



Guidelines
for the
Clinical Use
of
Radioactive Materials (RAM)
And
Radiation-Producing Machines (RPM)

CPM 122

This guideline is intended as a resource document for the safe use of radiation in the clinical setting. If you have questions or comments, please contact the Office of Radiation Safety at (414) 805-6540.

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Section I: General Policies

Management Control and Responsibilities

Management Policy Statement

Radiation Safety Program [CPM.0120]

The Medical College of Wisconsin (MCW) is licensed by the State of Wisconsin, Department of Health Services (DHS) to use radioactive materials (RAM) for clinical and research applications at facilities located at Froedtert Memorial Lutheran Hospital (FMLH) and MCW. The RAM license is a broadscope license for the use of unsealed and sealed sources for clinical human use and biomedical research including for the use of cobalt-60 as sealed sources in teletherapy irradiators, biomedical research and for the use of cesium-137 as sealed sources for use in self-shielded irradiators for the irradiation of materials, e.g., small animals, biological samples, blood and blood products, excluding explosive and flammable materials. The Administrations of MCW and FMLH are responsible for the maintenance of the license and the activities governed by DHS. FMLH and MCW are jointly responsible for the implementation and review of a radiation safety program that conforms to DHS regulations, specific license conditions and other federal, state and local regulating agencies.

The radiation safety program is directed and monitored by the Radiation Safety Committee (RSC). The RSC is an administrative committee responsible for the oversight of RAM under the licenses. The day-to-day operation of the radiation safety program is provided by the Radiation Safety Office (RSO) under the direction of the Radiation Safety Officer (RSO). The RSO has been delegated the authority by FMLH and MCW administrations to address and resolve problems that could lead to noncompliance of regulations or DHS license conditions. The RSO is a member of the FMLH Environment of Care Committee for purposes of reporting and coordinating safety and emergency response activity.

Radiation Safety Committee (RSC)

The RSC is comprised of, but not limited to, the RSO, representatives from the administrations of FH and MCW, an authorized user from each type of use permitted under the license, a representative of the nursing service and ad hoc members deemed appropriate by the administration.

The responsibilities of the RSC regarding the use of radioactive material (RAM) are to establish policies and procedures for the use of RAM at the facilities under the license approve or deny applications for the use of RAM and review the radiation safety program with the assistance of the RSO.

Radiation Safety Office (RSO)

The day-to-day operation of the radiation safety program is conducted by the RS staff. The RSO oversees the RS and staff. The duties of the staff include monitoring RAM use, identifying radiation safety problems, verifying implementation of corrective actions and monitoring compliance with regulations.

Additionally, the RS initiates, recommends, and/or provides corrective actions for areas of concern, and occurrences of noncompliance with DHS regulations or license conditions. The RS, under the supervision of the RSO, is delegated the authority necessary to assure the radiation safety requirements are met, including the stoppage of any operation deemed unsafe.

Authorized User

The medical use of radiation, either RAM or RPM, shall only be with the knowledge and approval of the RSC. Applications for such use shall be submitted to the RS for review by the RSC. An applicant shall be a physician licensed to practice medicine in the state of Wisconsin and meet the training criteria designated by Wisconsin Administrative Code, DHS 157.

Staff

Individuals who come into contact with RAM or ionizing radiation from RAM and/or RPM have certain rights and responsibilities according to state and federal regulations. These are outlined in the DHS Form PPH 45027 - Notice to Employees, and the accompanying Supplement to Notice to Employees. These documents are posted in locations where RAM and RPM are used or stored.

Section II: Medical Use Operating Policies

Medical Use of Radiation/Radioactive Materials

The RSC shall approve authorized user physicians for medical use of RAM for diagnosis or therapy, and the therapeutic use of radiation (e.g., external beam teletherapy). Applicants must provide documentation of training and experience qualifications prior to approval by the RSC.

The use of radiation-emitting products in a manner other than that specified in the Registry of Sealed Sources and Devices requires approval from the appropriate Institutional Review Board (IRB).

All references in this manual to the term 'patient' refers to the patient or human research subject as referenced to in DHS 157.

The medical use of radionuclides/radiation in procedures not requiring a written directive shall be performed in such a manner as to maintain radiation exposure to employees and the public as low as reasonably achievable and in accordance with DHS regulations, license conditions, and the departmental Policy and Procedure manual.

The medical use of RAM/RPM requiring a written directive shall be performed in accordance with the written directive and in such a manner as to maintain radiation exposure to employees and the public as low as reasonably achievable. Specifically, radiation levels shall be maintained such that individual members of the public could not receive a radiation dose in excess of 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) in one year. Patients having been administered doses of unsealed RAM or radioactive implants shall not be released from control unless the total effective dose equivalent to any individual member of the public from exposure to the released

individual is not likely to exceed 5 mSv (500 mrem). Release of such patients shall be in accordance with DHS 157.62(8).

Medical Events [RSO-008]

Medical events are defined in DHS 157.72(1) for RAM and DHS 157.83(3) for RPM. A brief description is listed below, for full requirements; refer to the appropriate section of the DHS regulations:

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 50 mSv (5 rem) effective dose equivalent, 500 mSv (50 rem) to an organ or tissue, or 500 mSv (50 rem) shallow dose equivalent to the skin; **and**
 - a. The total dose delivered differs from the prescribed dose by 20 percent or more;
 - b. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
 - c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
2. A dose that exceeds 50 mSv (5 rem) effective dose equivalent, 500 mSv (50 rem) to an organ or tissue, or 500 mSv (50 rem) shallow dose equivalent to the skin from any of the following--
 - a. An administration of a wrong radioactive drug containing RAM;
 - b. An administration of a radioactive drug containing RAM by the wrong route of administration;
 - c. An administration of a dose or dosage to the wrong individual or human research subject;
 - d. An administration of a dose or dosage delivered by the wrong mode of treatment; or
 - e. A leaking sealed source.
3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 500 mSv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).
4. Any event resulting from intervention of a patient in which the administration of RAM or radiation results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician, shall be reported in the same manner as a medical event.

Any individual who knows of or suspects any occurrences that may meet the criteria listed above shall report such occurrences promptly to their immediate supervisor, the authorized user,

authorized medical physicist, authorized nuclear pharmacist, or a radiation safety staff member, as appropriate. Such occurrences shall be evaluated as potential medical events.

Reports of Medical Events

In general, reports of medical events shall be made by the RSO or designee after consultation with the authorized user and authorized medical physicist/nuclear pharmacist, and a determination is made that an occurrence may constitute a medical event.

Reports of medical events shall be in accordance with DHS 157.72(1) for RAM and DHS 157.83(3) for RPM. A brief description is listed below, for full requirements; refer to the appropriate section of the DHS regulations:

When a medical event is determined to have occurred (other than those involving therapy machines), a report shall be made to DHS, Radioactive Materials Section no later than the end of the next calendar day.

DHS –Medical Event Reporting phone Number (608) 267-4797

A written report shall be submitted to DHS within 15 days after discovery of the medical event.

1. The written report must include--
 - a. The licensee's name;
 - b. The name of the prescribing physician;
 - c. A brief description of the event;
 - d. Why the event occurred;
 - e. The effect, if any, on the individual(s) who received the administration;
 - f. What actions, if any, have been taken or are planned to prevent recurrence; and
 - g. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.
2. The report may not contain the individual's name or any other information that could lead to identification of the individual.

[From DHS 157.72]

A licensee shall notify the referring physician of the event and also notify the person who is the subject of the medical event no later than 24 hours after its discovery unless the referring physician personally informs the licensee either that the physician will inform the person or that, based on medical judgement telling the person would be harmful. A licensee is not required to notify the person without first consulting the referring physician. If the referring physician or the affected person cannot be reached within 24 hours, a licensee shall notify the person as soon as possible thereafter. A licensee may not delay any appropriate medical care for the person, including any necessary remedial care resulting from the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the person who is

the subject of the medical event may be made instead to that person's responsible relative or guardian. If a verbal notification is made, a licensee shall inform the person or appropriate responsible relative or guardian that a written description of the event may be obtained from the licensee upon request. A licensee shall provide the written description if requested.

If the person who is the subject of the medical event was notified under 1., a licensee shall also furnish within 30 days after discovery of the medical event a written report to the person by sending either of the following:

- a. A copy of the report that was submitted to the department.
- b. A brief description of both the event and the consequences as they may affect the person.

Further guidance on patient privacy with regards to reports of medical events is provided in the DHS regulations.

Sentinel Events - Fluoroscopy [CPM.0124]

Occurrences where patients receive an x-ray dose of 15 Gray or more through a single entrance field will be reported to the Froedtert Hospital Quality Review Committee. An incident report will be completed.

Definitions

Investigational Level - An investigational level is established based on cumulative time of fluoroscopic x-ray exposure over a period of six months. For cases that exceed the investigational level, the technical parameters of the exposure will be reviewed to determine whether a reportable dose has been received. The investigational level is:

A cumulative fluoroscopy exposure to a single field of 100 minutes or more.

A cineradiography or digital subtraction angiography exposure to a single field of 10 minutes or more.

A combined fluoro/cine exposure to a single field according to the following formula:

$\text{fluoro minutes} + (10 \times \text{cine minutes}) > 100$

Reportable Dose - A fluoroscopic x-ray dose to a single field greater than 15 Gray (1500 rad).

The total fluoroscopy time, cineradiography and/or digital subtraction time for every patient will be recorded in the patient record.

Cases where the investigational level is exceeded will be reported to the Radiation Safety Officer. The Radiation Safety Officer, with assistance from Radiology Physics, will make a determination as to whether a reportable dose has occurred.

Reportable doses will be reported to the Froedtert Hospital Quality Review Committee.

Radiation Therapy Inpatients [RSO-200]

Patients undergoing therapy involving RAM that cannot be released shall be given a private room. For patients undergoing therapy with unsealed radionuclides, a private sanitary facility must also be provided.

The door to the patient's room shall be visibly posted with a 'Caution Radioactive Materials' sign and instructions concerning how long and where visitors may remain in the room.

Items such as linens and trash from such rooms shall be monitored with an appropriate radiation detector on its most sensitive scale, or such items shall be treated as radioactive waste.

Staff caring for such patients shall receive safety instruction, initially and at least annually. Training shall include:

- a. Patient or human research subject control;
- b. Visitor control;
- c. Contamination control;
- d. Size and appearance of the brachytherapy sources, if in use;
- e. Safe handling and shielding instructions;
- f. Waste control; and
- g. Notification of the RSO, or his/her designee, and the authorized user if the patient or the human research subject has a medical emergency or dies.

A radiation survey shall be made to determine compliance with applicable dose limits in all occupiable adjacent areas.

In general, for I-131 thyroid treatments and temporary Cs- 137 or Ir-192 brachytherapy implant patients, 4SW Room 20 should be used. I-125 Gliosite and I-125 eye plaque patients should be housed in any room on 5NW. Use of any other rooms shall be cleared in advance by RS.

Adjacent rooms to these areas may need to be kept vacant during periods when these patients are undergoing radiation therapy. In such cases, RS will post instructions concerning these areas and inform the staff of such restrictions.

Patient Care

Staff –providing care for patients undergoing radionuclide therapy shall have training, initially and at least annually, in radiation safety techniques and procedures commensurate with care they provide to the patient. The utilization of pregnant staff must conform with the FMLH/MCW Embryo/Fetus Monitoring Policy CPM 121). Instructions shall be placed in the patient's chart with specific instructions as the care of the patient and any special precautions that may be in effect.

Environmental Services (EVS) – EVS staff may enter a brachytherapy patient's room for light housekeeping such as emptying waste baskets. EVS staff are not to enter a patient room after the patient has received a therapeutic iodine-131 dose.

All personnel involved with radiation therapy procedures shall adhere to the ALARA principles for radiation exposure:

Time – Spend only the amount of time nearest the patient that is required for ordinary and safe nursing care.

Distance – When not delivering direct care requiring close proximity, increase your distance as much as practical.

Shielding – Position yourself behind the bedside shield as much as practical for brachytherapy patients.

If issued, dosimeters (film badges) are to be worn as directed and returned at the end of the shift. Monitors are not to be shared or traded with other individuals in any circumstance.

Patients undergoing radiation therapy procedures are to remain in their room unless otherwise directed on the physicians order sheet.

Visitors – Patients may have visitors during radionuclide therapy. RS will post instructions to visitors on the door, informing them to where visitors are allowed in the room and how long they may remain. Visitors may be allowed to receive a dose of up to 5 mSv (500 mrem) if the visit is planned and approved prior to the treatment. See DHS 157.23(1)(c).

Medical Emergency Procedures of an Inpatient Following Therapeutic Dose of Radionuclides or Implantation of Radiation Devices

The Radiation Oncology Department shall be notified immediately of medical emergency procedures of a patient containing a brachytherapy implant. The RS shall be notified as soon as practical in the event of medical emergency procedures of a patient containing a therapeutic dose of radionuclides or brachytherapy implant.

Nursing Department – Notify the Radiation Oncology Department (for brachytherapy patients only) immediately and the RS (for patients receiving therapeutic RAM implant or therapeutic dose) as soon as reasonably possible if emergency surgery is required; or in the event of any medical emergency procedures requiring intensive medical intervention, or if there is a change of condition or mental status; or in the case of cardiac arrest (code 4), begin the necessary medical procedures prior to contacting the Radiation Oncology Department. Insure that any precautions or instructions received from the RS or Radiation Oncologist are attached to the patient's chart accompanying the patient to surgery in the case of emergency surgery.

Radiation Oncology Department (brachytherapy patients only) – Evaluate the need to remove the source(s) from the patient undergoing brachytherapy treatment requiring medical emergency care.

Radiation Safety staff – Inform nursing and medical staff of precautions necessary to keep radiation exposure as low as reasonably achievable. Perform radiation surveys, as appropriate, where medical procedures were performed including operating suites, recovery rooms and personnel in the case of emergency surgery. Monitor tissue or devices removed during surgery for radioactivity. Inform Pathology of possible receipt of radioactive devices or tissues from surgery.

Operating Room – Follow precautions that accompany radioactive patient to surgery. Clearly identify devices or tissues removed during surgery before sending to appropriate departments as potentially radioactive.

Pathology Department –

Inform the RS as soon as reasonably possible of the receipt of any potentially radioactive devices or tissues received from surgery. Follow precautions that accompany the radioactive body to the morgue.

Notification and Questions

Medical questions should be directed to the appropriate medical service. Medical questions regarding the therapy procedure or protocol should be directed to the Radiation Oncology Department for brachytherapy procedures and Nuclear Medicine for therapeutic radiopharmaceutical I-131 procedures. Radiation safety questions should be directed to the RS. Telephone numbers are listed in the Nursing Instructions posted in the patient's chart.

Death of an Inpatient Following Therapeutic Dose of Radionuclides or Implantation of Radiation Devices [CPM.0160]

A. Death of a Radioactive Inpatient

1. In the rare event that an inpatient dies while still containing a therapeutic quantity of RAM, the treating radiation oncologist or nuclear medicine physician and the RS shall be notified immediately.

B. Notification of the Medical Examiner

1. The Medical Examiner must be notified in the event of the death of a radioactive inpatient. If the Medical Examiner accepts the case, the Radiation Safety Officer must get approval from the Medical Examiner before removing any implants. ([See Corporate Policy CPM.0072-Death of a Patient](#))

C. Notifications

1. If the patient was treated with a permanent implant or with a therapeutic amount of a radiopharmaceutical, the RSO shall notify:

a. The patient's nurse of precautions for handling the body prior to transferring the body to the morgue, including instructions and precautions for the patient transporter.

b. The morgue staff/medical examiner prior to starting a postmortem.

c. The RSO should discuss radiation safety precautions with funeral home personnel prior to the release of the body to the funeral home.

D. Removal of Temporary Implants

1. If the body contains a temporary implant, the sources shall be removed prior to starting a postmortem or transferring the body to the funeral home. After the sources have been removed, the RSO shall perform a radiation survey to confirm that no sources remain in the body. When it is confirmed that all sources have been retrieved, postmortem care may be initiated or the body may be transferred to the funeral home.

E. Precautions During Autopsy

1. Patients treated with seed implants will have the radioactive source localized to the area where the seeds were implanted. The RSO or radiation oncologist may advise the pathologist/medical examiner where the seeds are located and that area may be excised before the rest of the autopsy proceeds. Migration of seeds initially implanted in the prostate has been reported to occur. The pathologist/medical examiner should be made aware of this possibility so that seeds found outside the prostate may be excised, if possible. The excised tissue is to be segregated from the body until surveyed for radiation.

2. Sectioning of the excised tissue may be done immediately with Radiation Safety assistance so that any seeds may be removed from sections saved for pathological examination.

3. The excised area including the seeds may then be replaced in the body at the conclusion of the autopsy. It is possible to slice through seeds during sectioning of an excised tissue. The pathologist should be warned of this possibility and advised to proceed cautiously. It is rare that the body of a patient will be delivered to autopsy shortly after administration of a therapeutic radiopharmaceutical. If death occurred shortly after administration (i.e., within 24 to 48 hours), a considerable amount of activity will be present in blood and urine. In such cases, the autopsy should be supervised by the RSO and personal monitors may be issued to Pathology personnel according to the judgment of the RSO.

4. Tissue samples taken by the pathologist/medical examiner for analysis shall be monitored for measurable levels of radiation. Determination of any residual activity in tissue samples should be made by the RSO before release of the samples to the laboratory.

5. If death occurred at any time > 48 hours post administration, it may be expected that there will be little, if any, activity in blood or urine and that the activity will be present only in residual thyroid tissue, if any, or in metastatic disease sites.

6. Personal monitors may be issued to Pathology/medical examiner personnel according to the judgment of the RSO.

7. Tissue samples should be handled as described above.

F. Preparation for Burial without Autopsy or Embalming

1. If the attending radiation oncologist, nuclear medicine physician or RSO believes that the effective dose likely to be received by personnel preparing the body for burial without autopsy or embalming will approach 5 mSv (500 mrem), the treating physicians or RSO should provide radiation precaution information to the family of the deceased. In most cases, precautions will be limited to restricting the time spent near the body to provide reasonable assurance that family members will not receive > 5 mSv (500 mrem) effective dose.

G. Preparation for Burial by Embalming

1. The administering physician or RSO should notify the morgue, funeral home and/or medical examiner that the body contains therapeutic quantities of RAM and should provide personnel who embalm the body with precautions to minimize radiation exposure and radioactive contamination. If the maximal dose equivalent rate at 30 cm from any surface of the body is < 0.5 mSv h⁻¹, no special precautions are necessary.

2. Embalming is conducted by injecting an embalming fluid into the body and flushing body fluids into the drain. During the embalming of bodies that contain therapeutic radiopharmaceuticals, personnel involved in the procedure should follow precautions similar to those used for infection control (i.e., use of gloves and protective clothing) to avoid personal contamination. Careful cleaning of equipment in the usual manner will remove radioactive contamination.

3. When embalming bodies that contain permanent implants such as ¹²⁵I or ¹⁰³Pd, personnel should avoid standing next to the area of the body that contains the implant.

4. The RSO should discuss the exposure rates to personnel involved in the embalming procedure and provide guidance on the times and distances. It is recommended that the effective dose to personnel be limited to 0.25 mSv per embalmed body.

A. Notification of Death

1. Upon the death of a radioactive inpatient, the nursing staff/attending physician shall immediately notify the treating radiation oncologist or nuclear medicine physician and the Radiation Safety Office.

B. Notification of the Medical Examiner

1. The Medical Examiner must be notified in the event of a death. If the Medical Examiner accepts the case, the Radiation Safety Officer must get approval from the Medical Examiner before removing any implants.

C. Notification

1. The Radiation Safety Office shall promptly notify:

a. The patient's nurse of precautions for handling the body prior to transferring the body to the morgue, including instructions and precautions for the patient transporter.

b. The morgue staff/medical examiner prior to starting a postmortem of the specifics of the therapy and necessary precautions.

c. The funeral home personnel to discuss the specifics of the therapy and necessary precautions prior to releasing the body to the funeral home.

D. Removal of Temporary Implants

1. A radiation oncologist shall remove temporary brachytherapy implants prior to starting a postmortem or transferring the body to the funeral home by a radiation oncologist or treating surgeon.

2. An ophthalmic surgeon shall remove eye plaques.

E. Permanent Implants and Radiopharmaceuticals

1. If the patient was treated with a permanent implant or with a therapeutic amount of a radiopharmaceutical, the RSO shall notify the morgue/medical examiner prior to starting a postmortem or transferring the body to the medical examiner and/or funeral home, and the RSO should discuss radiation safety precautions with morgue personnel prior to postmortem procedures.

2. Lab Specimens

- a. Lab specimens such as lymph node biopsies and fully decayed Brachytherapy implant seeds require no special handling or labeling precautions. Whenever permanent implant brachytherapy seeds are found during specimen dissection, the seeds shall be monitored with a Geiger counter to see if they are still radioactive.

3. Brachytherapy implant seeds that test positive with the Geiger counter should not be handled with the fingers. Pick up these seeds with tweezers or tongs and put in a container labeled Caution - Radioactive Material (labels are provided by the RS). Contact the RS for specific handling and disposal instructions.

F. Precautions During Autopsy

1. Patients treated with permanent seed implants will have the radioactive source localized to the area where the seeds were implanted. The RSO or radiation oncologist may advise the pathologist/medical examiner where the seeds are located and that area may be excised before the rest of the autopsy proceeds.

- a. The pathologist/medical examiner should be made aware of this possibility so that seeds found outside the prostate may be excised, if possible.

- b. The excised tissue is to be placed in a separate area.

- c. Sectioning of the excised tissue should be with Radiation Safety assistance so that any seeds may be removed from sections saved for pathological examination.

- d. The pathologist/medical examiner shall be warned of the possibility of slicing through seeds during sectioning of an excised tissue and advised to proceed cautiously.

- e. If the body of a patient is delivered to autopsy shortly after administration of a therapeutic radiopharmaceutical (within 24 to 48 hours), the autopsy should be supervised by the RSO.

2. Personal monitors shall be issued to Pathology personnel according to the judgment of

the RSO.

3. Tissue samples taken by the pathologist for analysis should be held until the activity has decayed below measurable levels (e.g., for ten half lives).

4. Determination of any residual activity in tissue samples should be made by the RSO before release of the samples to the laboratory. If death occurred at any time > 48 hours post administration, it may be expected that there will be little, if any, activity in blood or urine and that the activity will be present only in residual thyroid tissue, if any, or in metastatic disease sites.

G. Release of Bodies to the Funeral Home

1. Clinical pathology laboratory/morgue personnel shall notify funeral home personnel of the type of radioactivity the body contains and the procedure for contacting the RS for precautions.

H. Preparation for Burial without Autopsy or Embalming

1. If the attending radiation oncologist, nuclear medicine physician or RSO believes that the effective dose likely to be received by personnel preparing the body for burial without autopsy or embalming will approach 5 mSv, the treating physicians or RSO shall provide radiation precaution information to the family of the deceased, if practical.

2. Suggested precautions will be limited to restricting the time spent near the body to provide reasonable assurance that family members will not receive > 5 mSv (500 mrem) effective dose.

I. Preparation for Burial by Embalming

1. The administering physician or RSO shall notify the Medical Examiner and/or funeral home, if practical, that the body contains therapeutic quantities of RAM and should provide personnel who embalm the body with precautions to minimize radiation exposure and radioactive contamination.

2. If the maximal dose equivalent rate at 30 cm from any surface of the body is < 0.5 mSv/hr (50 mrem) no special precautions are necessary.

3. During the embalming of bodies that contain therapeutic radiopharmaceuticals, personnel involved in the procedure should follow standard precautions similar to those used for infection control (i.e., use of gloves and protective clothing) to avoid personal contamination.

4. Careful cleaning of equipment in the usual manner will remove radioactive contamination.

5. When embalming bodies that contain permanent implants such as ¹²⁵I or ¹⁰³Pd, personnel should avoid standing next to the area of the body that contains the implant.

6. The RSO should discuss the exposure rates to personnel involved in the embalming procedure and provide guidance on the times and distances.

7. It is recommended that the effective dose to personnel be limited to 0.25 mSv (25 mrem) per embalmed body.

[Release of Patients \[CPM.0125\]](#)

A patient may be released from control after being administered unsealed RAM or implants containing RAM if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (500 mrem). The release shall be in accordance with DHS 157.62(8).

The department administering the therapy shall provide the released patient or patient's parent or guardian with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (100 mrem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (100 mrem), assuming there were no interruption of breast-feeding, the instructions must also include

- Guidance on the interruption or discontinuation of breast-feeding; and
- Information on the potential consequences, if any, of failure to follow the guidance.

The RS shall maintain a record of the basis for authorizing the release of an individual as required by DHS 157.62(8).

As a general policy, release of patients shall be in accordance with the recommendations of NRC Regulatory Guide 8.39, Release of Patients Administered Radioactive Materials. Patients who are administered activities of RAM greater than those listed in Column 1 of Table 2 in Reg Guide 8.39 must be given instructions, including written instructions, on how to maintain doses to other individuals as low as reasonable achievable.

Records

In general, radiation safety program records are to be maintained in a readily accessible form for at least three years. The type of records and the duration for which they shall be maintained is detailed in DHS 157.

Records of personnel dosimetry are to be maintained indefinitely.

[Monitoring Radiation Dose \[CPM.0123\]](#)

Occupational Dose Limits

The following definition of occupational dose is derived from DHS 157.03:

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to RAM. Occupational

dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered RAM and released under DHS 157.62(8), from voluntary participation in medical research programs, or as a member of the public.

Exposure Type	Annual Limits for Radiation Workers		ALARA Level I (per calendar quarter)		ALARA Level II (per calendar quarter)	
	mSv	mrem	mSv	mrem	mSv	mrem
Whole Body	50	5,000	1.25	125	3.75	375
Extremity or Skin*	500	50,000	12.5	1,250	37.5	3,750
Individual Internal Organs	500	50,000	12.5	1,250	37.5	3,750
Lens of the Eye	150	15,000	3.75	375	11.25	1125
Embryo/Fetus	5	500	0.5/month	50/month	1/month	100/month

ALARA Levels

ALARA Levels are action levels put in place to alert RS before an individual may exceed any of the applicable dose limits.

Level 1 – The RSC is notified at the next quarterly meeting.

Level 2 – RS conducts an investigation of the circumstances involved in the exposure, and makes recommendations for dose reductions, as needed. The results of the investigation are reported to the RSC at the next quarterly meeting.

Radiation Exposure During Pregnancy [CPM.0121]

Radiation Exposure of the Embryo/Fetus

Pregnant women occupationally exposed to radiation have the option of limiting radiation exposure to their embryo/fetus to 5 mSv (500 mrem) during pregnancy. To do so, the woman must voluntarily notify the RS in writing of her pregnancy and the estimated date of conception (month and year only).

Declaration of Pregnancy – RS will make available a form letter for the purposes of declaring pregnancy. The employee may choose to use the form letter, or provide her own written notification. The declaration must contain, at a minimum, the name of the employee, a statement that she is pregnant, her estimated date of conception (month and year only) and the department/service of employment.

The Declaration may be sent to the employee's immediate supervisor, or to RS. If the immediate supervisor is notified, the supervisor must promptly notify RS.

RS will provide information to the declared pregnant woman concerning the health effects/risks associated with exposure of the fetus during pregnancy, methods of maintaining radiation exposure within the dose limits, and by following the As Low As Reasonably Achievable (ALARA) principle. RS will evaluate the working conditions to determine compliance with fetus/embryo radiation exposure limits.

Minors

Persons under the age of 18 who are employed or volunteering in areas where they may be exposed to radiation are limited to 10% of any of the applicable limits in Table 1.

Monitoring of Individuals for Radiation Exposure

Individuals who are likely to receive a dose in excess of 10% of any of the applicable limits in Table 1, any individuals who enter a high radiation area, or any individual who is within 6 feet of an operating medical fluoroscope are required to be monitored for radiation exposure.

Dosimeters (film badges) are obtained through RS. Individuals requesting a dosimeter must complete the Dosimeter Application Form. A copy of this form may be obtained from RS or online at either the Radiation Safety website on the FH Intranet or on the RS Internet website, located at www.mcw.edu/radsafe.

If assigned a dosimeter, please follow these rules.

1. Wear the monitor while on duty in areas where RAM/RPM are in use. Store the dosimeter in a cool, dry place away from sources of radiation when not in use.
2. Do not tamper with the monitor. Protect it from damage.
3. Notify RS as soon as practical of a lost or damaged dosimeter.
4. Notify RS as soon as practical of any suspected high exposure or contamination of the monitor.
5. Whole Body dosimeters – film or TLD badges are to be worn at collar level near the neck. If a lead apron is worn, the film badge is to be worn at collar level near the neck outside of the apron.
6. Extremity dosimeter – finger TLD rings are to be worn on the finger under disposable gloves of the hand where the greatest exposure is anticipated. When handling radionuclides the preferred position of the TLD chip is on the palm side of the hand.
7. Special purpose dosimeter – in some cases dosimeters will be issued by RS for the purposes of monitoring special procedures. In such cases, specific instruction will be given by RS.
8. Exchange the dosimeter as directed by RS. Dosimeters are exchanged either quarterly or monthly. Please turn in old dosimeters promptly.

9. Never wear a dosimeter assigned to another individual or let another individual wear your badge.
10. Upon termination of employment or if the monitor is no longer required, return the dosimeter to RS. If you would like a copy of your radiation exposure history while working at FMLH, submit a signed request that includes your name, social security number, department, dates of employment and address to which you want the report released.

Results of individual monitoring are available on request from RS.

Bioassays

Any individual who is likely to receive an internal dose of greater than 10% of any of the applicable limits in Table 1 shall be monitored for internal dose. Individuals who prepare or administer doses of I-131 in quantities greater than 30 mCi shall be monitored for thyroid uptake of radioiodine.

Results of Individual Monitoring

Dosimetry results are sent to individuals who receive a dose in excess of 10% of any of the applicable limits in Table 1 at the end of each calendar year. Dose reports for these same individuals must also be sent to the Radiation Protection Section of the Wisconsin DHS.

Any individual who is monitored for radiation exposure may obtain the results upon request from RS.

Surveys and Monitoring

Surveys for radiation levels or contamination shall be made at the end of each day in areas where RAM is in use, except where patients are confined pursuant to DHS 157.62(8). Such surveys should be capable of determining compliance with the occupational and/or members of the public dose limits.

Survey instruments used to determine compliance with the dose limit shall be calibrated annually by the RS or other persons qualified to perform survey meter calibrations.

Receipt of RAM

Radioactive Material, Receipt of [CPM.0165]

In general, packages containing RAM shall be monitored for external radiation levels and for removable contamination as soon as possible upon receipt, but no later than three hours after receipt. Packages received after working hours must be surveyed at the beginning of the next working day.

If external radiation levels or removable surface contamination exceeds any of the applicable limits, RS shall be notified immediately.

Posting Requirements

All personnel working with or handling RAM are responsible for the following guidelines pertaining to the proper labeling and storage of RAM. The room, area or receptacle where RAM is used or stored shall be posted with the radiation symbol and an appropriate “Caution” sign of one of the following:

- “Radioactive Materials” – an area or room in which there is used or stored an amount of RAM exceeding 10 times the quantities listed (μCi) in DHS 157, Appendix F.
- “Radiation Area” – an area accessible to individuals where radiation levels could result in an individual receiving a dose equivalent in excess of 0.5 mSv (5 mrem) in one hour 30 centimeters from the radiation source or from any surface that the radiation penetrates.
- “High Radiation Area” – an area accessible to individuals in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (100 mrem) in one hour 30 centimeters from the radiation source or from any surface that the radiation penetrates.

The entrance door of a patient room of each patient admitted for compliance with DHS 157.62(8) shall be posted with a “Caution Radioactive Materials” sign and a note on the door or in the patient’s chart of where and for long to visitors may stay. All accessible adjacent areas shall be posted in compliance with the rules listed above.

No one may declassify any of the above areas unless the approval of the RSO is obtained. Area signs cannot be removed unless instructed by the RSO.

Exceptions to the posting rules listed above are as follows:

- Rooms or other areas occupied by patients are not required to be posted provided that the patient could be released from confinement pursuant to DHS 157.62(8).
- A room or area is not required to be posted with a caution sign due to the presence of a sealed source, provided the radiation level at 30 cm from the surface of its container does not exceed 0.5 mSv/hr (5 mrem).
- Temporary (less than 8 hours) radionuclide work areas do not require posting or labeling as long as the RAM is constantly attended by a user who has control over the area and will minimize exposure to personnel.

Labeling Requirements

Lab equipment, counter tops, glassware, waste containers and any items that are used with and may be contaminated by RAM must be clearly labeled “Radioactive.” Until an appropriate survey has been performed that determines that contamination is below the limits for unrestricted release, no such label shall be removed.

Each syringe and vial that contains unsealed RAM must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

Storage and Security of RAM/RPM

RAM shall be secured against unauthorized removal or access and shall be stored only in restricted or controlled areas. RAM not in storage shall be controlled and kept in constant surveillance.

Unbreakable containers are recommended for storage of RAM. Radioactive liquids should not be stored in open containers. Freezers used for storage of RAM shall be kept reasonably free of frost. When defrosting a freezer, caution shall be used to prevent the spread of possible contamination. Radioactive gases and volatile radionuclides shall be stored in a negative air flow hood.

RPM shall be secured to prevent unauthorized use or removal when unattended.

Syringe and Vial Shields

Syringe shields should be used for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated. In such cases, other protective measures should be used to keep exposures ALARA.

Section III: Use of Diagnostic Medical X-Ray Equipment [CPM.0119]

Definitions:

A. Healing Arts

1. A profession concerned with the diagnosis and treatment of human maladies, including the practice of medicine, dentistry and osteopathy, chiropractic and podiatry.

B. Licensed Independent Practitioner (LIP)

1. A licensed practitioner as defined by the State of Wisconsin; a Doctor of Allopathic or Osteopathic Medicine, Optometrist, Oral Surgeon, Dentist, Chiropractor, Podiatrist or Clinical Psychologist who is appointed to the Hospital's Medical Staff; who possesses a current license, certification or registration; and who is permitted by law to provide care, treatment, teaching or research services in the Hospital without direction, supervision or requirement for a collaborative practice agreement.

C. Non-Physician Provider (NPP)

1. Physician Assistant (PA-C)
2. Advanced Practice Nurse Prescriber (APNP)

D. Radiologic Technologist (RT)

1. An individual credentialed by the American Registry of Radiologic Technologists (ARRT) or in the process of achieving board credentialing.

E. Operates Fluoroscopic Equipment

1. To select exposure technique factors, position the tube or detector (image intensifier), actuate the exposure control or directly order the use of fluoroscopic imaging equipment.

Policy:

A. Persons may not be exposed to the direct beam unless authorized by a LIP of the healing arts.

B. The following are authorized to operate x-ray equipment:

1. LIP certified by the American Board of Radiology or in the process of achieving board certification.

2. LIP and NPP who are privileged through the Medical Staff process having successfully completed training to include the following:

- a. Principles and operation of the fluoroscopic x-ray system.
- b. Biological effects of x-ray.
- c. Principles of radiation protection.
- d. Fluoroscopic outputs.
- e. High level control options.
- f. Dose reduction techniques for fluoroscopic x-ray systems.
- g. Applicable state and federal regulations.

3. Radiologic Technologists who are trained in the safe use of fluoroscopic x-ray systems.

C. The LIP, NPP or RT are responsible for maintaining radiation protection controls during the operation of portable x-ray equipment, and will not operate the equipment unless all individuals within six (6) feet of the x-ray tube, exposed area of the patient or image intensifier are protected by 0.25 mm lead equivalent shielding and are properly wearing the appropriate radiation monitoring dosimeter (film badge).

[X-Ray Radiation Protection \[CPM.0118\]](#)

Definitions

A. Healing Arts

1. A profession concerned with the diagnosis and treatment of human maladies including the practice of medicine, dentistry and osteopathy.

B. Licensed Independent Practitioner

1. Doctor of Allopathic or Osteopathic Medicines, Oral Surgeon or Dentist who is credentialed by the Hospital and permitted by law to provide care, treatment, teaching or research services in the Hospital without direction or supervision.

Policy

A. Staff Protection

1. Doors to X-ray rooms must be closed during all X-ray examinations. All persons, including any patients who cannot be removed from the room, shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that all parts of the person's body are at least two meters from all of the following:

- a. the tube head
- b. the direct beam
- c. the nearest part of the examined patient's body being struck by the direct beam

2. Operators of c-arm configuration units, which do not operate at a tube current in excess of 0.2 mA, are exempt from the requirement to wear a leaded apron provided the operator wears a personnel dosimeter as required by HFS 157.25(2).

B. Shielding of Patients

1. Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the direct beam, except for cases in which the shielding would interfere with the diagnostic procedure or for computed tomographic (CT scans) examinations.

2. Persons may not be exposed to the direct beam except for healing arts purposes and unless such exposure has been authorized by a licensed independent practitioner of the healing arts. Deliberate exposure for any of the following purposes is prohibited:

- a. Exposure of a person for training, demonstration or other non-healing arts purpose.
- b. Exposure of a person for healing arts screening, except as authorized by the Wisconsin Department of Health and Family Services, Radiation Protection Section.

C. Holding the Patient or Film

1. When a patient or film must be provided with additional support during a radiation exposure, all of the following applies:

- a. The human holder shall be instructed in personal radiation safety and protected as required by the policy above. Written safety procedures are required.
- b. In those cases where the patient must hold the film, any portion of the body other than the area of clinical interest struck by the direct beam shall be protected by not less than 0.5 millimeter lead equivalent material.

2. Each facility shall have leaded shielding garments and devices available in sufficient

numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

D. Inspection of Protective Aprons

1. All leaded shielding garments and devices shall be radiographed or fluoroscopically inspected on acceptance and at least every two years for defects and replaced if defective. Lead items will be tagged with a unique identifier so the staff may easily verify that it passed inspection. If at any time a visual inspection reveals possible defects, radiographic inspections shall be performed. Garments not in use should be properly hung to prevent cracks.

2. Documentation of the inspection will include the garment's unique identification code, description of the apparel, location/department, inspection date and condition of the garment. This is the responsibility of the Radiation Safety Department/RSO with assistance from the Radiology QA Coordinator.

E. Exposure Factors

1. Proper exposure factors will be available at each diagnostic X-ray system. They should include the following information for each view; body part and orientation, anatomical size or thickness (pediatrics may utilize age), X-ray field size, grid, source-to-receptor distance, focal spot, kV and mAs or AEC.

F. Safety Procedures

1. Written safety procedures shall be made available to X-ray operators, including patient holding procedures and any restrictions of the operating technique required for the safe operation of a particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures.