RADIATION SAFETY MANUAL

2ND EDITION

Olympic
HEALTH PHYSICS

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Handbook for the Use of Radioactive Materials

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Introduction

The use of radioactive materials in medicine is highly regulated by federal and state agencies. Radioactive material uses are overseen the US Nuclear Regulatory Commission (or delegated state agency) to regulate byproduct (nuclear reactor produced) material, and by state statute to regulate other (such as cyclotron produced) radioactive material. In order to possess or use radioactive material, a current radioactive material license is required.

License
The facility uses radioactive materials for diagnostic imaging and therapeutic purposes under a license issued by the regulatory authority. The license is issued to the facility and specifically lists the physicians who can be authorized users of radioactive materials. The locations where radioactive materials may be used, management, the Radiation Safety Officer, and the individual authorized users all have specific responsibilities under this license.

Rules and Regulations
The facility must comply with the applicable regulations, with license conditions, with statements made in the license application, and with the rules contained in this procedure manual. The regulatory agency will conduct inspections, most often unannounced, to check for compliance with the various rules, regulations, and the safe use of radioactive materials.

In addition, activities involving shipping radioactive materials may be regulated by the US Department of Transportation, and radiopharmaceuticals may have additional FDA requirements.

Policies and Procedures
The rules, policies, and procedures contained in this procedure manual are incorporated into the radioactive materials license by reference. Any modification to this manual may require a license amendment and approval by the regulatory agency.

X-Ray
This manual does not address the use of x-ray or other machine-produced radiation. However, the exposure limits for radiation workers are the same for both x-ray and the use of radioactive materials.

Locations of Use
Changes to Locations of Radioactive Materials Use must be evaluated by the RSO, approved by the regulatory agency, and a license amendment must be received by the facility in advance of the location change. An example would be changing the location of a room used for nuclear treadmill procedures. The new location requires approval as described above, and the previous location requires a radiation survey prior to release for unrestricted use.

Radiation Safety Committee Charter

Purpose
The Radiation Safety Committee (RSC) functions in conjunction with the Radiation Safety Officer to support medical center executive management by providing oversight for the use of radioactive materials authorized by the license.

The Committee shall:

- Ensure that licensed material and radiation producing equipment will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures.
- Ensure that licensed materials are used in compliance with applicable regulations and medical center license.
- Ensure that the use of licensed material is consistent with the ALARA philosophy.
- Identify radiation safety program problems and solutions.

Composition
The Committee shall be chaired by a member of the Medical Staff. Members that are required to comprise a forum are indicated by "*" in the table below. Voting members shall include:

Membership (Department / Position)	Guests
Chair, RSC*	Ad hoc
Radiation Safety Officer*	Health Physicist
Administration*	
Nursing*	
Medical Imaging Representative	
Medical Imaging Physician*	
Radiation Oncology Physician*	
Radiation Oncology Representative	
Cardiac Cath Lab Representative	
Quality Management Representative	

Duties
The RSC has been granted requisite authority by medical center executive management to review and regulate all use of radioactive material in the medical center.

The Committee shall:

- Provide oversight for the safe use of radioactive materials to ensure occupational and public radiation doses are As Low As Reasonably Achievable, (ALARA).
- Prepare records and report committee results as required by executive management and regulation; and ensure the records document executive management approvals for actions.
- Coordinate with other medical center committees as needed.
- Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, and decisions.

- Recommend remedial action to correct any deficiencies identified in the Radiation Safety Program.
- Complete and/or provide oversight for the Radiation Safety Program through periodic reviews and audits, to include:
    - Annual radiation safety program review in accordance with the ALARA program.
    - Review or audit, as needed, based on the radioactive materials scope of uses.
    - Evaluation of results from audits, reviews, and inspections to determine possible generic issues or trends, identify root causes, specify corrective actions, and determine if any results are applicable to other uses of radioactive materials.
    - Oversight and follow-up to resolve health and safety issues and radiation safety program deviations, as needed.
    - Review occupational radiation doses at least quarterly.
- Review, at least quarterly, any identified health and safety issues or possible radiation safety program deviations from regulatory compliance or required practices.
- Ensure that the byproduct material license is amended, if required, prior to any changes in facilities, equipment, policies, procedures, and personnel.
- To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, CT radiation safety, and quality assurance oversight.

Meetings
The Committee shall:

- Meet as often as necessary to conduct its business but not less than once in each calendar quarter.
- Committee membership must include the Radiation Safety Officer, a management representative, a representative from each type of authorized use, and a representative from Nursing Service.
- Decisions will be made by a simple majority vote by a quorum of committee members. All committee members are eligible to vote. A quorum shall consist of no less than 50% of members. The Chair will refrain from voting except when necessary to break a tie.

Duties of the Radiation Safety Officer

Authority

The Radiation Safety Officer (RSO) has the authority to enforce the rules and regulations regarding the use of radioactive materials, radiation protection, and the provisions of the radioactive materials license. Specifically, the RSO has the authority to stop the use of radioactive materials if, in his or her judgment, such use is considered unsafe or illegal. The RSO has the authority to delegate Radiation Safety Program tasks and functions as necessary. *Any authorized user named in this license may assume the RSO's duties in the RSO's absence.*

Duties

- The RSO is responsible for all aspects of the Radiation Safety Program, including compliance with the rules and regulations, maintenance of all required records, and the submittal of any required reports.
- The RSO establishes and implements procedures to comply with the regulations, the license, and the radiation safety manual.
- The RSO directs and reviews the work of those performing delegated Radiation Safety Program tasks and functions.
- The RSO has specific duties to keep radiation exposures as low as reasonably achievable (ALARA). See the ALARA program in the radiation safety manual.
- The RSO is responsible for maintaining the license by requesting license amendments from the regulatory authority as needed, paying necessary fees, or other items required to keep the license up to date.
- The RSO arranges for radiation exposure monitoring as necessary and reviews exposure reports.
- The RSO investigates and reports overexposures, accidents, spills, losses, thefts, medical events, unauthorized uses, and other deviations from approved radiation safety practice, and implements corrective action as necessary.
- The RSO evaluates all new uses of radioactive materials and acts as consultant to other authorized users and management.
- The RSO will review research projects utilizing radioactive materials in human subjects to ensure compliance with the current Radioactive Materials License as well as applicable regulations.
- The RSO evaluates the need for, and calls for, outside assistance as necessary.
- The RSO conducts, or provides for, training as required by regulation.
- The RSO establishes and maintains record systems for all radiation area surveys, wipe tests, leak tests, calibration of instruments, and personnel dosimetry reports.
- The RSO annually notifies, in writing, each radiation employees accrued radiation dose.
- The RSO ensures 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.
- The RSO posts conspicuously "Notice to Employees" and notices of items of noncompliance resulting from regulatory inspections, as required.
- The RSO takes 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.

- The RSO ensures that radioactive material and waste is both properly secured from unauthorized access at all times and properly disposed.
- The RSO maintains, or causes to be maintained, written records of all Radiation Safety Committee (if one is extant) meetings, actions, recommendations, and decisions.
- Associate Radiation Safety Officers (ARSO) will perform duties involving the radiation safety program under the supervision and authorization of the Radiation Safety Officer and Radiation Safety Committee (if one is extant). The ARSO will perform only those duties they are qualified for by training and experience and authorized to perform by the RSO and/or RSC. Upon written request the ARSO may also be named on the radioactive materials license.

ALARA Program

Management Commitment
We, the management of the facility are committed to the program described in this Attachment for keeping exposures (individual and collective) **as low as 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 Officer (RSO), facility management, and Authorized Users.

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.

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.

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.

Radiation Safety Officer
Review of Proposed Users and Uses
The RSO 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 exposures ALARA.

When considering a new use of radioactive material, the RSO 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.

The RSO will ensure that the user justifies their procedures and that doses will be ALARA (individual and collective).

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.

Delegation of Authority
The judicious delegation of RSO authority is essential to the enforcement of an ALARA program. The Management will delegate authority to the RSO (and ARSO, as appropriate) for enforcement of the ALARA concept. Management will support the RSO in those instances where it is necessary for the RSO to assert authority. Where the RSO has been overruled, Management will record the basis for its action.

Review of ALARA Program
The RSO will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept. The RSO will perform documented quarterly review of occupational radiation exposure, with particular attention to instances where Investigational Levels in the table 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.

The RSO 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.

Education Responsibilities for ALARA Program
The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts. 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.

Cooperative Efforts for Development of ALARA Procedures
The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials. 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.

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 initiate and require changes in the program to maintain exposures ALARA.

Authorized Users
New Procedures
For new procedures involving potential radiation exposures, the authorized user will consult with, and receive the approval of, the RSO during the planning stage before using radioactive materials for a new procedure. 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.

Responsibility
The authorized user will explain the ALARA concept and their commitment to maintain exposures ALARA to all persons under their supervision. 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.

Persons Who Receive Occupational Radiation Exposure
The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions. The worker shall be informed of recourses available if they feel that ALARA is not being promoted on the job.

Establishment of Investigational Levels
In order to monitor individual occupational external radiation exposures, Investigational Levels will be established. This institution 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 the table below. These levels apply to the exposure of individual workers.

Investigational Levels (mrem per calendar quarter)		
Body Region	**Level I**	**Level II**
Whole Body, Head and Trunk, Active Blood Forming Organs, Lens of Eyes, or Gonads	125	375
Hands and Forearms, Feet, Ankles	1875	5625
Skin of Whole Body	750	2250

The Radiation Safety Officer will review and record on Form 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. The following actions will be taken at the Investigational Levels:

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 values for the Investigation Level I.

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.

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 5 or its equivalent will be presented to Management following completion of the investigation. The details of these reports will be recorded.

Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in the Table.
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 RSO 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 above will be followed.

Certification
I hereby certify that the facility has implemented and will maintain the ALARA Program set forth above.

_____ _____

Management Representative Date

Radiation Safety Training Program

Responsibility
The RSO shall conduct, or arrange for, all radiation safety training required by the regulations, the license, and this manual.

Radiation Workers
New technologists, temporary technologists, and other previously trained personnel shall be given on the job training to acquaint them with facility policies and procedures.

Annual refresher training shall be given to radiation workers covered by this license. If the training is conducted elsewhere, the RSO shall request and maintain the records of such training. Subjects covered include:

- ALARA philosophy and requirements.
- Changes to regulations, policies, or procedures.
- Worker rights and responsibilities.
- Any incidents, accidents, inspection findings, or corrective actions taken.
- General radiation safety and emergency procedures.
- Specific procedures such as ordering, using, and administering radioactive materials.
- Female radiation worker specific information such pregnancy declaration.

Other Workers
The RSO shall provide for training of employees whose duties may require them to enter a radioactive materials restricted area and whose exposure is likely to exceed the exposure limit for members of the general public. These employees may include nursing, housekeeping, maintenance, and security personnel. Subjects covered include:

- Locations of radioactive materials in the restricted areas.
- Methods of radiation protection; time, distance, and shielding.
- The ALARA philosophy and requirements.
- Radiation safety precautions and security requirements appropriate to their duties.
- Worker rights and responsibilities.
- Procedures for reporting unusual or emergency conditions to the RSO.

Records
Training shall be documented and records kept for inspection by DOH.

Radiation Exposure Monitoring

Dosimetry Management
Radiation workers will be provided whole body beta/gamma radiation exposure monitoring badges. In addition, nuclear medicine technologists and physicians who handle or inject radiopharmaceuticals will be issued extremity badges. The badges will be exchanged monthly, unless the RSO determines a different frequency is appropriate.

If a technologist has been issued a concurrent badge elsewhere, the RSO will request and review the results from the issuing facility's report covering the time the technologist was working at the facility. The RSO will investigate any unusual exposure to determine the source of the exposure and if corrective action may be necessary.

The RSO will review all exposure reports, will maintain the exposure report records, will issue annual and overexposure reports to employees, and will determine the need for outside assistance.

Procedures for Ordering Radioactive Material

An Authorized Nuclear Medicine Technologist will place all orders for radioactive materials and will ensure the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

A system for ordering and receiving radioactive material will be established and maintained. The system will consist minimally of the following:

1. Ordering of Routinely Used Materials
    a. Written records that identify the nuclide, compound, activity levels, and supplier, etc., will be used.
    b. The written records will be referenced when opening or storing radioactive shipments.
2. Ordering of specially used materials (e.g., therapeutic doses)
    a. A written request will be obtained from the physician who will perform the procedure.
    b. Persons ordering the material will reference the authorized user's written request when placing the order. The physician's request will indicate nuclide, compound, chemical form, activity level, etc.
    c. The physician's written request will be referenced when receiving, opening, or storing the radioactive material.
3. Written records will be maintained for all ordering and receipt.

During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department secure receipt location.

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 and take them directly to nuclear medicine.

Security of Radioactive Materials

Security of licensed materials requires all licensed radioactive materials that are stored in controlled or unrestricted areas to be secured from unauthorized access or removal, so that individuals who may not be knowledgeable about radioactive materials cannot be exposed to or contaminated by the material, and untrained individuals cannot access or remove the material for unauthorized use. When licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or unnecessarily exposed to the material, or prevent persons from removing the material from the area.

An example of an unrestricted or controlled area is a treadmill room that is accessed by various staffs during the day so it cannot be secured. Another example would be a surgical suite where I-125 seed implants may occur.

Restricted areas where radioactive materials are stored or prepared for use must be secured at all times when unoccupied.

An example of a restricted area is an imaging room where radioactive materials are stored, a hot lab, or a stress lab.

Procedures for Safely Opening Packaging Containing Radioactive Material

1. Put on gloves and visually inspect the package.
   - If the package shows obvious damage which may have damaged the contents, detain the delivery driver if possible - the delivery vehicle may be contaminated.
   - Check the radiation level at one meter from the package using an energy compensated probe such as an end window or cylinder probe. However, using a pancake detector for a radioactive package survey is acceptable but will likely over-respond to higher energy isotopes like I-131 due to its energy response characteristics. If a pancake detector is used for a radioactive package survey, a mR/hr reading 40% higher than package transport index is likely to be observed. A second check using the cylinder probe (if one is available) is recommended.
   - A "White-I" package should be at background, (<0.05 mR/hr). A "Yellow-II or III"one meter radiation level should match the Transportation Index written on the package label (unless a pancake detector is used for the survey, see above).
   - Check the radiation level at the surface of the package. A "White-I" should be 0.5 mR/hr or less. A "Yellow-II" should be 50 mR/hr or less. A "Yellow-III" should be 200 mR/hr or less.
   - If any reading is higher than anticipated, the inside shielded container may be open or leaking. Resurvey using the cylinder probe or an energy compensated probe. If the reading is still higher, **stop and call the RSO.**

2. Before opening the package.
   - Take a wipe sample to check the outside surfaces of the package for removable contamination.
   - The allowable limit is 24,000 dpm/100 cm^2, which is about 1000cpm with the pancake probe.
   - If the wipe sample shows greater than 100 cpm, the container may be leaking. **Stop and call the RSO. Inform the carrier.**
   - If the wipe sample shows greater than 24,000 dpm/100 cm^2, or about 1,100 cpm with pancake probe, the state DOH and the carrier must be informed. See below.

3. Open the package and inspect.
   - Gloves must be worn unless the material is a sealed source.
   - Check the label and packing slip to make sure it is what you ordered.
   - Assume the inner container is possibly contaminated and handle it accordingly to prevent the spread of contamination.

4. If all inspections are acceptable:
   - Record the receipt of the material and the results of the surveys.
   - If it is a sealed source, place the source technical data sheets that accompany the source in an appropriate file or binder.
   - Survey the empty shipping container with the pancake probe in a low background area. If it is not contaminated it may be used to return radioactive materials to the vendor or commercial radiopharmacy.
   - If the shipping container is radioactive but not in excess of the limits described in the next paragraph, it may be set aside for decay according to procedures in the Radioactive Waste section of this manual.

5. If all inspections are not acceptable, a report may be required.
    - As noted above, dose rates greater than 200 mR/hr at the surface or 10 mR/hr at one meter, or contamination levels greater than 24,000 dpm/100 cm^2 require reporting to the regulatory agency and the carrier.
    - For emergencies, call the radiation emergency line.

Shipment or Return of Radioactive Sealed Sources.

- Staff who perform radioactive materials shipments must have completed DOT HazMat training prior to the shipment date.
- Staff must either use the commercial radiopharmacy for sealed source pick-up and return to the manufacturer or the procedure supplied by the manufacturer for direct return of spent sealed sources used for imaging instrument quality control.
- Track and obtain a receipt document from the final sealed source recipient (either the commercial radiopharmacy, e.g., Cardinal Health, or the manufacturer, e.g. Siemens or Eckert and Ziegler/IPL) and attach it to the source's original technical data sheet and hold on file for inspection. Source receipts MUST reference the transferred sealed source serial number(s). This procedure ensures a cradle to grave record necessary for transfer of sealed sources. Call the RSO for assistance if needed.
- For Radiation Oncology HDR sources (High Dose Rate Afterloading Brachytherapy), the sources must be exchanged by the manufacturer's service representatives who assume all responsibility for source packaging and return shipments. All shipping documentation must be held on file for inspection, including source return receipts.

Return of Spent or Unused Radiopharmaceuticals to the Radiopharmacy

For return of unsealed radioactive materials to the commercial radiopharmacy, the commercial radiopharmacy assumes all shipping responsibility. Under the provision of 49 CFR 173.421, packages of radioactive materials meeting certain criteria may be returned to the radiopharmacy as Limited Quantity Shipments. These criteria are:

- The amount of radioactive material in the package does not exceed a specific limited quantity shipment amount referenced below,
- The radiation level at any point on the external surface of the package does not exceed 0.5 millirem per hour,
- The non-fixed, (removable), contamination on the external surface of the package does not exceed 6600 dpm/300 cm^2, (49 CFR 173.443 [A][2]).

Procedure

- Ensure that the radioactive material being returned does not exceed the specific limits for a Limited Quantity Shipment. These limits are printed on the inside lid of the DOT Type 7A radiopharmacy container.
- Determine that the radiation level at any point on the external surface of the container does not exceed 0.5 millirem per hour by surveying the package prior to shipment.
- Perform a wipe test of 100 cm^2 on three sides of the container using a suitable wipe material and assay the wipe. The assay should not exceed 6600 dpm / 300 cm^2. The shipping container action level is a reading >100 cpm using a pancake detector, or roughly twice background.

General Rules for Safe Use of Radioactive Material

Lab Coats
Wear laboratory coats or other protective clothing at all times in areas where dispersible radioactive material is used.

Gloves
Wear disposable gloves at all times while handling dispersible radioactive materials.

Hand Monitoring
Monitor hands and clothing for contamination after each procedure or before leaving the immediate area.

Shielding
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).

Eating and Drinking
Do not eat, drink, smoke, chew, or apply cosmetics in any area where radioactive material is stored or used. Do not store food, drink, or personal effects with radioactive material (e.g., in refrigerator).

Dose Assay
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 percent unless authorized by the physician. **Note:** Unit doses of beta-emitting or alpha-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 unless license conditions require otherwise.

For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity versus the Written Directive order written by the physician who prescribes the procedure.

Dosimeters
Wear personnel monitoring devices (film badge, TLD, OSL, etc.) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. 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.

Wear extremity dosimetry during elution of generator, and preparation, assay, and injection of radiopharmaceuticals or when handling sealed sources.

Radioactive Waste
Dispose of radioactive waste only in specially designated drains or properly shielded and labeled receptacles.

Surveys
Survey nuclear medicine work area for contamination after each procedure or at the end of the day. Decontaminate as necessary. Document all results.

Labeling
Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, as applicable.

Transportation
Always transport radioactive material in shielded and labelled containers.

Medical Events

Medical events in nuclear medicine are defined as radiation exposures to the patient of 5 rem effective dose equivalent or 50 rem dose equivalent to any organ **AND** one or more of the following:

- The wrong patient.
- The wrong radiopharmaceutical.
- The wrong route of administration.
- The wrong dose.

If a medical event is suspected:

- Inform the RSO immediately**.**
- Preserve all evidence such as labels, syringe, vial, paperwork, etc.
- The RSO will determine if the event is a reportable misadministration.

If the event is a reportable medical event:

- The regulatory agency must be informed by telephone no later than the next calendar day at _____.
- Inform the referring physician within 24 hours.
- Inform the patient within 24 hours, unless the referring physician agrees to inform the patient or advises that it would be harmful to the patient.
- Written reports must be filed within 15 days.

Other medical events involve an administration of greater than 20% of the intended dosage of sodium iodide I-131 or any other radiopharmaceutical therapy drug.

Mislabeled drugs may be a violation of FDA regulations, but not regulations governing the use of radioactive materials.

Radiation 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 _____

RSO Cell Phone or Home Phone _____

Loss, Theft, Fire, Explosion, or Vehicle Accident

Follow the procedures outlined in the 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

Radiation Safety Officer _____

RSO Cell Phone or Home Phone _____

Local Police	911
Local Fire Department	911

The Radiation Safety Officer, in turn, must immediately notify the regulatory authority, Radiation Emergency Response and other local authorities as indicated.

The radiation worker should inform emergency workers of the possibility of a radiation hazard, should help them keep the area secure, and should explain to emergency personnel the location of the radioactive device or material, 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 worker is seriously injured or incapacitated and must be removed from the site be emergency personnel for medical treatment

Alternate names and telephone numbers designated by Radiation Safety Officer.

The decision to implement a major spill/contamination procedure instead of a minor spill/contamination procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated, and radiotoxicity of the spilled material.

For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than 5 times the lowest Annual Limit of Intake (ALI), an alternative spill/contamination procedure may be to restrict access pending complete decay.

Note: A report to the Department may be required.

Use the following Table as general guidance to determine whether a major spill/contamination procedure or a minor spill/contamination procedure will be implemented. All spills or contamination involving Ra-226 are considered major spills.

Relative Hazards of Common Radionuclides			
Radionuclide	Millicurie	Radionuclide	Millicurie
P-32	1	Tc-99m	100
Cr-51	100	In-111	10
Co-57	10	I-123	10
Co-58	10	I-125	1
Fe-59	1	I-131	1
Co-60	1	Sm-153	10
Ga-67	10	Yb-169	10
Sr-85	10	Hg-197	10
Sr-89	1	Au-198	10
Y-90	1	Tl-201	100

Estimate the amount of radioactivity spilled. Initiate a major or minor spill/contamination procedure, based on the above information. Spills above these mCi amounts are considered major, and below these levels are considered minor. Spills involving curie quantities of PET radionuclides should initially be considered major spills; either downgrade to minor spill after decay or restrict access pending complete decay.

Area Survey Procedures

Radiation Survey
The survey requirement is met by completing a radiation survey at the end of each day unsealed form radioactive materials are used. The radiation survey uses a survey meter coupled to a pancake detector to locate small spills or other areas of contamination and identify radiation levels. Records of daily radiation surveys must be maintained for at least three years following the most recent inspection. Records do not need to be kept of informal surveys, such as monitoring your hands and clothing with the pancake detector after an injection or when leaving the hot lab.

Daily Surveys
The radiation level survey is a primary tool for the RSO to implement the ALARA Program. Knowing when and where radiation levels are at their highest allows the RSO to make recommendations to the staff on measures they can take to reduce their exposure.

Washington state regulations require radiation levels in unrestricted areas be less than 2 mR/hr, and must not result in any member of the public receiving more than 100 mrem in a year. Occupancy factors may be taken into account when calculating the 100 mrem per year value. However, radiation levels should be kept to a minimum or not more than 0.05 mR/hr in unrestricted areas.

Survey Procedure
Survey work surfaces and other locations in the imaging rooms, hot lab, treadmill rooms and injection areas after radiopharmaceuticals have been prepared and/or administered, usually toward the end of the day using a radiation detector coupled to a pancake detector, or equivalent. Scan work surfaces by moving the detector slowly about 1 cm from work surfaces and at a movement rate of about one detector width per second looking for unusual count rates (cpm) that could indicate surface contamination or unusual exposure rates (mR/hr) that could indicate a spill or an unshielded source. Also check trash cans and floors near doorways to unrestricted areas to determine if radioactive contamination has spread outside the restricted areas, (imaging rooms, hot lab, injection areas, etc.). Record the results in mR/hr to document radiation exposure rates do not exceed regulatory limits.

The action level for work surfaces other than behind the L-block is 0.05 mR/hr or about twice background. The daily survey record should show the date, instrument used, background level, survey results, the survey meter used, and technologist initials. Survey results below the action level can be documented as negative for contamination. If the action level was exceeded, record the corrective action taken, such as, “cleaned the area, resurvey negative”.

The ALARA concept requires the RSO to establish exposure limitation goals, so the action level for exposure levels in restricted areas is 0.7 mR/hr. Weekly radiation level surveys are performed in the same areas as the daily surveys. Special attention should also be given to radiopharmaceutical storage areas, radioactive waste storage areas, and patient injection areas. The weekly survey may be documented as a daily survey since the survey locations are essentially the same.

As with the other surveys, the weekly exposure rate survey record should show the date, instrument used, background level, survey results, and who did the survey. Survey results below the action level can

show “negative”. If the action level was exceeded, record the corrective action taken, such as informing the RSO.

Note that weekly wipe surveys for loose surface contamination are no longer required by regulation and are therefore unnecessary unless a spill has occurred and a determination of fixed vice removable contamination is needed.

Surveys of Inpatient Rooms or Other Areas Remote from the Nuclear Medicine Department Where Diagnostic Radiopharmaceutical Injections Are Performed

The following safety guidance should be followed when performing diagnostic radiopharmaceutical injections in areas remote from the nuclear medicine department, such as in an inpatient room. After the radiopharmaceutical administration, a conventional radiation survey using a geiger counter may not be possible due to the presence of the radioactive patient. Therefore, either collect all potentially contaminated items and return them to the nuclear medicine hot lab for survey and proper disposal, or if a spill is suspected, perform wipe tests of the suspicious areas and analyze them using the survey meter in a low background area. If radioactive contamination is located, associated radiation levels must be reduced to background levels if possible, and all removable radioactive materials cleaned from room floors, room furniture, or room furnishings.

Reminder: In all of the above scenarios, waterproof gloves must be worn whenever handling unsealed form radioactive materials or associated potentially contaminated objects.

Call the RSO if radiation survey assistance is required or to report fixed radioactive contamination levels that exceed regulatory limits, (>2 mR/hr in the patient’s room).

Procedure for Safe Use of ^{99m}Tc-DTPA Aerosols

When administering 99mTc-DTPA as an aerosol, the room bust be adequately ventilated to keep the airborne concentrations low enough so as not to exceed the occupational dose limits, or dose limits to the public, (i.e. < 2 mrem/hr and < 100 mrem per year). The ventilation can be by either direct ventilation to the atmosphere or collection in a shielded container that is held for decay prior to disposal.

Precautions
Always wear gloves when handling unsealed radioactive materials and the administration device, (nebulizer). Always use a syringe shield when preparing 99mTc DTPA for use with the nebulizer. Carefully inject the prescribed dosage of 99mTc-DTPA into the nebulizer to avoid contaminating the outside of the device or any other components. Decontaminate the shield using routine methods if the shield or surrounding area becomes contaminated with radioactivity.

Procedure
Explain the procedure using demonstrations if necessary and allow the patient to become with the device prior to placing the mouthpiece on the patient and starting the oxygen. The nebulizer will deliver about 1-2 mCi per minute over about 5 minutes of delivery time. If the patient is unable to retain the mouthpiece, immediately discontinue the procedure and turn off the oxygen.

When the procedure is finished, gather all potentially contaminated articles and place them in a labeled container for decay as radioactive waste.

Emergency Procedures
If the mouthpiece is accidentally allowed to discharge 99mTc-DTPA into the room for extended time periods, evaluate by measuring the radiation dose rate in the room without the patient present. Normal ventilation will reduce the airborne radioactivity from the air very rapidly due to particle size and suspension characteristics. Return the patient to the room when the activity has sufficiently cleared to obtain diagnostic images.

Surface contamination has not been shown to be a problem when using the 99mTc-DTPA delivery device; although a health physics best practice is to scan the room for contamination prior to imaging the next patient, if contamination is suspected.

Radioactive Waste

Unit dose syringes will be returned to the pharmacy according to their instructions. Other waste will be segregated by half-life, and will be deposited in designated radioactive waste containers. Waste containers will be shielded or kept in a shielded enclosure. Approved "sharps" containers will be used for needles. Sealed sources or long lived radionuclides will be returned to the vendor according to their instructions or transferred to a licensed waste broker. No radioactive material other than patient excreta will be disposed of in the sewer unless authorized by the RSO.

Safety Procedures
Gloves and lab coats should be worn when handling radioactive waste. Hands, clothing, and the work area should be checked for contamination at the end of the procedure. Care should be taken to avoid injury by contaminated needles.

Waste in Trash
In order to avoid inadvertently releasing contaminated items in the normal trash, survey the normal trash at the end of the day. If contamination is found, remove the contaminated item or label the entire bag as radioactive waste.

Return of Unused or Remnant Radiopharmaceuticals to the Vendor
Under the provision of 49 CFR 173.421, packages of radioactive materials meeting certain criteria may be returned to the radiopharmacy as Limited Quantity Shipments. These criteria are:

- The amount of radioactive material in the package does not exceed a specific amount,
- The radiation level at any point on the external surface of the package does not exceed 0.5 millirem per hour,
- The non-fixed, (removable), contamination on the external surface of the package does not exceed 6600 dpm/300 cm2, (49 CFR 173.443 [A][2]).

Procedure:

- Ensure that the radioactive material being returned does not exceed the specific limits for a Limited Quantity Shipment. These limits are printed on the inside lid of the DOT Type 7A radiopharmacy container.
- Determine that the radiation level at any point on the external surface of the container does not exceed 0.5 millirem per hour by surveying the package prior to shipment.
- Perform a wipe test of 100 cm2 on three sides of the container using a suitable wipe material and assay the wipe. The assay should not exceed 6600 dpm / 300 cm2. The shipping container action level is a reading >100 cpm using a pancake detector, or roughly twice background.

Decay Waste
Waste will be appropriately segregated by half-life. When a container is filled, the bag is labeled "Radioactive, half-life = *X* hours/days, date" and logged into the waste record. The waste will be stored for at least 10 half-lives, based on the longest half-life in the bag. After 10 half-lives, the bag is carefully monitored with the pancake probe. Any bag reading over 100 cpm, or about twice background, will be returned to the waste area. If the bag contains no detectable radioactivity, an entry is made in the records, and it is released as normal trash. Obliterate all exterior "Radioactive" labels. If "Radioactive"

labels are visible through the bag, place the bag in an opaque over pack so that the “Radioactive” labels are not visible.

Sink Disposal of Radioactive Materials

Disposing of radioactive materials into the sanitary sewer is permissible provided the radioactive material and compound is water soluble and effluent concentrations in uCi/cc do not exceed the applicable limits. Water solubility of the material to be disposed of must be determined in advance of the disposal.

If a sewer disposal is necessary, use the sink in the hot lab. Pour the liquid into the center of the drain to minimize splash, followed by running cold or lukewarm water for at least 15 minutes to flush the material through the piping and p-trap.

Notify the RSO of the disposal within 24 hours. Indicate the sink location, your name, the release date, the radioactive compound disposed, and the amount in mCi.

The RSO will perform the effluent release calculation and account for the sewer releases in the annual ALARA Audit and Sewer Release Calculation.

Records

Records must be kept of all radioactive material that is received, used, and disposed of. For radiopharmaceuticals, the receipt and patient log is the main record for this purpose, and it accounts for the material except for waste not returned to the pharmacy. Waste containers will be marked, and records will be kept of the type of waste going into each container. The same record will show how each container is disposed of, whether by decay or transfer. For release after decay, the record will show the date, instrument, background reading, waste container reading, and the initials of the person performing the disposal.

Waste records must be maintained for a period of 3 years or until the regulatory agency authorizes their disposal.

Radiopharmaceutical Therapy

Purpose
This document establishes policies for a quality management program in Nuclear Medicine regarding administration of radiopharmaceutical therapy dosages of sodium iodide I-131 in amounts greater than 30 microcuries or any therapeutic radiopharmaceutical other than I-131. Directives contained herein are appended to the Nuclear Medicine and Radiation Safety procedure manuals to ensure the highest level of patient care service in Nuclear Medicine while minimizing risks to patients, technical personnel, and the general public.

Policy
A written directive specific for each patient will be issued by an authorized user prior to administration of any therapeutic or diagnostic dosage of sodium iodide I-131 in excess of 30 microcuries, or any therapeutic radiopharmaceutical other than I-131. This directive will include identification of the radiopharmaceutical, the dosage to be administered, and the route of administration if other than I-131, and will be signed by the authorized user. No administration of said radiopharmaceutical by any Nuclear Medicine personnel (technologist or authorized user) will be permitted in the absence of a signed written directive with all the specified elements completed, except in documented cases of emergency.

Prior to radiopharmaceutical dosage administration, the individual responsible for said administration will verify in writing that the material to be administered is in accordance with the written directive. Said individual will verify and record on the directive the identification information of the radiopharmaceutical dose received and intended for administration, including radiopharmaceutical name and calibration information. The quantity of radiopharmaceutical will then be confirmed by measurement in the nuclear medicine dose calibrator, with the quantity measured recorded on the directive sheet in the space provided. The person responsible for the administration will then sign and date his/her verification of the radiopharmaceutical information. This signature will also affirm that said individual understands how to carry out the written directive. If this individual has any questions or does not feel he/she has such understanding, said worker is instructed to contact the authorized user prior to proceeding.

Prior to administration of the radiopharmaceutical, the individual responsible for the administration will verify the identity of the patient as the individual whose name appears on the written directive. At least two methods of verification are required, at least one of which should be elicited directly from the patient, except in such rare circumstances where said individual is medically incapable of providing such response. In the case of patient incapacity to respond, an accompanying relative may provide the required verification attesting to the identity of the patient as the individual named on the written directive. The individual recording the verification information will sign and date the written directive in the space provided. Patient identification methods will be indicated by said individual through completion of the Written Directive. Verification that female patients of child-bearing age are not pregnant and not nursing will be obtained and documented.

Oral directives and revisions to written directives are allowed under specified conditions. Regulations of this part will be consulted and adhered to when deviation from this policy is considered.

Annual Review

Scope

A 20% sampling of radiopharmaceutical diagnostic or therapy dosages of I-131 sodium iodide greater than 30 microcuries or any therapeutic radiopharmaceutical other than I-131 will be reviewed annually, unless fewer than 50 dosages occur. In this case, all dosage administrations will be reviewed. This review will involve examination of information recorded on the written directives and will document any discrepancies between the radiopharmaceutical name, dose, and route of administration specified by the authorized user and that administered. Presence of all required documentation and verification of patient identification will also be noted. If possible, said review shall be performed by an individual other than the authorized user(s) at this institution.

Actions to Address and Resolve Problems

A written report of the results of the annual review will be included in the facility annual radiation safety program audit, including recording of any deviations from established policies, and recommendations proposed to correct program deficiencies. The need for new or revised policies, procedures, or increased training or supervision will be assessed in this review. This document will be overseen by the authorized user(s) and will include specific recommendations for implementation of necessary policy or procedure revisions.

Maintenance of Records

Copies of all written directives, program annual reviews, and annual review follow-up reports will be retained in the Nuclear Medicine department for a minimum of three years. These records will be made available for external regulatory agency review.

Release of Individuals Containing Unsealed Radioactive Materials

Purpose
The consist of the rationale for calculation of family radiation exposure and patient release criteria for I-131, as well as guidelines to assist in determining when written instructions must be provided to patients. Additional guidance for female patients who are breast feeding is also provided.

Only those patients who have been cleared for treatment by authorized user physician interview may qualify for treatment with sodium iodide I-131 in amounts greater than 33 mCi, prior to release. NUREG 1556, Vol. 9., Revision 2, Appendix U provides the rationale for the release of patients based on administered activity or exposure rate at 1 meter. For patients given I-131 in amounts greater than 33 mCi, a patient specific release calculation will be performed using the following equation

$$D(\infty) = \frac{34.6 * \Gamma * Q_e}{100cm^2} E_1 T_p (0.8)(1 - e^{-0.693 \frac{8.02}{T_p}}) + (E_2 F_1 T_{1eff} * e^{-0.693 \frac{8.02}{T_p}}) + (E_2 F_2 T_{2eff} * e^{-0.693 \frac{8.02}{T_p}})$$

The maximally exposed individual dose should not exceed 500 mrem. A copy of the patient specific calculation should be retained with the written directive and other patient records for a period of 3 years.

An example patient specific calculation can be found on the next page.

Written Instructions
When I-131 activity is greater than 7 mCi, the authorized user physician will complete a patient instruction form prior to authorizing the treatment and release of individuals containing radioactive material. These written instructions along with a verbal explanation on actions recommended to maintain doses ALARA to other individuals will be provided to the patient.

IMPORTANT: These instructions apply to the use of I-131 NaI only and do NOT apply to I-131 Bexxar patient treatments. Contact the RSO for special treatment and release instructions for I-131 Bexxar patients.

Breast Feeding and Pregnancy Precautions
It is extremely important to verify the pregnancy and breast feeding status of female patients who are scheduled for radiopharmaceutical therapy treatments. Pregnancy status verification must include a negative serum HCG blood test within 72 hours for female patients of child bearing age. Test results should be documented in the patient's chart prior to radiopharmaceutical therapy administration.

The procedure must be delayed and the authorized user physician must be notified if the patient may be pregnant or breast feeding.

Reference
Refer to Appendix U of NUREG 1556, Volume 9, Revision 2.

Example

Patient Specific Calculations for Release of Individuals Containing I-131 Sodium Iodide

Date:	1/1/2000
Last Name:	Doe
First Name:	John
Date of Birth:	1/1/1950
MRN:	123456

Based on the equation:

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

Initial Dose in mCi (Q_0)	100.000
Half Life (days) (T_p):	8.04
Gamma Ray Const.	2.2
Dist from Source (cm)	100
ExtraThyroidal Uptake Fraction (F_1)	0.95
ExtraThyroidal Effective Half-Life - T_1eff (day)	0.32
Thyroidal Uptake Fraction (F_2)	0.05
Thyroidal Effective Half-Life - T_2eff (day)	7.3
Occupancy Factor 1st Day (E_1)	0.75
Occupancy Factor Subsequent Days (E_2)	0.25

Multiplier	1st Day Fraction	Fraction from Extrathyroidal Component	Fraction from Thyroidal Component
0.7612000	0.1352809	0.0738687	0.0886910

Dose to the maximally exposed individual (rem)
0.227

Can this patient be released?	Yes

See NUREG 1556 Vol 9. App. U for details.

Radiation Safety Procedures for In-Patient Therapeutic Use of Radiopharmaceuticals

All patients treated with unsealed radiopharmaceuticals, (such as I-131) in quantities sufficient to require hospitalization will be placed in a private room with a private toilet. The large surfaces in the room and toilet area which are most likely to be contaminated will be covered with absorbent pads or protective material as appropriate for 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, remote controls, and other items which are difficult to decontaminate. Plastic bags or wrappings which are waterproof and easily disposable should be used on 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.

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.

1. The patient's room will be properly posted or attended.
   A. 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.
   B. 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.
   C. Radiation levels in unrestricted areas will be maintained below regulatory limits.

2. All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.

3. 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 their designee, checked for contamination and contamination survey results recorded, and disposed as normal or radioactive waste, as appropriate.
4. 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 their designee. Items may be returned for normal use, held for decay, or decontaminated, as appropriate.
5. 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.
6. 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 for inspection by the Department.

7. **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 should be placed in the designated waste container. Contact the radiation Safety Officer or the Nuclear Medicine Department for proper disposal of the contents of the designated 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 the Nuclear Medicine Department.
   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 the Nuclear Medicine Department.
   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 the Nuclear Medicine Department. **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.
   (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 the Nuclear Medicine Department.** 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 the Nuclear Medicine Department. 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 8 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 the Nuclear Medicine Department 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 and the Nuclear Medicine Department immediately.

N. When the patient is discharged, call the Radiation Safety Officer or the Nuclear Medicine Department and request that the room be surveyed for contamination and released for use before re-making the room.

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).

Nursing Instructions for In-Patients Treated with Sodium Iodide I-131

Place this form on treatment room door AND in the patient's chart

- ☐ 1. Visitors are not permitted within the first 24 hours unless approved by the Radiation Safety Officer, or designee
- ☐ 2. Patient may not leave room.
- ☐ 3. Visitors under 18 are not permitted.
- ☐ 4. Pregnant visitors are not permitted.
- ☐ 5. Personnel dosimetry must be worn by radiation workers entering the room.
- ☐ 6. Dosimetry will be worn for supplementary personnel monitoring of individual tasks.
- ☐ 7. Post the patient room door with a "Caution, Radioactive Materials" sign.
- ☐ 8. Place laundry in linen bag and save.
- ☐ 9. Housekeeping and other staff (except as permitted by the Radiation Safety Officer) may not enter the room.
- ☐ 10. Patient must have a private room with a private toilet.
- ☐ 11. Disposable gloves and booties must be worn while attending patient. Dispose of the gloves and booties in designated containers.
- ☐ 12. Patient must use disposable utensils. Dispose of the utensils and food waste in the designated containers.
- ☐ 13. All items must remain in room until approved for removal by the Radiation Safety Officer, or designee.
- ☐ 14. Smoking is not permitted.
- ☐ 15. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer, or designee.

In addition to the above training instruction, I attest that I have viewed and completed the required radiation safety training module for patients undergoing I-131 therapy.

______________________ Date:_________	______________________ Date:_________
Signature *(RN, LPN, CNA, etc)*	Signature *(RN, LPN, CNA, etc)*
______________________ Date:_________	______________________ Date:_________
Signature *(RN, LPN, CNA, etc)*	Signature *(RN, LPN, CNA, etc)*
______________________ Date:_________	______________________ Date:_________
Signature *(RN, LPN, CNA, etc)*	Signature *(RN, LPN, CNA, etc)*
______________________ Date:_________	______________________ Date:_________
Signature *(RN, LPN, CNA, etc)*	Signature *(RN, LPN, CNA, etc)*
______________________ Date:_________	______________________ Date:_________
Signature *(RN, LPN, CNA, etc)*	Signature *(RN, LPN, CNA, etc)*

In case of an **EMERGENCY** contact:

Nuclear Medicine at ext: _____________, **or** Radiation Safety Officer at: ______________.

Treatment Room Survey Worksheet

(Inpatient Therapies Only)

Patient's Name: _____ Room No. _____

Physician's Name: _____ Date and Time of Administration: _____

Radionuclide Administered _____ Dose: _____ mCi

Date and Time of Administration _____

Checklist

[ ] Written Directive completed as required
[ ] "Caution Radioactive Materials" sign posted on door
[ ] "Nursing Instructions" reviewed and signed by nursing staff; posted on door
[ ] Nursing staff provided appropriate dosimetry device
[ ] Initial exposure rate surveys are complete

DURING THERAPY SURVEYS

Exposure Surveys

(measured after the patient has been treated, with the patient in bed)

Date	Time	Tech	Survey Meter (S/N)	BKGD (mR/hr)	at Bedside (mR/hr)	at 1 meter (mR/hr)	at door (mR/hr)	Adjacent rooms (mR/hr)

POST DISCHARGE SURVEYS

Room Release Surveys

(measured after the patient has been discharged, intended for unrestricted room release)

Location	Date	Time	Tech	Survey Meter (S/N)	BKGD (mR/hr)	Scanning Survey (mR/hr)	Wipe (cpm)	Action Taken

Trigger Levels: No area may exceed 2 mR/hr. No removable contamination may exceed 1000 dpm/100 cm^2 (which, when measured with a pancake probe is 100 cpm/100 cm^2).

Room released for unrestricted use to Nursing on _____ (date) at _____ (time) by _____ (tech).

Written Directive

Patient Name:_____ Patient ID#: _____

Radiopharmaceutical name: _____ Dose:_____ mCi

Route of administration if other than I-131: _____

Approved by: _____ Date:_____
Authorized User Signature

Radiopharmaceutical Dose Verification: *To be completed by person preparing therapy dose*

Radiopharmaceutical being administered: _____
Lot number or see attached pharmacy slip: _____
Actual dose from dose calibrator:_____ mCi
Calculated percent difference from prescribed dose: _____%
Name and signature of individual administering:_____
Date:_____

If there is any doubt with regard to any aspect of this therapeutic administration or the implementation of this written directive, please contact the authorized user before proceeding.

Patient identified by a minimum of two methods: (Check items which apply)

[ ] Name on nuclear medicine request matches hospital ID bracelet.
[ ] Patient recites correct social security number.
[ ] Patient recites correct Date of Birth.
[ ] Positive identification by relative or legal guardian.
[ ] Positive drivers license identification.
[ ] Other method _____
[ ] Yes [ ] No [ ] N/A Female patient pregnant.
[ ] Yes [ ] No [ ] N/A Female patient nursing.

Name and signature of verifier:_____

Date:_____

Completeness of document verification: I attest that all sections of this form were properly completed prior to the therapeutic radiopharmaceutical administration.

Name (print): _____

Technologist Signature:_____ Date:_____

Patient Specific Release Instructions for Patients Treated with Radioactive Iodine-131 as Sodium Iodide for Hyperthyroidism, Graves', or Toxic Nodule

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The following requirements must be followed to authorize the release of patients who have been administered I-131 as sodium iodide, in order to reduce radiation exposure to others. These instructions meet the regulatory requirements.

- [ ] Patient will remain at home, not stay in a hotel room, and refrain from using public transportation or attending public gatherings, such as church, school, or sporting events, for 3 days following radioactive I-131 treatment.
- [ ] Patient will sleep alone for the first 3 days, and maintain a distance of one meter (about 3 feet) from others for the first 4 days following the above treatment.
- [ ] Patient will refrain from mouth-to-mouth contact and sexual intercourse for 3 days following treatment.
- [ ] Patient will have exclusive use of a bathroom for 2 days following radioactive I-131 treatment. Wash your hands with soap and plenty of water after going to the bathroom.
- [ ] Patient will flush the toilet two times after each use for 3 days following radioactive I-131 treatment.
- [ ] Patient will use separate eating utensils and wash them separately for the first 3 days following treatment. Do not prepare food for others.
- [ ] Patient will use separate towels and washcloths for the first 3 days following treatment. Launder your towels, bed linens, and clothing separately.
- [ ] Patient will not use disposable plates and utensils for the first 5 days following treatment.
- [ ] Women of reproductive age agree to use appropriate means to avoid pregnancy for at least six months.

IMPORTANT: A copy of these instructions must be provided to the patient for take-home reference.

Patient's Statement: I certify that I can comply with the above requirements and that I have received a copy of this document. I have received information on how to contact my physician in the event of a problem related to my thyroid cancer treatment. I authorize Dr. _____ to treat the following condition: _____, which has been explained to me in professional and lay language to include risks, benefits, and alternatives specific to me and my treatment.

_____

Print Patient Name

_____ _____

Patient Signature Date

_____ _____

Physician Signature Date

Patient Specific Release Instructions for Patients Treated with Radioactive Iodine-131 as Sodium Iodide for Thyroid Cancer / Ablation

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The following requirements must be followed to authorize the release of patients who have been administered I-131 as sodium iodide, in order to reduce radiation exposure to others. These instructions meet the regulatory requirements.

- [ ] Patient will remain at home, not stay in a hotel room, and refrain from using public transportation or attending public gatherings, such as church, school, or sporting events, for 5 days following radioactive I-131 treatment.
- [ ] Patient will sleep alone for the first 5 days, and maintain a distance of one meter (about 3 feet) from others for the first 5 days following the above treatment.
- [ ] Patient will refrain from mouth-to-mouth contact and sexual intercourse for 5 days following treatment.
- [ ] Patient will have exclusive use of a bathroom for 2 days following radioactive I-131 treatment. Wash your hands with soap and plenty of water after going to the bathroom.
- [ ] Patient will flush the toilet two times after each use for 3 days following radioactive I-131 treatment.
- [ ] Patient will use separate eating utensils and wash them separately for the first 3 days following treatment. Do not prepare food for others.
- [ ] Patient will use separate towels and washcloths for the first 5 days following treatment. Launder your towels, bed linens, and clothing separately.
- [ ] Patient will not use disposable plates and utensils for the first 5 days following treatment.
- [ ] Women of reproductive age agree to use appropriate means to avoid pregnancy for at least six months.

IMPORTANT: A copy of these instructions must be provided to the patient for take-home reference.

Patient's Statement: I certify that I can comply with the above requirements and that I have received a copy of this document. I have received information on how to contact my physician in the event of a problem related to my thyroid cancer treatment. I authorize Dr. _____ to treat the following condition: _____, which has been explained to me in professional and lay language to include risks, benefits, and alternatives specific to me and my treatment.

_____

Print Patient Name

_____ _____

Patient Signature Date

_____ _____

Physician Signature Date

Appendix A - Definitions

1. **Accelerator Produced Radioactive Material.** Radioactive material produced as the result of operating a particle accelerator.

2. **Agreement State.** Any state, territory, or possession of the United States that, by agreement with the Nuclear Regulatory Commission (DOH), has assumed regulatory authority over byproduct, source, and certain small quantities of special nuclear material.

3. **As Low As Reasonably Achievable (ALARA).** The principle that personnel exposures must be maintained as low as possible consistent with existing technology, cost, and operational requirements.

4. **Byproduct Material.** Radioactive material (except Source and Special Nuclear Material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using Source or Special Nuclear Material. ***NOTE:*** *Byproduct material, source material, and special nuclear material are defined in Title 10 Code of Federal regulations (CFR) 20.*

5. **Human Use.**The internal administration of radioactive materials, or the external administration of ionizing radiation from radioactive materials, to humans.

6. **Incident.** For this Handbook, an incident is an undesirable event involving radioactive material such as a fire or explosion involving radioactive material, a loss or theft of radioactive material, a spill of radioactive material, a release of radioactive material that exceeds permissible limits, a radiation exposure of personnel that exceeds permissible limits, the contamination of personnel with radioactive material, or a medical event defined in 10 CFR 35.2. The term incident includes any event that must be reported to the regulatory agency pursuant to 10 CFR 20.1906(d), 20.2201, 20.2202, 20.2203, 21.21, 30.9(b), 30.50, 35.33, and 35.59.

7. **License.** Written authorization from the regulatory agency to receive, possess, use, or transfer Byproduct, Source, or Special Nuclear Material or to receive, possess, use, or transfer naturally occurring radioactive material or accelerator-produced radioactive material.

8. **Licensed Material.** Radioactive material possessed under the auspices of the facility Radioactive Materials License. This includes byproduct material, accelerator-produced radioactive material, or naturally occurring radioactive material and any source material and special nuclear material.

9. **Low-Level Radioactive Waste (LLRW).** Radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or Byproduct Material as defined in Section 11e(2) of the Atomic Energy Act of 1954 (AEA-54), i.e., uranium or thorium tailings and waste.

10. **Medical Event.** For this Handbook, a medical event is the administration to humans of:
    a. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 involving the wrong patient or wrong radiopharmaceutical, or when both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

b. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or when the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.
c. A gamma stereotactic radiosurgery radiation dose involving the wrong patient or wrong treatment site; or when the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose.

d. **Brachytherapy Radiation Dose**
   1) A brachytherapy radiation dose involving the wrong patient, wrong radioisotope, or wrong treatment site ***NOTE:*** *excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site*; or
   2) Involving a sealed source that is leaking when, for a temporary implant, one or more sealed sources are not removed on completion of the procedure; or
   3) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

11. **Mixed LLRW (Mixed LLRW).** Low-level radiological wastes that also contain chemical constituents that the Environmental Protection Agency (EPA) defines as hazardous in 40 CFR 261, Identification and Listing of Hazardous Waste.

12. **Naturally Occurring Radioactive Material.** Radioactive material that occurs in nature; that is, carbon-14, radium-226, thorium-232, uranium-238, etc.

13. **Nuclear Regulatory Commission.** An agency established by Title II of the Energy Reorganization Act of 1974 (Public Law 93-438) to regulate Byproduct, Source, and Special Nuclear Material as provided for by the AEA-54, as amended. Within the regulatory agency, final authority rests with the five member Commission acting as a body.

14. **Prescribed Dosage.** The quantity of radiopharmaceutical activity as documented in a written directive or either in the diagnostic clinical procedures manual or in any proper record according to the directions of the authorized user for diagnostic procedures. ***NOTE:*** *A written directive is an order in writing for a specific patient, dated and signed by an authorized user before the administration of a therapeutic radiopharmaceutical or sodium iodide I-131 or I-125 in quantities greater than 30 uCi*.

15. **Radiation Safety Officer (RSO).** An individual with specific education and professional experience in radiation protection practice appointed by a facility director and approved by the Radiation Safety Committee to manage radiation safety programs. ***NOTE:*** *The term "Radiation Safety Officer" is a functional title and does not denote an occupational code. An RSO should be the most technically qualified person available. The RSO must have the education and professional experience needed for the position.*

16. **Radioactive Material.** Materials whose nuclei, because of their unstable nature, decay by emission of ionizing radiation. The radiation emitted may be alpha or beta particles, gamma or X-rays, or neutrons.

17. **Restricted Area.** An area or room posted to limit access for protection of individuals against undue risks from radiation and radioactive material. ***NOTE:*** *Restricted areas do not include areas within a posted room that is designated for residential use or as a non-radioactive materials use area.*

18. **Source Material.** Uranium or thorium or any combination thereof in any physical or chemical form; or ores that have, by weight, one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium, or any combination thereof. Source Material does not include Special Nuclear Material.Source Material is not currently authorized by the Radioactive Materials License.

19. **Special Nuclear Material.** Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235; any other material that the regulatory agency determines to be Special Nuclear Material, and any material artificially enriched by the foregoing. Special Nuclear Material does not include Source Material.Special Nuclear Material is not currently authorized by the Radioactive Materials License.

20. **Unrestricted Area.** An unrestricted area is any area that is not a restricted area (as restricted area is defined in this Handbook).

21. **User.** For this Handbook, a user is:

    a. A person specifically named on the Radioactive Materials License as authorized to handle or to supervise handling radioactive materials listed on the license.
    b. A person approved by the radiation safety committee to handle or supervise the handling of radioactive materials listed on the Radioactive Materials License.

22. **Written Directive.** An order in writing for a specific patient, dated and signed by an authorized user before the administration of a radiopharmaceutical or radiation that has this information:

    a. **For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.**
    b. **For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131.** The radiopharmaceutical, dosage, and route of administration.
    c. **For gamma stereotactic radiosurgery.** Target coordinates, collimator size plug pattern, and total dose.
    d. **For high-dose-rate remote afterloading brachytherapy.** The radioisotope, treatment site, and total dose.
    e. **For all other brachytherapy.** Before implantation, the radioisotope, number of sources, and source strengths, and after implantation, but before completion of the procedure, the radioisotope, treatment site, and total source, strength, and exposure time (or, equivalently, the total dose).

Appendix B – Exempt Quantities

These exemptions apply to accelerator produced and naturally occurring radioisotopes and are in addition to those in Title 10 Code of Federal Regulations (CFR) 30.71, Schedule B.

RADIONUCLIDE	MICROCURIES
Beryllium-7	0.1
Cesium-129	100
Cobalt-57	100
Gallium-6a through 6f	100
Gold-19	10
Germanium-68	10
Indium-111	100
Iodine-123	100
Iron-52	10
Potassium-43	10
Radium-226	0.01
Rubidium-81	10
Sodium-22	10
Xenon-127	100
Yttrium-87	10

NOTE: *These exemptions do not apply to radioactive material in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.*

Appendix C – Incidents Reportable to the Radiation Safety Officer and Regulatory Agency

When an incident occurs, staff must ensure that actions immediately necessary to protect the safety of patients, staff, the public, and the environment take priority over reporting requirements.

1. Incidents shall be reported to the RSO as described in this paragraph. The RSO will ensure that all required reports are made to the regulatory agency and other regulatory agencies. ***NOTE:*** *Exception: Incidents requiring immediate reports may be made directly to the regulatory agency if RSO cannot be reached.*
2. The following establishes criteria and procedures for reporting incidents involving radioactive materials to the RSO.

    a. Reporting Immediately. Report the following immediately by telephone, but no later than 3 hours following discovery:
        1. Any event, such as fire, explosion, or toxic gas release that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of permitted material that could exceed regulatory limits.
        2. Any event that causes or threatens to cause an individual to receive dose equivalents above limits listed in 10 CFR 20.2202(a)(1) Notification of Incidents, or the release of materials in excess of limits described in 10 CFR 20.2202(a)(2).
        3. Receipt of a package or packages with external radiation levels or removable surface contamination that exceed the limits specified in 10 CFR 20.1906(d), Procedures for Receiving and Opening Packages.
        4. Any lost, stolen, or missing radioactive materials in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to 10 CFR 20.

    b. Reporting no later than the next calendar day. Any medical misadministration, as defined in 10 CFR 35.2, must be reported by telephone no later than the next calendar day after discovery.

    c. Reporting within 24 hours. An incident report by telephone is required within 24 hours of discovery for the following:
        1. Any event that causes or threatens to cause an individual to receive dose equivalents in excess of limits described in 10 CFR 20.2202(b)(1), or release of radioactive material as described in 10 CFR 20.2202 (b)(2).
        2. Any unplanned contamination event that meets all of the following criteria:
            a. Requires access to the contaminated area, by workers, or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry to the area.
            b. Involves a quantity of radioactive material greater than five times the lowest annual limit of intake (ALI) in Appendix B to 10 CFR 20.1001 to 20.2401.
            c. Requires restricting access to the area for a reason other than to allow radionuclides with a half-life of less than 24 hours to decay before decontamination.
        3. Any event in which equipment is disabled or fails to function as designed when:
            a. The equipment is required to be operational by regulation or conditions of a permit to prevent releases exceeding regulatory limits, or to prevent exposure to radiation

and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident.

b. The equipment is required to be available and operable.

c. No redundant equipment is available and operable to perform the required safety function.

4. Any event requiring unplanned medical treatment at a medical facility of a person with spreadable radioactive contamination on the person's clothing or body.
5. An unplanned fire or explosion that damages any permitted radioactive material or any device, container, or equipment containing such material when:
    a. The quantity of material exceeds five times the lowest ALI specified in Appendix B to 10 CFR 20.
    b. The damage affects the integrity of the radioactive material or its container.

d. Reporting within 5 Calendar Days. Whenever a leak test of a sealed source reveals the presence of 0.005 microcurie or more of removable contamination, a report must be filed within 5 calendar days. ***NOTE:*** *Leak testing is required by regulatory agency regulations, MML permit conditions, or facility regulations.*

e. Reporting within 15 Calendar Days. A written report, containing the information listed in 10 CFR 35.33, shall be submitted within 15 days of discovery of a medical misadministration, as defined in 10 CFR 35.2.

f. Reporting within 25 Calendar Days. Reports are required in writing within 25 calendar days of discovery for the following:
    1. Lost, stolen, or missing radioactive material in a quantity greater than ten times the quantity in Appendix C to 10 CFR 20, that is still missing at the end of the 25 days.
    2. Dose that exceeds the occupational dose limits specified in 10 CFR 20.1201, Occupational Dose Limits for Adults, or 10 CFR 20.1207, Occupational Dose Limits for Minor.
    3. Dose that exceeds the limits for an embryo or fetus of a declared pregnant woman in 10 CFR 20.1208, Dose Limits to an Embryo or Fetus.
    4. Dose to a member of the public that exceeds the limits in 10 CFR 20.1301, Dose Limits for Individual Member of the Public.
    5. Dose that exceeds any applicable limit in the permit.
    6. Doses in excess of the ALARA constraints for air emissions established under 10 CFR 20.1101(d).
    7. Levels of radiation or concentrations of radioactive material in a restricted area in excess of any applicable limit in the facility permit.
    8. Levels of radiation or concentrations of radioactive material in an unrestricted area in excess of ten times any applicable limit in 10 CFR Part 20, or in the facility permit even if persons were not exposed in excess of the limits in 10 CFR 20.1301.

g. Reporting within 50 Calendar Days. Reports are required in writing within 50 calendar days of the discovery of defects or failures to comply as described in 10 CFR 21.21.

h. Content of Telephone Reports. Telephone reports of incidents, including medical events, accidents, defects, or non-compliances, shall include to the extent that the information is available at the time:

1. Names of organization and individual making the report, call-back telephone number, fax number, and mailing address.
2. Brief description of the incident, including date, time, and location.
3. Radionuclides, activities, and chemical and physical form of the material involved.
4. Any personnel exposure data available.

i. Content of Written Reports. Reports submitted in writing shall include:
1. Name of organization and individual making the report, telephone number, fax number, and mailing address.
2. Description of event, including probable cause(s).
3. The manufacturer and model number (if applicable) of any equipment that failed or malfunctioned.
4. The exact location of the event.
5. Date and time of the event.
6. Radionuclides, activities, and chemical and physical form of the material involved.
7. Corrective actions taken or planned, estimated completion time, and expected results.
8. Measures or estimates of surface contamination.
9. Measures or estimates of radiation levels.
10. Measures or estimates of air and/or water release.
11. Extent of exposure of persons to radiation or radioactive material.
12. An assessment of exposures and risks to all other facilities, locations and persons.
13. Federal, state or local organizations or agencies notified.
14. Radioactive Materials Permit Number.
15. For reports of medical event, all information listed in 10 CFR 35.33.