ Accuracy _____ Original Activity/Date _____ / _____

Decay Factor _____ Current Activity _____

Exposure Rate at Specified Distance _____

CALIBRATED BY: _____ DATE: _____

ATTACHMENT D

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR *

All radiopharmaceuticals must be assayed for conformance of the activity to the prescribed dose to an accuracy of 20 percent. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

1. Test for the following:

- A. Instrument constancy (daily)
- B. Instrument accuracy (upon installation and annually thereafter)
- C. Instrument linearity (upon installation and quarterly thereafter)
- D. Geometrical variation (upon installation and after repair)

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

3. Test for Instrument Constancy

Instrument constancy means that there is reproducibility, within a stated degree of precision, in measuring a constant activity over time. Assay at least one relatively long-lived reference source such as Cs-137, Co-57, or Ra-226 using a reproducible geometry before each day's use of the instrument. Preferably, at least two reference sources (for example, 3-5 mCi/111-175 megabecquerels of Co-57 and 100-200 μ Ci/3.7-7.4 megabecquerels of Cs-137, or 1-2 mg/37-74 megabecquerels Ra-226 (with appropriate decay corrections)) will be alternated each day of use to test the instrument's performance over a range of photon energies and source activities.

- A. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).
- B. Measure background level at same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.
- C. Calculate net activity of each source, subtracting out background level.
- D. Indicate the predicted activity of each source based on decay calculations and the ± 5 percent limits on the graph (as deemed necessary by the licensee.)
- E. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.

* See ANSI N42.13-2004 "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides" (American National Standards Institute, Inc., 25 West 43rd Street, New York, NY 10036).

Attachment D (Section 2) (Continued)
METHODS FOR CALIBRATION OF DOSE CALIBRATOR *

- F. **Variations greater than ± 5 per cent from the predicted activity indicate the need for instrument repair or adjustment.**

Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

4. **Inspect the instrument on a quarterly basis** to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see Manufacturer's Instructions).

5. **Test of Instrument Linearity**

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will use a vial of Tc-99m whose activity is equivalent to the **maximum** anticipated activity to be assayed (**i.e., the first elution from a new generator or largest unit dose/multi-dose measured.**)

- A. Assay the Tc-99m vial in the dose calibrator, and subtract background level to obtain net activity in millicuries or becquerels.
- B. Repeat Step 5.A at time intervals of 6, 24, 30, and 48 hours after the initial assay.
- C. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay Time* (hr)	Correction Factor
0	31.633
6	15.853
24	1.995
30	1
48	0.126

Example: If the net activity measured at 30 hours was 15.625 mCi (578.1 megabecquerels), the calculated activities for 6 and 48 hours would be $15.625 \text{ mCi} \times 15.853 = 247.7 \text{ mCi}$ (9.165 gigabecquerels) and $15.625 \text{ mCi} \times 0.126 = 1.97 \text{ mCi}$ (72.89 megabecquerels), respectively.

- D. On log-log coordinate paper, plot the measured net activity (for each time interval) versus the calculated activity (for the same time interval),
- E. The activities plotted should be within ± 5 percent of the calculated activity of the instrument is linear and functioning properly. **(ERRORS GREATER THAN ± 5 PERCENT INDICATE THE NEED FOR REPAIR OR ADJUSTMENT OF THE INSTRUMENT.)**
- F. If instrument linearity cannot be corrected, it will be necessary in routine assays to use either
- (1). an aliquot of the eluate that can be accurately measured, or
 - (2). the graph constructed in Step 5.D to relate measured activities to calculated activities.

NOTE: The "Calicheck" or "Lineator" systems may be used in lieu of the serial decay method above.

* Assay times should be measured in whole hours and correction factors should be used to the third decimal place as indicated. $T_{1/2} = 6.02$ hours has been used in calculating these correction factors.

Attachment D (Section 2) (Continued)
METHODS FOR CALIBRATION OF DOSE CALIBRATOR *

6. 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 ± 2 percent. *(Even though correction factors may be provided by the manufacturer, the accuracy of these should be checked.)* When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

To measure variation with volume of liquid, a 30-cc vial containing 2 mCi (74 megabecquerels) of Co-57 or other appropriate radionuclide in a volume of 1 ml will be used.

- A. Assay vial at the appropriate instrument setting, and subtract background level to obtain net activity.
- B. Increase the volume of liquid in the vial by steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake the vial to mix the contents and assay as in Step 6.A. **(Follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)**
- C. 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, 2.02 and 2.00 mCi are measured for 4, 8 and 10 ml volumes and 10 ml is the reference volume selected.

$$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

- D. 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.
- E. The true activity of sample is calculated as follows:

True Activity = Measured Activity x Correction Factor

Where the correction factor used is for the same volume and geometrical configuration as the sample measured.
- F. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial, and a correction factor may be calculated.
- G. **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.

Attachment D (Section 2) (Continued)
METHODS FOR CALIBRATION OF DOSE CALIBRATOR *

An alternative 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).

7. Test for Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides, including Cs-137, and Ba-133, using appropriate reference standards whose activities have been calibrated by comparisons with standard sources that have been assayed by NIST and documented.

The activity levels of the reference sources used should approximate those levels normally encountered in clinical use (e.g., Co-57, 3-5 millicuries/111-175 megabecquerels) giving adequate attention to source configuration. Identify in your application the three sources that you will use. State nuclide, activity, and calibration accuracy. The lower-energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples, to be measured for the best accuracy.

- A. Assay the reference standard in the dose calibrator at the appropriate setting, and subtract the background level to obtain the net activity.
- B. Repeat Step 7.A for a total of three (3) determinations, and then average the results.
- C. The average activity determined in Step 7.B should agree with the certified activity of the reference source within ± 5 percent after decay corrections.
- D. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.
- E. Keep a log of these calibration checks.
- F. **Calibration checks that do not agree within ± 5 percent 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 radionuclides.
- G. At the same time the instrument is being initially calibrated at the licensee's facility with the reference standards, place a long-lived source in the calibrator, set the instrument, in turn, to the various radionuclide settings to be used (Cs-137, I-131, Tc-99m, I-125, etc.) and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more reference standards. **Keep a log of these initial and subsequent readings.**

Attachment D (Section 2) (Continued)
CALIBRATION OF DOSE CALIBRATOR

1. Sources Used for Linearity Test

(Check as appropriate)

- Entire** first elution from new Mo-99/Tc-99m generator
- _____ **mCi of Tc-99m**

OR

- Other * (specify) _____

2. Sources Used for Instrument Accuracy and Constancy Tests

<u>Radionuclide</u>	<u>Suggested Activity in mCi</u>	<u>Activity</u>	<u>Accuracy</u>
Co-57	3-5 (111-175 megabecquerels)	_____	_____
Ba-133	0.1-0.5 (3.7-18.5 megabecquerels)	_____	_____
Cs-137	0.1-0.2 (3.7-7.4 megabecquerels)	_____	_____
Ra-226	1-2 (37-74 megabecquerels)	_____	_____
_____ Other		_____	_____

3. The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator.

OR

- Equivalent procedures are attached.

* For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equal to the highest activity assayed.

Attachment D

Section 3

DIAGNOSTIC INSTRUMENT CALIBRATION AND QUALITY CONTROL PROGRAM

INSTRUMENT	TEST/PROCEDURE	FREQUENCY
	Camera Uniformity	Daily
	Camera Resolution	Weekly
	Camera Center of Rotation	Per Manufacturer
	Camera Resolution	Per Manufacturer
	Camera Uniformity	Per Manufacturer

Approved By: _____ Date: _____

ATTACHMENT E

PERSONNEL TRAINING PROGRAM

1. The Radiation Safety Officer or (designee's title) _____ shall **provide instruction to radiation workers** prior to working with radioactive material. Instruction shall include, but is not limited to:
 - A. General radioactive safety rules.
 - B. Personnel monitoring program (e.g., use, exchange, storage, records, and reports).
 - C. Radiation and contamination survey program.
 - D. Accident, incident, and emergency procedures.
 - E. Radioactive materials work procedures.
 - (1) Ordering, receipt, and opening procedures.
 - (2) Storage.
 - (3) Dispensing (including Molybdenum contamination tests for Molybdenum 99/Technetium 99m generators, if used).
 - (4) Administration.
 - (5) Waste packaging and storage.
 - (6) Transportation procedures.
 - F. Applicable state and federal rules and regulations and license conditions.
 - G. Appropriate phone, pager, etc. contact numbers for expeditious contact with the RSO.

2. The Radiation Safety Officer or (designee's title) _____ shall **provide instruction to ancillary personnel**, such as clerical, nursing, housekeeping, and security personnel, whose duties may require them to work in the vicinity of radioactive material. The instruction shall include, but not be limited to:
 - A. All terms of the license pertinent to radiation safety.
 - B. Identification of areas where radioactive material is used or stored.
 - C. Potential hazards associated with radioactive material.
 - D. Radiological safety procedures appropriate to their respective duties.
 - E. Pertinent state and federal regulations.
 - F. Rules and procedures of the license.
 - G. Obligation to report unsafe conditions to the Radiation Safety Officer.
 - H. Appropriate response to emergencies or unsafe conditions.
 - I. Right to be informed of their radiation exposure and bioassay results.

ATTACHMENT E (Continued)

PERSONNEL TRAINING PROGRAM

J. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by WAC 246-020.

K. Appropriate phone, pager, etc. contact numbers for expeditious contact with the RSO.

The Radiation Safety Officer shall verify that personnel shall be properly instructed before assuming duties with, or in the vicinity of, radioactive materials, during annual refresher training, and whenever there is a significant change in duties, regulations, or terms of the license.

Approved By: _____ Date: _____

ATTACHMENT F

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL

1. An Authorized Nuclear Medicine Technologist will place all orders for radioactive materials and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
2. A system for ordering and receiving radioactive material will be established and maintained. The system will consist minimally of the following:
 - A. Ordering of routinely used materials:
 - (1) Written records that identify the nuclide, compound, activity levels, and supplier, etc., will be used.
 - (2) The written records will be referenced when opening or storing radioactive shipments.
 - B. Ordering of specially used materials (e.g., therapeutic doses)
 - (1) A written request * will be obtained from the physicians who will perform the procedure.
 - (2) Persons ordering the materials will reference the authorized user's written request when placing the order. The physician's request will indicate nuclide, compound, activity level, etc.
 - (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.
 - C. Written records will be maintained for all ordering and receipt.
3. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.
4. During off-duty hours, if packages are not delivered directly to the locked Nuclear Medicine Department delivery area, security personnel or other designated individuals will accept delivery of packages containing radioactive material in accordance with the procedures outlined in the sample memorandum on the following page.

* In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to administration.

SAMPLE * MEMORANDUM

“PACKAGE RECEIPT”

TO: Security personnel _____

FROM: Administrator _____

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive between 4:30 p.m. and 7:00 a.m. or on Sundays shall be signed for by the security guard on duty and be taken immediately to the Nuclear Medicine Department. Unlock the door, place the package **on top of the counter immediately to the right of the door**, and relock the door.

IF THE PACKAGE IS WET OR APPEARS TO BE DAMAGED, **immediately** contact the hospital Radiation Safety Officer. **Ask the carrier to remain** at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: _____

OFFICE PHONE: _____

HOME PHONE: _____

* Submit a copy of your own facility's memorandum, revised, as appropriate.

APPROVED BY: _____ DATE: _____

ATTACHMENT G

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in WAC 246-221-160 (more than 20 Ci/740 gigabecquerels) for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within three hours of receipt if received during working hours, or within 18 hours if received after working hours, in accordance with the requirements of WAC 246-221-160 **All shipments of liquids greater than exempt quantities will be tested for leakage.** The Department will be notified in accordance with the regulations if removable contamination exceeds 0.01 μCi or 370 becquerels per 100 cm^2 , or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1m).
2. **FOR ALL PACKAGES, the following additional procedures for opening packages will be carried out.**
 - A. **Put on gloves to prevent hand contamination.**
 - B. **Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.**
 - C. **Measure exposure rate** at 3 feet (or 1m) from package surface and **record**. If reading is greater than 10 mR/hr, stop procedure and notify Radiation Safety Officer.
 - D. **Measure surface exposure rate** and **record**. If reading is greater than 200 mR/hr, stop procedure and notify Radiation Safety Officer.
 - E. **Open the package** with the following precautionary steps:
 - (1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.
 - (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition,* packing slip, and label on container.
 - (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
 - (4) Check also that shipment does not exceed possession limits.
 - F. **Wipe external surface of final source container** and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., μCi or $\text{Bq}/100 \text{ cm}^2$, etc.). Check wipes with a thin end-window or pancake G-M survey meter, and take precautions against the spread of potential contamination as necessary.

* In the case of special order, also compare with authorized user's written request.

ATTACHMENT G (Continued)

**PROCEDURES FOR SAFELY OPENING PACKAGES
CONTAINING RADIOACTIVE MATERIAL**

G. **Monitor the packing material and packages** for contamination before discarding.

- (1) **If contaminated**, treat as radioactive waste.
- (2) **If not contaminated**, obliterate or remove radiation labels before discarding in regular trash.
- (3). **Maintain records of the results** of checking each package, using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

Approved by: _____ --- Date: _____

Attachment G (Continued)
SAMPLE

"RADIOACTIVE PACKAGE RECEIPT RECORD"

1. P.O. No. _____ Survey Date _____ Time: _____

Surveyor _____

Survey Instrument, serial #, and most recent calibration date _____

2. **Condition of Package**

O.K. Punctured Wet Crushed

(Other)

3. Radiation Units of Label (T.I.): _____ (mR/hr)

4. Label: White-I Yellow-II Yellow-III

5. **Measured Radiation Levels**

A. Package surface _____ mR/hr

B. 3 feet or 1 meter from surface _____ mR/hr

6. Do packing slip and vial contents agree?

A. Radionuclide _____ yes _____ no, difference _____

B. Amount _____ yes _____ no, difference _____

C. Chem Form _____ yes _____ no, difference _____

7. **Wipe results**

A. Outer _____ NET CPM (x EFF: _____) = _____ DPM

B. Final source contained _____ NET CPM (x EFF: _____) = _____ DPM

8. **Survey results of packing material and cartons** _____ CPM

Background is _____ CPM

9. **Disposition of package after inspection** _____

10. If Department/carrier notification required, give time, date and persons notified.

Approved By: _____ Date: _____

ATTACHMENT H

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

Check appropriate boxes which apply to, and will be used at, your facility.

- 1. Wear laboratory coats or other protective clothing at all times in areas where dispersible radioactive material is used.
- 2. Wear disposable gloves at all times while handling dispersible radioactive materials.
- 3. Monitor hands and clothing for contamination after each procedure or before leaving the immediate area.
- 4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances, such as pediatric cases, when their use would compromise the patient's well-being. In these cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).
- 5. A. Do not eat, drink, smoke, chew, or apply cosmetics in any area where radioactive material is stored or used.
B. Do not store food, drink, or personal effects with radioactive material (e.g., in refrigerator).
- 6. A. Assay each patient dose in the dose calibrator prior to administration. Do not use any dose which differs from the prescribed dose by more than 20 per cent. **Note:** Unit doses of beta-emitting radionuclides which have been assayed by the nuclear pharmacy within 12 hours prior to actual administration need only a copy of that pharmacy assay.
B. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity versus the order written by the physician who will perform the procedure.
- 7. Wear personnel monitoring devices (film badge, TLD, OLD, etc.) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level (or on fingers). Personnel monitoring devices when not being worn to monitor occupational exposure must be stored in a designated low-background area, as must the controls for such devices
- 8. Wear extremity dosimetry during elution of generator, and preparation, assay, and injection of radiopharmaceuticals.
- 9. Dispose of radioactive waste only in specially designated drains or properly shielded and labeled receptacles.
- 10. Never pipette by mouth.
- 11. Survey laboratory work area for contamination after each procedure or at the end of the day. Decontaminate as necessary.
- 12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, as applicable.
- 13. Always transport radioactive material in shielded containers.

Approved by: _____

Date: _____

ATTACHMENT I

EMERGENCY PROCEDURES

MINOR SPILLS

1. **Notify** – Notify persons in the area that a spill has occurred.
2. **Prevent the spread** – Cover the spill with absorbent paper.
3. **Clean up** – Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.
4. **Survey** – With a low-range, thin-window G-M survey meter, check the area around the spill, feet, hands, and clothing for contamination.
5. **Report** – Report incident to the Radiation Safety Officer.

MAJOR SPILLS

1. **Clear the area** – Notify all persons not involved in the spill to vacate the room.
2. **Prevent the spread** – Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all potentially contaminated personnel to prevent the spread.
3. **Shield the source** – If possible, the spill should be shielded, but only if it can be done without further contamination and without significantly increasing your radiation exposure.
4. **Close the room** – **Leave the room and lock the door(s) to prevent entry.**
5. **Call for help** – Notify the Radiation Safety Officer immediately.
6. **Personnel Decontamination** - Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water, then resurvey. Repeat as necessary.

Radiation Safety Officer _____

Office Phone _____

Home Phone _____

LOSS, THEFT, FIRE, EXPLOSION, OR VEHICLE ACCIDENT

Follow the procedures outlined in the Washington State Department of Health Radiation Emergency Handbook. Principally this shall include:

1. **Secure the area around the accident. Keep unauthorized people away. Alert people in vicinity of the presence of radioactivity and a possible hazard.**
2. **Do not leave the site** - Send a helper or onlooker to notify the following:
 - A. Radiation Safety Officer _____
Work phone _____ Home phone _____

ATTACHMENT I (Continued)

EMERGENCY PROCEDURES

B. Local Police _____

C. Local Fire Department, where applicable _____

3. The Radiation Safety Officer, in turn, must immediately notify the State of Washington, Radiation Emergency Response (206) 682-5327, which is

(206) N-U-C-L-E-A-R

and other local authorities as indicated.

4. The radiation worker should inform emergency workers of the radiation hazard possibly existing, should help them keep the area secure, and should explain to the emergency personnel the location of the radioactive device or chemical and the extent of the possible hazard. **In no case should the radiation worker leave the site** until qualified experts arrive, unless, of course, the operator is seriously injured or incapacitated, and must be removed from the site by emergency personnel for medical treatment.

Alternate names and telephone numbers designated by Radiation Safety Officer.

_____	_____
_____	_____
_____	_____
_____	_____

Approved by: _____

Date: _____

ATTACHMENT J

AREA SURVEY PROCEDURES

1. **All nuclear medicine elution, preparation, and injection areas will be surveyed daily** with an appropriate low-range survey meter and decontaminated if necessary.*
2. **Non-Nuclear Medicine Laboratory areas** where only small quantities of radioactive material are used (less than 100 Ci/7.4 megabecquerels) **will be surveyed monthly**.
3. **Waste storage areas and all other non-nuclear medicine laboratory areas will be surveyed weekly**.
4. **The weekly and monthly surveys will consist of:**
 - A. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.05 mR/hr.

AND/OR

- B. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 1000 dpm per 100 cm² for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.
5. A permanent record will be kept of **all survey results, including negative results**. The record will include:
 - A. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.05 mR/hr (for weekly surveys).
 - B. **Daily contamination survey results in CPM or DPM.**
 - C. Clearly legible name of person conducting the survey.
 - D. Drawing of the area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
 - E. Measured exposure or count rates including background values, keyed to locations on drawing. Identification of survey meter(s) used by serial number, including probes, and date of most recent calibration.
 - F. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective actions, and any appropriate comments.
6. Area will be cleaned if the contamination level exceeds 1000 dpm/200 cm².

* For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, the identification of survey instrument used, and the survey results (including background) will be recorded.

Approved by: _____

Date: _____

ATTACHMENT K

WASTE STORAGE AND DISPOSAL

Note: Licensees are encouraged to reduce the volume of waste sent to shallow-land burial sites used by commercial waste disposal firms. Important steps in volume reduction are to segregate radioactive from non-radioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials into the sanitary sewer in accordance with WAC 246-221-190.

1. A. **Liquid waste** will be disposed (check as appropriate):

- In the sanitary sewerage system in accordance with WAC 246-221-190
- By commercial waste disposal service (see Item 1.D.). **
- Other (specify): _____
- N/A, no liquid waste will be disposed (except patient excreta)

B. **Mo-99/Tc-99m generators** will be (check as appropriate):

- Returned to the manufacturer for disposal.
 - Held for decay * until radiation levels with all shielding removed, as measured in a low background area with a low-level survey meter, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed in normal trash. **
 - Disposed by commercial waste disposal service (see Item 4). ***
 - N/A, no generator use is planned.
 - Other (specify): _____
-

* Be sure waste storage areas are diagrammed and described in Item 12, and are surveyed as required by Attachment J.

** Generators may contain long-lived radioactive contaminants. Therefore, the generator columns will be segregated.

*** If US Ecology waste disposal site in Richland is to be used, a Washington State site use permit is required prior to disposal. (Call 360-407-6000, at the Washington State Department of Ecology, for application.)

ATTACHMENT L

RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USE OF RADIOPHARMACEUTICALS

1. All patients treated with unsealed radiopharmaceuticals, (such as I-131) in quantities sufficient to require hospitalization will be placed in a private room that has a toilet. The large surfaces in the room and toilet area which are more likely to be contaminated will be covered with absorbent pads or protective material as appropriate to the amount of contamination to be expected. Special attention should be given to objects likely to be touched by the patient, e.g., telephones, doorknobs, and other items that are difficult to decontaminate. Plastic bags or wrappings that are waterproof and easily disposable should be used on the smaller items.

NOTE: It is understood that certain patients may be treated with quantities of therapeutic radioactive material which until recently would have required hospitalization but whom now may be released from the control of the medical institution/facility while still containing quantities of radioactive material in excess of Table 1 values of Regulatory Guide 8.39, "Release of Patients Containing Radioactive Material" In such cases, compliance with appropriate sections of that guide must be documented for inspection by the Department.

The Department believes one of the most important protocols for early release of patients is the application of a critical and active screening process to determine which patients are, and are not, suitable for such early release.

The procedures in this Attachment are for those who fail such screening and who must remain hospitalized in accordance with the quantities of radioactive material specified in Table 1 of Regulatory Guide 8.39., and for any other patients whom the prescribing physician believes should remain hospitalized until levels are low enough (e.g. less than 33 millicuries of Iodine-131) to warrant discharge.

2. The patient's room will be properly posted or attended in accordance with WAC 246-221-120 and WAC 246-221-130.
3. Dose rate surveys of the patient's room **and surrounding areas** will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured in circumjacent rooms, at the patient's bedside, and 3 feet (1 m) from the patient and at the entrance to the room. If a movable shield is also used, measurements will be taken and recorded with and without the shield in place. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times on the patient's chart and on their door. The results of daily surveys will be used to recalculate permitted times, which will be posted on the patient's chart and on their door.
4. The form "Nursing Instructions for Patients Treated with Iodine 131 or Other Radiopharmaceuticals" (or a similar form containing all the requested information) will be completed **immediately after administration** of the treatment dose. A copy will be posted with or in the patient's chart.
5. Radiation levels in unrestricted areas will be maintained below the limits specified in WAC 246-221-060.
6. All linens will be surveyed for contamination before being removed from the patient's room and if necessary, will be held for decay.
7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated and labeled container. The material will be **collected daily** by the Radiation Safety Officer or his designee, checked for contamination and contamination survey results recorded, and disposed as normal or radioactive waste, as appropriate.
8. Non-disposable items used for these patients will be held in plastic bags in the patient's room and will be checked for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use, held for decay, or decontaminated, as appropriate.
9. If urine or emesis from therapy patients is collected, it will be stored for decay in the radioactive waste storage area. Such stored wastes will be retained until they have reached background levels as measured with a low-level survey meter. They will then be released to the sanitary sewerage system.

ATTACHMENT L (Continued)

RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USE OF RADIOPHARMACEUTICALS

10. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination, decontaminated as necessary, all radioactive waste and waste containers removed, and documentation completed and maintained.
11. **Nursing Instructions**
 - A. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these restrictions before caring for patients. **Call the Nuclear Medicine Department or the Radiation Safety Officer with any questions about the care of these patients.** Nursing personnel who attend the patient will wear personnel monitoring devices as advised by the Radiation Safety Officer or required by the license or regulations.
 - B. Visitors will be limited to those 18 years of age or over unless other instructions by the physician are noted on the precaution sheet on the patient's chart.
 - C. Patients must remain in bed while visitors are in the room, and visitors should remain at least 3 feet (and behind any shielding present) from the patient.
 - D. Patients containing radioactive material are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department or RSO.
 - E. **No nurse, visitor, or attendant who is pregnant or nursing shall be permitted in the room of a patient who has received a therapeutic amount of radioactive material until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant or nursing.**
 - F. **Attending personnel** should wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins, or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. **Gloves should be left in the patient's room in the designated waste container.** These gloves need not be sterile or surgical in type.
 - G. **Disposable items** should be used in the care of these patients, whenever possible. These items hold be placed in the designed waste container. Contact the radiation Safety Officer of their designee for proper disposal of the contents of the designed waste container.
 - H. **All clothes and bed linens** used by the patient should be placed in the laundry bag provided and left in the patient's room to be checked by the Radiation Safety Officer or their designee.
 - I. **All non-disposable items** should be placed in a plastic bag and left in the patient's room to be checked by the Radiation Safety Officer or their designee.
 - J. **Surgical dressings** should be changed only as directed by the physician. Leaking from a puncture wound may stain the dressing dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or their designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.
 - K. **FOR I-131 PATIENTS**
 - (1) The sanitary sewer will be used for disposal of patient excreta. The toilet should be flushed several (3 or 4) times after each use. If the patient is bedridden, a separate urinal or bedpan should be flushed several times with hot soapy water after each use.

ATTACHMENT L (Continued)

**RADIATION SAFETY PROCEDURES FOR
THERAPEUTIC USE OF RADIOPHARMACEUTICALS**

- (2) If the nurse helps to collect the excreta, disposable gloves should be worn. Afterward, hands should be washed with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste container for disposal by the Radiation Safety Officer or his designee.
- (3) Patients treated with I-131 will use disposable plates, cups, and eating utensils.
- (4) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and floor. **In any situation where the patient's room may be contaminated or if radioactive urine and/or feces is spilled, call the Radiation Safety Officer or their designee, telephone: _____**. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.
- (5) Keep all contaminated wastes and vomitus in plastic bags in the patient's room for disposal by the Radiation Safety Officer or their designee. Feces need not be routinely saved unless ordered on the chart. The same toilet should be used by the patient at all times and should be well flushed (3 times,) after each use. The Radiation Safety Officer will establish procedures for disposal of wastes (see Item 12 below).
- L. If a nurse, attendant, or anyone else knows or suspects that their skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer or his designee immediately. This person should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.
- M. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or their designee or the Nuclear Medicine Department immediately.
- N. When the patient is discharged, call the Radiation Safety Officer, or designee, or the Nuclear Medicine Department and request that the room be surveyed for contamination and released for use before re-making the room.

12. WASTE DISPOSAL

When contaminated wastes are transported to the Waste Storage/Disposal Area, precautions will be taken to minimize external irradiation of personnel. Stored wastes will be shielded to maintain exposure to personnel in restricted and unrestricted areas as low as reasonably achievable (ALARA).

Approved by: _____

Date: _____

Attachment L (Continued)

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH IODINE 131, OR OTHER RADIOPHARMACEUTICALS

Patient's Name _____

Room No. _____ Physician's Name _____

Radionuclide Administered _____

Location of Administration and Name of Actual Administrator _____

Date and Time of Administration _____

Dose Received _____ Method of Administration _____

Exposure Rates in mR/hr
(indicate shielded/unshielded status of measurements)

<u>Date</u>	<u>Instrument Used</u> (include serial number)	<u>10 feet</u> <u>from bed</u>	<u>3 feet</u> <u>from bed</u>	<u>Bedside</u>	<u>Adjacent</u> <u>Rooms</u>	<u>Surveyor</u>
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____

COMPLY WITH ALL CHECKED ITEMS)

- 1. Visiting time permitted _____
- 2. Visitors must remain _____ feet from patient.
- 3. Patient may not leave room.
- 4. Visitors under 18 are not permitted.
- 5. Pregnant or breastfeeding visitors are not permitted.
- 6. Personnel dosimetry must be worn as required.
- 7. Dosimetry will be worn for supplementary personnel monitoring of individual tasks.
- 8. Tag the following objects and fill out the tag
 - Door Chart
 - Bed Wrist
- 9. Place laundry in linen bag and save.

Attachment L (Continued)

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH IODINE 131, OR OTHER RADIOPHARMACEUTICALS

- 10. Housekeeping may not enter the room until the patient is discharged and the room has been released for unrestricted use.
- 11. Patient must have a private room.
- 12. Disposable gloves must be worn while attending patient.
- 13. Patient must use disposable utensils.
- 14. All items must remain in room until approved for removal by the Radiation Safety Officer, or designee.
- 15. Smoking or chewing tobacco is not permitted.
- 16. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer, or designee.
- 17. Other instructions.

IN CASE OF AN EMERGENCY CONTACT:

Name of Radiation Safety Officer	ON-Duty Telephone Numbers	OFF-Duty Telephone Numbers

Approved _____ Date: _____

ATTACHMENT M

RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USE OF SEALED SOURCES *

1. All patients treated with temporary brachytherapy sealed sources will be placed in a private room that has a private toilet.
2. The patient's room will be properly posted or attended in accordance with WAC 246-221-120 and WAC 246-221-130.
3. **Documented dose rate surveys of the patient's room and circumjacent areas will be conducted as soon as practicable after sources are implanted.** Exposure rate measurements (indicate shielded/unshielded) will be taken at 3 feet (1m) from the patient with sources implanted, at the patient's bedside, at 3 feet (1m) from the bed, and at the entrance to the room. The Radiation Safety Officer, or designee will then determine how long a person may remain at these positions and will post these times and the exposure rate at 3 feet (1m) from the patient on the patient's chart.
4. Immediately after sources are implanted, the form "Nursing Instruction for Patients Treated with Brachytherapy Sources" will be completed and attached to the patient's chart.
5. Radiation levels in unrestricted areas will be maintained below the limits specified in WAC 246-221-060.
6. Nurses caring for brachytherapy patients will be assigned personnel dosimetry. Extremity monitoring will also be assigned to nurses who must provide extended personal care to the patient. Pocket dosimeters may be assigned **in addition** to, but not in place of, other personnel dosimetry.
7. **At the conclusion of treatment, a survey will be performed** in accordance with WAC 246-240-254 to ensure that all sources other than permanent implants have been removed from the patient and that no sources remain in the patient, the patient's room or in any other area occupied by the patient. At the same time, all radiation signs will be removed and all dosimetry devices assigned to nurses will be collected. If the patient is to be discharged, the final survey will also include a notation on the patient's chart that the activity remaining in the patient (if any) meets conditions for release from the hospital.
8. **Instructions to Nurses**
 - A. Special restrictions may be noted on the precaution sheet on the patient's chart. **Nurses should read these instructions before caring for the patient.** The Radiation Safety Officer should be contacted to answer any questions about the care of these patients in regard to radiation safety precautions.
 - B. Nurses should spend only the minimum time necessary near a patient for routine nursing care. Obtain and wear appropriate dosimetry as instructed by the Radiation Safety Officer.
 - C. When a nurse is assigned to a therapy patient, dosimetry should be obtained immediately from the Radiation Safety Officer, or designee. **Dosimetry shall be worn only by the nurse to whom it is issued and shall not be exchanged among nurses.**
 - D. **Pregnant or breastfeeding nurses should not be assigned to the personal care of these patients.**
 - E. Never touch needles, seeds, capsules, or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and put it in the far corner of the room or in the shielded container provided; contact Radiation Therapy, the Radiation Safety Officer, or the Nuclear Medicine Department at once.
 - F. Bed baths given by the nurse should be omitted while the sources are in place.

* Be sure to submit complete responses to Items 21a through 21f in addition to referencing procedures in Attachment M.

ATTACHMENT M (Continued)

**RADIATION SAFETY PROCEDURES FOR
THERAPEUTIC USE OF SEALED SOURCES**

- G. While perineal care is not given during gynecologic treatment the perineal pad may be changed when necessary unless orders to the contrary have been written.
- H. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist and **MAY NOT BE DISCARDED** until directed by the radiologist. Dressings should be kept in a basin until checked by the Radiation Safety Officer, or designee.

**SPECIAL ORDERS WILL BE WRITTEN FOR ORAL HYGIENE
FOR PATIENTS WITH ORAL IMPLANTS.**

- I. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered, **but** these items should be saved for a check with the radiation survey meter to ensure that no sources have been inadvertently displaced into them.
- J. **All bed linens must be checked** with a radiation survey meter before being removed from the patient's room to ensure that no dislodged sources are present.
- K. Patients must stay in bed unless orders to the contrary are written. In any event, patients must remain in their assigned rooms during the treatment period.
- L. Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.
- M. Visitors should sit at least 3 feet (1m) from the patient, behind any shielding present, and should remain no longer than the time specified on the form posted on the patient's door chart.
- N. **No nurse, visitor, or attendee who is pregnant or breastfeeding shall be permitted in the room of a patient while brachytherapy sources are implanted in the patient.** Female visitors should be asked whether they are pregnant or breastfeeding.

O. Emergency Procedures

- (1) If an implanted source becomes loose or separated from the patient, or
- (2) If the patient dies, or
- (3) If the patient requires emergency surgery, immediately call:

Telephone No. _____ (days) _____ (nights)

P. At the conclusion of treatment, call the Radiation Safety Officer to:

- (1) **Survey the patient and room.**
- (2) **Count the radiation sources** to be sure that all temporary implants have been removed prior to discharging the patient, and
- (3) **Record a summary of the final survey results** on the patient's chart.

If any permanent implants are to remain in the patient, the Radiation Safety Officer will brief the patient on precautions for minimizing radiation exposure to others after discharge from the hospital.

Approved by: _____ Date: _____

Attachment M (Continued)

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH BRACHYTHERAPY SOURCES

Patient's Name _____

Room No. _____ Physician's Name _____

Nuclide and Activity _____

Location of Administration _____

Actual Administration By _____

Date and Time of Administration _____

Exposure Rates in mR/hr
(indicate shielded/unshielded status of measurements)

<u>Date</u>	<u>Instrument Used</u> (include serial number)	<u>10 feet</u> <u>from bed</u>	<u>3 feet</u> <u>from bed</u>	<u>Bedside</u>	<u>Adjacent</u> <u>Rooms</u>	<u>Surveyor</u>
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____

(COMPLY WITH ALL CHECKED ITEMS)

- 1. Visiting time permitted _____
- 2. Visitors must remain _____ feet from patient (and behind any shielding present)
- 3. Patient may not leave room.
- 4. Visitors under 18 are not permitted.
- 5. Pregnant or breastfeeding visitors are not permitted.
- 6. Dosimetry must be worn.
- 7. Dosimetry will be worn for supplementary personnel monitoring of individual tasks.
- 8. Tag the following objects and fill out the tag
 - Door Chart
 - Bed Wrist
- 9. Place laundry in linen bag and save.
- 10. Housekeeping may not enter the room.
- 11. Patient must have a private room.
- 12. Disposable gloves must be worn while attending patient.

Attachment M (Continued)

**NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH
BRACHYTHERAPY SOURCES**

- 13. All items must remain in room until approved for removal by the Radiation Safety Officer, or designee.
- 14. **A RELEASE SURVEY MUST BE PERFORMED AND DOCUMENTED BEFORE THE PATIENT IS DISCHARGED.**
- 15. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer, or designee.
- 16. **Contact the Radiation Safety Officer when temporary sources (non-permanent implants) are removed** to perform a survey to be sure all sources are removed from the patient, to do a physical source count, and to be sure no sources remain in the room.
- 17. Other instructions.

IN CASE OF AN EMERGENCY CONTACT:

Name of Radiation Safety Officer

ON-Duty

OFF-Duty

Telephone Numbers

Approved by: _____ Date: _____

ATTACHMENT N
RADIOACTIVE GAS AND AEROSOL
SUPPORTING INFORMATION

A. Tc-99m AEROSOL

- 1. Tc-99m aerosol will be administered utilizing an approved and shielded device.
- 2. Tc-99m aerosol waste will be collected in the approved, shielded trap and held for decay/disposal, as appropriate.

B. XENON 133

XE-133 will be administered using an approved and shielded device.

1. Variables

(a). Average number of studies expected per week: _____

(b). Average activity per patient dose: _____

(c). Desired possession limit: _____ mCi or Bq. (This should be sufficient to provide for shipments whose calibration dates are several days after receipt.)

(d). **Are use and storage areas area under negative pressure?** Yes No

C. ADMINISTRATION/TRAP APPARATUS FOR XE-133

Manufacturer: _____

Model: _____

D. ADMINISTRATION/TRAP APPARATUS FOR AEROSOL

Manufacturer: _____

Model: _____

E. PROCEDURE FOR SAFE USE

- The following use procedures shall be followed:

Storage (Xe)

Xenon 133 will always be stored in shielded containers in a space under negative pressure.

Radiation surveys of storage areas will be done to ensure that radiation levels are at acceptable levels.

Precautions (Xe & Aerosol)

The following steps will be taken to minimize leakage and accidental losses:

- (1) The ventilation system shall be functioning properly.
- (2) Nose clips will be used when a mouthpiece is used, and a mask whenever the patient is unable or unwilling to retain the mouthpiece. The patient will be allowed to breathe into the device for a few moments before the dose is administered so the patient will become used to it. **The dose shall not be administered if it appears the patient may panic and remove the mask or mouthpiece.**
- (3) No more studies per week shall be performed than the patient load value found in B.1.a.

Waste (Xe & Aerosol)

Gas and aerosol are absorbed by organic materials especially rubber, so syringes, vials, tubing, etc., that may have contained gas or aerosol will be monitored and disposed as radioactive waste, if contaminated.

F. EMERGENCY PROCEDURES (Xe & Aerosol)

- The following emergency procedures shall be followed.

In the event a dose of gas or aerosol is released into the Imaging Room, the average concentration in the air will be many times the occupational exposure limit. The following actions will be taken:

- (1) The technologist shall remove the patient from the room immediately.
- (2) The technologist will shut and lock the door(s), and notify the RSO immediately.
- (3) The technologist will wait _____ minutes before re-entering the use area.
- (4) The technologist will then monitor the radiation level in the room. When it has returned to normal, it is safe to resume work.

G. DISPOSAL (Xe)

- Xenon will be disposed by unrecirculated exhaust to the exterior of the building
 - Xenon will be disposed by charcoal trap.**
- (1). The trap will be surveyed for dose rate every week patients are examined.
 - (2). The manufacturer's specifications and frequency shall be followed in determining trapping efficiency and when trap is saturated.
 - (3). Traps will be disposed in accordance with procedures in Attachment K.

Approved by: _____ Date: _____

ATTACHMENT O

**PERSONNEL MONITORING, BIOASSAY,
AND SEALED SOURCE LEAK TEST PROGRAM**

1. Personnel Dosimetry

Supplier (Firm): _____

Copy of NVLAP certification enclosed/attached: Yes No

Type:

Extremity

- Beta-Gamma
- Neutron
- TLD
- Luxel
- OSD

Whole Body

- Beta-Gamma
- Neutron
- TLD
- Luxel
- OSD

Exchange frequency: Monthly Quarterly Every two weeks
 WB Ext WB Ext Ext

Results reviewed by: RSO RSC HP Consultant

Person responsible for device exchange and storage of controls: _____

Records maintained by: _____

Responsible for reports to personnel: _____
(Annual and unusual and/or overexposure)

2. Bioassay Program

Iodine:

Will follow program as defined by Regulatory Guide 8.20.

Only capsule form will be used. Bioassay will only be done if capsule opened, crushed or breached.

Analysis performed by: (Consultant/Firm) _____

If analysis in-house only, performed by: _____

Instrumentation: _____ Calibration Standard: _____

Attach sample procedures and dose calculations, sample of records maintained and report to personnel; records maintained by: _____

ATTACHMENT O (Continued)

**PERSONNEL MONITORING, BIOASSAY,
AND SEALED SOURCE LEAK TEST PROGRAM**

3. **Sealed Source Leak Test**

- Outside vendor will provide entire leak test service.**

Authorized leak test vendor used: _____

Materials license number, issuing agency, and copy of NVLAP certification: _____.

- Licensee will take wipe tests with approved leak test kit and have authorized vendor analyze leak tests.**

Leak test kit manufacturer: _____

Model number: _____

Tests taken by: _____

Tests analyzed by: _____

- Licensee will take and analyze own leak tests.**

Sampling material: _____

Tests taken by: _____

Analytical instrument: _____

Counting standard: Nuclide: _____ Activity: _____

Sample procedure(s) calculation, and record form (enclosed/attached):

Approved by: _____

Date: _____

ATTACHMENT P

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

(Name of Licensee and License Number)

(Date)

1. Management Commitment

- A. We, the management of this (medical facility, hospital, etc) are committed to the program described in this Attachment for keeping exposures (individual and collective) **as low as is reasonably achievable (ALARA)**. In accordance with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policies, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) * and a Radiation Safety Officer (RSO).
- B. We will perform a documented formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.
- C. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented, or we will be prepared to describe the reasons for not implementing them.
- D. In addition to maintaining doses to individuals as far below the limit as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee **

A. **Review of Proposed Users and Uses**

- (1). **The RSC will thoroughly review** the qualifications of each applicant with respect to the types and quantities of materials and uses for which they have applied, to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
- (2). 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 systematic procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in the proposed use.

* Private practice physician licensees and institutions with only one modality of radioactive material use do not require an RSC.

** The RSO on private physician licenses will assume the responsibilities of the RSC under Section 2.

ATTACHMENT P (Continued)

**MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT
MEDICAL INSTITUTIONS ALARA**

- (3). **The RSC will ensure** that the user justifies their procedures and that doses will be ALARA (individual and collective),

B. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program).

- (1). **The RSC will delegate authority to the RSO** for enforcement of the ALARA concept.
- (2). **The RSC will support the RSO** in those instances where it is necessary for the RSO to assert authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's next meeting.

C. Review of ALARA Program

- (1). **The RSC will encourage all users** to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- (2). **The RSC will perform a documented quarterly review of occupational radiation exposure**, with particular attention to instances where Investigational Levels in Table P-1 (below) are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).*
- (3). **The RSC will evaluate and document our institution's overall efforts for maintaining exposures ALARA on an annual basis.** This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer (RSO)

- A. **Annual review of the radiation safety program.** The RSO will perform a documented annual review of the radiation safety program for adherence to ALARA concepts. Review of specific procedures may be conducted on a more frequent basis.

B. Education Responsibilities for ALARA Program

- (1). **The RSO will schedule** briefings and educational sessions to inform workers of ALARA program efforts.
- (2). The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that **management, the RSC, and the RSO are committed to implementing the ALARA concept.**

C. Cooperative Efforts for Development of ALARA Procedures

- (1). **The RSO will be in close contact with all users and workers** in order to develop ALARA procedures for working with radioactive materials.
- (2). **The RSO will establish and document procedures** for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

ATTACHMENT P (Continued)

**MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES
AT MEDICAL INSTITUTIONS ALARA**

D. Reviewing Instances of Deviation from Good ALARA practices.

The RSO will document and investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

4. Authorized Users

A. New Procedures Involving Potential Radiation Exposures

- (1). **The authorized user will consult with**, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.
- (2). **The authorized user will evaluate** all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

B. Responsibility of Authorized User to Persons under Their Supervision.

- (1). **The authorized user will explain the ALARA concept** and their commitment to maintain exposures ALARA to all persons under their supervision.
- (2). **The authorized user will ensure** that persons under their supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Persons Who Receive Occupational Radiation Exposure

- A. The worker will be instructed** in the ALARA concept and its relationship to working procedures and work conditions.
- B. The worker shall be informed** of recourses that are available if they feel that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels in order to monitor individual occupational external radiation exposures.

This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure 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 P-1 below. These levels apply to the exposure of individual workers.

Table P-1

	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, ankles	1875	5625
(3) Skin of whole body *	750	2250

ATTACHMENT P (Continued)

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

The Radiation Safety Officer will review and record on Form RHF-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring not less than once in any calendar quarter as required by WAC 246-221-230. The following actions will be taken at the Investigational Levels stated in Table P-1.

A. Quarterly exposure of individuals to less than Investigational Level I.

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

B. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II. *

The RSO will review the exposure of each individual whose quarterly exposure equals or exceeds Investigational Level I and will report the results of the review at the first RSC meeting following the quarter when the exposure was recorded. If the exposure 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 exposure 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.

* Not normally applicable to nuclear medicine operations except those using significant quantities of beta-emitting nuclides.

C. Exposure equal to or greater than Investigational Level II.

The RSO will investigate and document in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form RHF-5 or its equivalent will be presented to the RSC at the first RSC 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 Department inspectors for review at the time of the next inspection.

D. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table P-1.

In cases where a worker's, or a group of workers', exposures 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 must approve any revisions of, Investigational Level II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in Paragraph 6.C above will be followed.

ATTACHMENT P (Continued)

**MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES
AT MEDICAL INSTITUTIONS ALARA**

7. **Signature of Certifying Official** *

I hereby certify that this institution (or private practice) has implemented and will maintain the ALARA Program set forth above.

Signature _____ Date _____

Name (print or type) _____

Title _____

Institution (or private practice) Name and Address _____

* The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator) or, in the case of private practice, the licensed physician. In the case of a hospital or clinic, this is usually not the RSO.