Section I: General Policies

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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 (RS) 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.

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

individual is not likely to exceed 5 mSv (500 mrem). Release of such patients shall

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.

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.

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

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

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the RSO.

3. Tissue samples taken by the pathologist for analysis should be held until the activity has

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).

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 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

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

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

of the following:

an area or room in which there is used or stored an amount Aore512 Tf129.70 1

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.

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 exposn0(pt for)4d the rio not 0BT11peariz3(or)3(9(HF)**E**TBT1 0 (2.)] T**E**a)-6(y)c xp262

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.