

University of Maryland Baltimore

Radiation Safety Procedure

Procedure Number: 1.1

Title: Radiation Safety Program Organization and Administration

Revision Number: 0

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Technical Review and Approval:

Radiation Safety Officer

Date: _____

Radiation Safety Committee Approval:

Chair, Radiation Safety Committee

Date: _____

PROCEDURE 1.1 - RADIATION SAFETY PROGRAM ORGANIZATION AND ADMINISTRATION

1.0 PURPOSE:

This procedure outlines the organizational and administrative programs established by UMB to ensure that the Radiation Safety Program is implemented in a manner that provides an optimum level of radiological safety for affected workers, members of the public, and the environment. This procedure establishes organizational and administrative systems that will ensure effective program implementation and compliance with applicable regulations and licenses, in particular:

- Maryland State Regulations for the Control of Radiation, Part D, "Standards for Protection Against Radiation";
- Maryland State Regulations for the Control of Radiation, Part G, "Use of Radionuclides in the Healing Arts";
- Maryland State Regulations for the Control of Radiation, Part J, "Notices, Instructions, and Reports to Workers; Inspections"; and
- Maryland State Radioactive Material Licenses 07-014-01 and 07-014-04

2.0 SCOPE:

The requirements of this procedure apply to all ionizing radiation exposures resulting from the operation of UMB and other facilities that operate under UMB's Radiation Safety Program.

3.0 PROCEDURE:

3.1 *Environmental Health and Safety (EHS):*

EHS is charged with overall responsibility for providing the expertise and assistance necessary to ensure development and implementation of an appropriate Radiation Safety Program. Specific individuals and organizations are established within or authorized by EHS to carry out these functions, as discussed below.

3.2 **Director, EHS:**

The Director, EHS bears responsibility for providing overall management direction for the radiation safety program. The Director assigns specific individuals to carry out the necessary functions that ensure overall radiological safety and that ensure ongoing compliance with applicable regulatory and license requirements. The Director nominates a qualified individual to serve as the Radiation Safety Officer.

3.3 **Radiation Safety Officer (RSO):**

The RSO bears primary responsibility for the development and implementation of the Radiation Safety Program. The RSO works with the various Committees, Authorized Users, researchers, physicians, and other staff members to ensure affected individuals are properly trained, appropriate facilities are used, and appropriate precautions are implemented to ensure a high degree of radiological safety in all affected UMB facilities and in surrounding areas. The RSO ensures that all activities involving radioactive materials, x-ray producing machines and equipment capable of producing ionizing radiation are performed in accordance with approved policies and regulatory requirements. The RSO is authorized to stop an operation that he or she judges to be in violation of UMB policies. Furthermore, the Radiation Safety Officer may require specific actions to assure compliance with UMB policies and Federal and Maryland regulations.

3.3.1 RSO responsibilities:

Specific responsibilities of the RSO include:

- Conducting general surveillance of all radiation safety activities within his or her purview;
- Investigating overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practices and implement corrective actions, as necessary [G.7(b)(1)];
- Implementing written policies and procedures for [G.7(b)(2)];
- Authorizing the purchase of radioactive material;
- Receiving and opening packages of radioactive material;
- Storing radioactive material;
- Keeping an inventory of radioactive material;
- Using radioactive material safely;
- Taking emergency action if control of radioactive material is lost;
- Performing periodic radiation surveys;
- Performing checks and calibrations of survey instruments and other safety equipment;

- Disposing of radioactive material;
- Training personnel who work in or frequent areas where radioactive material is used or stored;
- Keeping a copy of all records and reports required by MDE regulations, a copy of applicable MDE regulations, a copy of each licensing request, license, and license amendments, and the written policy and procedures required by the regulations;
- Assisting the Radiation Safety Committee in the performance of its duties [G.7(b)(4)];
- Approving radioactive material authorizations;
- Evaluating equipment, physical facilities, operational techniques and procedures;
- Assigning and evaluating personnel monitoring equipment, establishing requirements for bioassay and special monitoring procedures, and keeping records of internal and external personnel exposure;
- Providing advice and supervision for decontamination;
- Preparing an annual report on the radiation safety program; and
- Other duties assigned by the Director, EHS.

3.4 *Radiation Safety Committee (RSC):*

The RSC provides assistance to EHS in the development of policies and procedures that will ensure the safe use of radiation and radioactive materials at UMB. The membership of the RSC includes all RSOs for licenses operating under the review of the RSC, a management representative, a nursing service representative, and one authorized user for each type of use [G.8.a(1)]. The RSC may assign specific individuals or subcommittees to execute its routine functions or to perform specific studies or tasks. The RSC is responsible for appointing the RSO(s) following consideration of any nominee(s) presented by the Director, EHS.

3.4.1 Specific responsibilities of the RSC include:

- Monitoring UMB's ALARA Program [G.8.b(1)]
- Review, on the basis of safety and with regard to the training and experience requirements of COMAR, and approve or disapprove any Authorized User, Authorized Nuclear Pharmacist, Radiation Safety Officer or Teletherapy Physicist before submitting a license application or request for amendment or renewal [G.8.b(2)]
- Review, on the basis of Board certification, the license, or permit identifying the individual, and approve or disapprove any individual prior to allowing that individual to work as an Authorized User or Authorized Nuclear Pharmacist [G.8.b(3)];

- Review on the basis of safety and approve or disapprove each proposed method of radioactive material use [G.8.b(4)];
- Review on the basis of safety, and approve or disapprove with the advice and consent of the RSO and the management representative, procedures and Radiation Safety Program changes prior to submittal for licensing action [G.8.b(5)];
- Review quarterly, with the assistance of the RSO, occupational radiation exposure records of all individuals working with radioactive materials [G.8.b(6)]
- Review quarterly, with the assistance of the RSO, all incidents and misadministrations involving radioactive materials with respect to cause and subsequent actions [G.8.b(7)]
- Review annually, with the assistance of the RSO, the radioactive material safety program [G.8.b(8)]; and
- Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the RSO [G.8.b(9)].

3.4.2 The RSC shall meet no less frequently than once each calendar quarter [G.8.a(2)].

3.4.3 The RSC shall maintain minutes of each meeting that include [G.8.a(3)]

- The meeting date;
- Members present;
- Members absent;
- A summary of deliberations and discussions.

3.5 ***Authorized Users:***

Any individual who wishes to manufacture, produce, acquire, receive, possess, use, or transfer radioactive material must be authorized by EHS and the RSC. The Authorized User is responsible for ensuring that the radioactive material is used, handled, and stored in accordance with the requirements of the UMB Radiation Safety Program and any other written or verbal instructions provided by EHS.

3.5.1 Specific responsibilities of the Authorized User include:

- Instructing individuals under their supervision in the principles of radiation safety as may be appropriate to the individual's activities (Note: Radiation safety training provided by EHS addresses general radiation safety principles. The AU's responsibilities in this regard extend only to those measures that are applicable to the specific materials and procedures in use) [G.10.a(1)];
- Reviewing the supervised individuals' use of radioactive material and records of that use and providing additional instruction as needed [G.10.a(2)];
- Remaining immediately available to communicate with supervised individuals [G.10.a(3)];
- Remaining physically present and able to supervise the individuals' activities with one hour's notice [G.10.a(4)];
- Ensuring that only those individuals who have been specifically trained and designated are permitted to administer radioactive materials to patients [G.10.a(5)].

3.5.1 Additional information applicable to Authorized Users is provided throughout the Radiation Safety Program implementing procedures.

3.6 Licenses:

The State of Maryland has issued several licenses to UMB that permit UMB's receipt, possession, storage, and use of specific types and quantities of radioactive material and specific radiation generating devices. These licenses also establish specific limits and programmatic requirements that must be observed by UMB and require that UMB implement programs ensure compliance with applicable regulatory requirements..

The licenses issued to UMB include the following:

- MDE 07-014-01, Broad Scope License
- MDE 07-014-04, Waste Incinerator License

3.7 Programs and Procedures:

UMB has developed and implemented a system of programs and procedures that, when implemented, ensure UMB's activities involving radiation and radioactive material are conducted safely and in compliance with applicable regulatory and license requirements. It is the responsibility of each individual involved in these activities to attend training as required, adhere to established

programs and procedures and other instructions, and be alert for and report unforeseen conditions.

- 3.7.1 UMB shall develop, document, and implement a radiation protection program sufficient to ensure compliance with COMAR Part D, "Standards for Protection Against Radiation." [D.101(b)] The UMB radiation protection program consists of the UMB Radiation Safety Program and its sub-tier procedures.
- 3.7.2 Requirements for procedure format and use include:
 - The RSO shall establish requirements for radiation safety procedure content and format;
 - The RSO shall ensure that radiation safety procedures are written in a clear and concise style that facilitates effective implementation;
 - Radiation safety procedures shall be reviewed by a technical reviewer appointed by the RSO. Following the technical review and resolution of all issues, the procedures shall be approved by the RSC. Reviews and approvals shall be indicated by signature and date.
- 3.7.3 Radiation safety procedures shall bear an implementation date and revision number.
- 3.7.4 The RSO shall appoint cognizant individuals to ensure radiation safety procedures in use are current and effective in achieving an appropriate level of radiological safety.
- 3.7.5 When the need for a new document or document revision is identified, the Radiation Safety Officer or other individual designated by the RSC will draft a new or revised document.
- 3.7.6 EHS will assign an appropriate document number or, if the required document is a revision of an existing document, the next sequential revision number.

3.7.7 The Originator will draft the document in a format established and accepted by the RSC. At a minimum, the accepted format will include:

- The document title, number, revision, and effective date;
- Sequential page numbering;
- The body must identify the Purpose, Scope, References, and any required procedural steps or other technical material required.

3.7.8 The RSO will coordinate review of the draft document by affected UMB staff members.

3.7.9 The RSO will review the draft and coordinate any required changes to ensure the document meets applicable regulatory and licensing requirements.

3.7.10 The RSO will ensure that any other documents that may be affected by the new or revised document are reviewed and revised as necessary.

3.7.11 Following completion of required reviews and resolution of comments, the RSO will coordinate review and approval of the document by the RSC.

3.7.12 Following review and approval by the RSC, the Chairman of the Radiation Safety Committee and the Radiation Safety Officer will sign the document to indicate approval. The RSC will assign the desired implementation date.

3.8 3.7.13 The Radiation Safety Officer or designated department head will identify and coordinate any required training arising out of the approved document. Individuals will be prohibited from implementing the process controlled by the document until successful completion of training, if required.

3.8 Training, Postings, and Briefings

3.8.1 UMB institutes a system of training, posted notices, briefings, and other informational vehicles to ensure affected individuals are aware of the presence of radiological hazards and proper protective measures.

3.8.2 Radiation Safety Training [J.12] – UMB institutes a program of radiation safety training for all individuals who may potentially receive an occupational dose (TEDE) exceeding 0.1 rem in a year. UMB’s radiation safety training program shall include instruction in:

- The health protection problems associated with exposure to radiation or radioactive material;
- Precautions or procedures to minimize exposure;
- Purposes and functions of protective devices;
- The applicable COMAR regulations and licenses and requirements to observe those regulations, to the extent within the employee’s control;
- The employee’s responsibility to report to UMB any condition that may constitute, lead to, or cause a violation of the Atomic Energy Act, COMAR, or UMB’s licenses, or any unnecessary exposure to radiation or radioactive material; and
- The radiation exposure reports that the employee may request.

3.8.3 For details on UMB’s Radiation Safety Training program, see Procedure 1.7, *Radiation Safety Training*.

3.9 Posting of Notices [J.11]

3.9.1 The RSO shall ensure that copies of the following documents are posted in the workplace. If the RSO believes that the size or number of required documents makes posting impractical, he or she may ensure that a notice is posted that describes the required documents and a location where they may be examined. Required documents include:

- The regulations in Parts D and J of the Maryland State Regulations for the Control of Ionizing Radiation; [J.11(a)(1)]
- The license(s), certificates of registration, and conditions or documents incorporated into the license(s) by reference or amendment; [J.11(a)(2)]
- The operating procedures applicable activities authorized by the license or registration; [J.11(a)(3)]
- Notices of violation involving radiological work conditions, proposed imposition civil penalties, or Orders issued pursuant to Part A of the Maryland State Regulations for the Control of Ionizing Radiation, and any responses from UMB to such Notices or Orders; [J.11(a)(1)] and

- Maryland Department of the Environment Form 279, Notice to Employees. [J.11(c)]
- 3.9.2 The RSO shall ensure that the notices of violation, orders, notices of civil penalties, and UMB responses listed above are posted within five working days of receipt or dispatch, as appropriate, and remain posted for at least five working days or until action correcting the violations is completed, whichever is later. [J.11(d)]
- 3.9.3 The RSO, through routine audits and directions to authorized users, shall ensure that the required notices, forms, licenses, and orders are conspicuously and clearly posted in a sufficient number of places to allow affected individuals to observe them on the way to or from affected work locations. [J.11(e)]
- 3.9.4 See Procedure 2.2, *Posting and Labeling for Radiation Safety*, for details on requirements for posting of radiological hazard warning signs and labels.

3.10 Presence of Representatives and Employees During MDE Inspections

- 3.10.1 The RSO shall coordinate activities as necessary to ensure that:
- UMB and its affiliated institutions provide reasonable access to MDE agents or representatives for the purpose of conducting required inspections of licensed activities; [J.14(a)]
 - MDE representatives and agents are permitted to speak privately with employees of UMB and its affiliated institutions; [J.14(b)]
 - MDE representatives or agents are notified of any individual who has been authorized employees to represent employees of UMB or its affiliated institutions during MDE inspections and authorized individuals are permitted to accompany MDE agents or representatives during inspections. [J.14(c)]
- 3.10.2 Any individual authorized to represent affected employees shall be:
- Routinely engaged in licensed activities and be trained in accordance with UMB requirements for Radiation Safety Training; [J.14(d)] or
 - Specifically approved by both UMB and the employees' representative. [J.14(e)]
- 3.10.3 If more than one individual has been authorized to represent affected employees, only one such authorized representative is permitted to

accompany MDE agents or representatives during each phase of the inspection. [J.14(e)]

3.11 Affected Employee Consultation With MDE and Request for Inspections [J.15 – J.16]

- 3.11.1 Affected employees engaged in licensed activities may speak privately with MDE agents or representatives without fear of reprisal or other adverse action. [J.15(a)]
- 3.11.2 Should any affected employee believe that any past or present condition contributes to or causes a violation of the Atomic Energy Act, COMAR regulations, or UMB's license, that employee may notify MDE agents or representative of such condition(s) either verbally or in writing without fear of reprisal or other adverse action. Such notification does not relieve the employee of his or her responsibility to notify UMB of such conditions, as discussed in Section 3.8 of this procedure. [J.15(b)]
- 3.11.3 Any employee or authorized employee representative who believes that licensed activities violate the Atomic Energy Act, COMAR, or UMB's license conditions regarding radiological working conditions may request an MDE inspection by giving written notice to MDE. The written notice shall set forth the specific grounds for the notice and shall be signed by the employee or representative. If the employee or representative wishes to remain unknown to UMB, he or she shall request that MDE protect his or her privacy. [J.16(a)]
- 3.11.4 Should MDE, upon review of an employee's or employees' representative written request for inspection, determine that an inspection is not warranted, the employee or representative may file a written statement of position with the Secretary of the Department of Environment seeking review of the decision or an informal conference. [J.17(a)]
- 3.11.5 UMB and its affiliated institutions shall not in any way discriminate against any employee who files any verbal or written complaint with MDE or who testifies in any proceeding resulting from such verbal or written complaint. [J.16(c)]

3.12 Planned Special Exposures

UMB does not foresee any situation in which it might be desirable to use the provisions of COMAR D.206, which permit planned special exposures exceeding the normal yearly occupational dose limits. Should UMB encounter such circumstances, the RSO shall oversee development, approval and implementation of appropriate written procedures that ensure compliance with the applicable regulations. [D.206]

3.13 Respiratory Protection Program

UMB does not foresee any situation in which it might be necessary to use the provisions of COMAR D.701 – D.703 governing the use of respiratory protection devices for controlling exposure to airborne radioactive material. Should UMB encounter such circumstances, the RSO shall oversee development, approval and implementation of appropriate written procedures that ensure compliance with the applicable regulations. [D.701 – D.703]

4.0 Records and Reports

4.1 Records

A wide variety of records are required to document the proper operation of the radiation safety program. Procedures for producing, reviewing, and maintaining radiation safety records are established in Procedure 1.2, *Radiation Safety Records*.

4.2 Reports

Maryland State regulations governing UMB's Radiation Safety Program establish requirements for reports addressing incidents, individual doses, and other matters. Requirements for preparing and filing these reports are established in Procedure 1.3, *Radiation Safety Reports*.

5.0 References:

COMAR, Sections A-J
UMB Radiation Safety Program
Maryland License MD-07-014-01
American National Standard, ANSI/ASQC Q9001-1994
USNRC Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs"