RADIATION SAFETY PROGRAM

(RSP)

THE UNIVERSITY OF MARYLAND (UM)

Revision Number: 2

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Technical Review and Approval:

_____ **Date:**_____

Radiation Safety Officer

Radiation Safety Committee Approval:

_____ **Date:**_____

Chair, Radiation Safety Committee

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FOREWORD

In the Radiation Safety Program (RSP) described in this document, the University of Maryland Baltimore (UMB) establishes commitments and describes programs for establishing and maintaining safe radiological conditions and ensuring compliance with the requirements of applicable State of Maryland regulations and licenses. In particular, the RSP addresses the requirements of the Code of Maryland Regulations (COMAR) 26.12.01.01, "Regulations for the Control of Ionizing Radiation," and UMB's State of Maryland Broad Scope and Waste Incineration Licenses (Nos. MD-07-014-01 and MD-07-014-04). This program has been developed and implemented to ensure adequate protection of employees, patients, and members of the public from the hazards arising from UMB's authorized use of radioactive materials. This RSP is intended to meet the various programmatic requirements found in COMAR for a documented Radiation Protection Program, Radioactive Materials Program, and ALARA Program.

To implement elements of the UMB RSP, various line organizations (e.g., Nuclear Medicine, Radiation Oncology, etc.) and the UMB Environmental Health and Safety Office (EHS) have developed implementing procedures. Following approval of the UMB RSP by the Radiological Health Program (RHP) of the Maryland Department of the Environment (MDE), substantive (non-editorial) changes to this RSP require approval by RHP/MDE. Changes to the various implementing procedures do not require prior approval by RHP/MDE provided the elements in the approved UMB RSP remain unchanged. The implementing procedures are made available to RHP/MDE representatives and may be subject to review for compliance assurance purposes. The Management Control section of the UMB RSP describes an orderly process implemented by UMB management for developing, approving, tracking, changes to facilities, equipment, and approved procedures.

The RSP describes the policies and programs adopted by UMB to foster a safety culture to assure safe and appropriate uses of radiation sources, including both radiation emitting devices and radioactive materials. UMB encourages a questioning attitude to radiation protection and safety. To assure competency and to discourage complacency, UMB has established in its program:

- Policies and programs that identify the protection and safety of patients, the public and workers as being of the highest priority;
- Technical organizations to identify and correct problems affecting protection and safety promptly in a manner commensurate with their importance;
- Clear guidelines for the responsibilities, qualifications and training of each individual;
- Lines of authority for decisions on protection and safety; and
- Organizational arrangements and lines of communications that result in an appropriate flow of information on protection and safety at and between the various affected individuals and organizations.

Throughout this document: “RSO” refers to the Radiation Safety Officer; “EHS” refers to Environmental Health and Safety; “RSC” refers to the Radiation Safety Committee; “MDE” refers to the Maryland Department of the Environment; “RHP” refers to the Radiological Health Program of the MDE; and “COMAR” refers to the Code of Maryland Regulations, Section 26.12.01.01, “Regulations for the Control of Ionizing Radiation.”

STATEMENT RESPONSIBILITY AND DELEGATION OF AUTHORITY

The University of Maryland Baltimore ("UMB") is a constituent institution of the University System of Maryland, which is a public incorporation and state entity under Maryland law. UMB uses radioactive materials under the authority of the UMB broad scope license (MDE-07-014-01).

As the President of UMB,

(1) I have determined that UMB can best comply with broad scope license requirements applicable to UMB by delegating authority for development, implementation and maintenance of a Radiation Safe Program for UMB employees, students, and patients, and members of the public, to a Radiation Safety Committee (RSC), Radiation Safety Officer (RSO), and Office of Environmental Health and Safety (EHS), of UMB. I have made those delegations.

(2) I have ultimate responsibility for oversight of UMB's Radiation Safety Program and ultimate responsibility for UMB activities associated with the broad scope license.

(3) I have authorized the Director of EHS to appoint an RSO. The RSO is authorized to work directly with the Director of EHS, the Vice President for Administrative Services, the Vice President for Academic Affairs, the UMB Deans, and me, to facilitate effective and immediate action on behalf of UMB management, especially in the event of emergency, in carrying out the Radiation Safety Program. I will make the fiscal, administrative and personnel resources of UMB available to implement the Radiation Safety Program in a lawful and effective manner.

(4) I have authorized the RSC to be appointed by the Vice President for Academic Affairs and to act as UMB's agent in matters involving policy, procedures, control and mediation arising from the use of radioactive materials.

(5) I direct the Vice President for Academic Affairs to appoint a chairman of the RSC. I charge the chairman with full responsibility for processing all RSC decisions regarding policies, procedures and corrective actions related to radiation safety.

(6) I authorize the RSO to act as my agent and to take all necessary and appropriate actions to ensure compliance with the State of Maryland's radiation safety regulations and to promote safety and reduce radiation hazards to all UMB employees, students, and patients, and to members of the public. This authority includes, without limitation, the authority to monitor and suspend use of radioactive materials at UMB facilities.

(7) The Center of Marine Biotechnology, the University of Maryland Medical System Corporation, and the University of Maryland Baltimore County, have requested that UMB makes the RSC, RSO and EHS available to assist them in developing and carrying out their own Radiation Safety Programs. I authorize the Director of EHS to enter into agreements with those entities to provide services for their Radiation Safety Programs and to include their uses of radioactive materials under the UMB broad scope license. I grant this authority subject to the understanding the ultimate responsibility and fiscal responsibility for the Radiation Safety Program at each of those institutions rests with that institution and its executive management, and is exercised by its own chief executive officer or designee. I understand that authority granted by those officers to the RSC, RSO and EHS may be terminated by them at the discretion of each institution's executive management.

_____
David J. Ramsay
President
University of Maryland Baltimore

ALARA POLICY STATEMENT

UMB management is committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). Consistent with this commitment, this program describes an administrative organization for radiation safety (including the Radiation Safety Committee and Radiation Safety Officer) and commitments to develop and implement necessary written policies, procedures, and instructions to foster the ALARA concept within UMB.

UMB will perform a formal annual review of the radiation safety program, including ALARA considerations. The review will include reviews of operating procedures and past dose records, inspections, etc., and consultations with radiation safety staff and/or outside consultants, as necessary.

Modifications to operating and maintenance procedures and to facilities and equipment will be made if these modifications will reduce individual and/or collective doses, unless the cost is considered to be unjustified. UMB will seek and implement improvements as may be reasonable and necessary.

CHAPTER 1 – RADIATION SAFETY PROGRAM ORGANIZATION

1.1 General Organizational Principles

UMB has charged several organizations with responsibility for development, implementation, and maintenance of an appropriate radiation safety program. These organizations include the Radiation Safety Committee; various line organizations that use radioactive material and radiation producing devices, and EHS.

1.2 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.

1.3 Radiation Safety Committee (RSC)

1.3.1 Authority

The UMB Radiation Safety Committee (RSC) derives its authority from the President, UMB and is authorized to act as UMB's agent in all matters involving policy, procedures, control and mediation arising from the use of radioactive materials. The Chairman of this Committee is appointed by the Vice President for Academic Affairs and has full authority and responsibility for:

- Identifying radiation safety problems;
- Initiating, recommending, or providing corrective actions for identified safety problems; and
- Verifying implementation of corrective actions.

Radioactive materials are used at UMMS, IHV, MBC, COMB, and UMBC. Each of these institutions delegates authority for development, implementation, and maintenance of the Radiation Safety Program for their employees, students, and members of the public to the UMB Radiation Safety Officer, and Environmental Health and Safety.

1.3 Radiation Safety Committee (RSC)

1.3.2 Management Controls

UMB will develop, implement, and maintain written procedures that establish the duties and responsibilities of the Radiation Safety Committee. At a minimum, these written procedures will reflect the duties and responsibilities established in applicable sections of COMAR and in the licenses issued to UMB by COMAR. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the duties and responsibilities are effectively discharged as required by the applicable procedures, regulations, and license conditions.

1.4 Radiation Safety Officer (RSO)

1.4.1 Authority

The Radiation Safety Officer derives his or her authority via the Director, EHS, who reports to the Office of the President of UMB. The Radiation Safety Officer is authorized to take all necessary and appropriate actions to ensure safety against potential radiation hazards to all employees, patients and visitors, and to ensure compliance with the State of Maryland RHP/MDE regulations (COMAR).

The Radiation Safety Officer is authorized to stop an operation upon notification to the Authorized User, if in the Radiation Safety Officer's judgment, that operation endangers public health and safety. This judgment shall take into consideration the health and welfare of any patients that may be involved in the operation. The Radiation Safety Officer is also authorized to stop an operation, upon notification or consultation with the Authorized User, if in the Radiation Safety Officer's judgment, that operation violates UMB policies (approved by the Radiation Safety Committee) concerning such operations (e.g., requiring immediate notification to the State of Maryland).

The Radiation Safety Office/EHS has the responsibility and authority to implement the policies and recommendations of the Radiation Safety Committee. The RSO also validates compliance with UMB Licenses, State of Maryland RHP regulations (COMAR), written policies, and procedures of UMB's Radiation Safety Program related to the use of radioactive materials.

1.4.2 Management Controls

UMB will develop, implement, and maintain written procedures that establish the duties and responsibilities of the Radiation Safety Officer. At a minimum, these written procedures will reflect the duties and responsibilities established in applicable sections of COMAR and in the licenses issued to UMB by COMAR. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the duties and responsibilities are effectively discharged as required by the applicable procedures, regulations, and license conditions.

1.5 Authorized Users

1.5.1 Research Authorized Users

Radioactive material and devices may only be procured and used with the approval of the Radiation Safety Committee and in accordance with the approved procedures related to safety, device specifications and limitations on type and quantity as approved by the Radiation Safety Committee.

All applications for the use of radioactive materials must be submitted to the Radiation Safety Committee or the appropriate subcommittee on the appropriate forms obtained from the Radiation Safety Office/EHS.

1.5.2 Physician Authorized Users

Radioactive material for medical use may only be administered to patients or human research subjects and radiation producing sources may only be used to irradiate patients or human subjects under the supervision of a physician approved by the Radiation Safety Committee and in accordance with the safety procedures, device specifications and limitations on type and quantity as approved by the Radiation Safety Committee.

All applications to supervise the medical use of radioactive materials or radiation producing devices must be submitted to the Radiation Safety Committee on the appropriate forms obtained from the Radiation Safety Office/EHS.

1.5.3 Medical Physicist Authorized Users

A medical physicist may only perform duties involving radioactive material for medical use and radiation producing sources to irradiate patients or human subjects under the supervision of a physician approved by the Radiation Safety Committee and in accordance with the safety procedures, device specifications and limitations on type and quantity as approved by the Radiation Safety Committee.

1.5.4 Nuclear Pharmacist Authorized Users

The Authorized Nuclear Pharmacist independently prepares and supervises preparation of radioactive material for medical use as requested by an authorized physician user and in accordance with the implementing procedures related to safety, equipment specifications and limitations on type and quantity as approved by the Radiation Safety Committee.

1.5 Authorized Users

1.5.5 Management Controls

UMB will develop, implement, and maintain written procedures that establish the duties and responsibilities of the Authorized Users. At a minimum, these written procedures will reflect the duties and responsibilities established in applicable sections of COMAR and in the licenses issued to UMB by COMAR. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the duties and responsibilities are effectively discharged as required by the applicable procedures, regulations, and license conditions.

1.6 Individuals

1.6.1 Individual Responsibility

Each individual at UMB and other facilities that are subject to UMB's Radiation Safety Program and who is occupationally exposed to radioactive materials or devices producing radiation is responsible for adhering to the UMB radiation safety policies and procedures.

1.6.2 Management Controls

UMB will develop, implement, and maintain written procedures that establish individual duties and responsibilities with respect to the Radiation Safety Program. At a minimum, these written procedures will reflect the duties and responsibilities established in applicable sections of COMAR and in the licenses issued to UMB by COMAR. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the duties and responsibilities are effectively discharged as required by the applicable procedures, regulations, and license conditions.

CHAPTER 2 - ALARA PROGRAM

2.1 Management Commitment

UMB is committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accordance with this commitment, UMB has established an administrative organization for radiation safety (described in Chapter 2 above) and developed the necessary written policies and programs to foster the ALARA concept within the institution. (UMB's ALARA Policy Statement is presented in the opening material of this document and endorsed by UMB management via approval of this document.) Under this organization, there is a clear delineation of the responsibilities of the Radiation Safety Committee, the Radiation Safety Officer, and the Operational Divisions/Departments for radiation safety.

2.2 Hierarchy of Controls

To the extent practicable, the ALARA process will be implemented through a system of design features and engineering controls (e.g., shielding, process controls, ventilation, etc.). When design features and engineering controls are not practicable, the ALARA process will be implemented through the development and use of administrative controls, such as enhanced training and procedural controls.

2.3 Modifications

Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures and cost is justified. UMB will establish appropriate controls over these modifications as necessary to ensure their continued effectiveness and implementation.

2.4 Investigational Levels

UMB will develop and implement quarterly investigational levels for individual dose equivalents. In no case shall the initial quarterly investigational level exceed 10% of the regulatory dose limits, adjusted to a quarterly level (i.e., 5000 millirem regulatory dose equivalent limit x 0.1 = 500 millirem yearly investigational level / 4 = 125 millirem quarterly investigational level). (Note: This example applies to total effective dose equivalent.) The RSC may establish lower investigational levels at its discretion as a means of establishing management control over and directing management attention to occupational radiation doses. For any specified operation/authorization, the RSC may authorize extension of the quarterly investigational level following assessment of the operation and practicable ALARA measures.

2.5 Records

The RSO or his designee will review and record on State of Maryland Form ND 216 or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than annually as required by Section D.1107 of COMAR.

2.6 Annual Review

The RSO will perform a formal annual review of the radiation safety program, including ALARA considerations. This review will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

2.7 Sum of the Doses to Groups of Individuals

In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2.8 Role of the Radiation Safety Committee

2.8.1 Review of Proposed Users and Uses

The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of equipment or materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

When considering a new use of radiation sources, the RSC will review the efforts of the applicant to maintain exposure ALARA. The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

2.8.2 Delegation of Authority

The RSC will delegate authority to the RSO for enforcement of the ALARA concept. The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC overrules the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

2.8.3 Review of ALARA Program

The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

The RSC will evaluate UMB’s overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, Authorized Users, workers, and management.

2.9 Role of the Radiation Safety Officer

2.9.1 Annual Review of the Radiation Safety Program

The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

2.9.2 Quarterly Review of Occupational Exposures

The RSO will review at least quarterly the external radiation doses of Authorized Users and workers to determine that their doses are ALARA in accordance with the provisions of this program and will prepare a summary report for the RSC.

2.9.3 Quarterly Review of Records of Radiation Surveys

The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

2.9.4 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.

2.9.5 Reviewing Instances of Deviation from Good ALARA Practices

The RSO will 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 implement changes in the program to maintain doses ALARA.

2.9.6 Cooperative Efforts for Development of ALARA Procedures

UMB will provide radiation workers opportunities to participate in formulating the procedures that they will be required to follow. The RSO and his/her staff will be available to all users and workers in order to develop ALARA procedures for working with radioactive materials. The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

2.10 Authorized Users

Authorized Users will consult with the RSO and/or RSC during the planning stage before using a radiation-producing device or radioactive materials for new uses. Authorized Users will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful and may be required for complex manipulations or equipment.

Authorized Users will provide written procedures for keeping exposures ALARA with each authorization request for a new use of radiation.

2.11 Management Controls

UMB will develop, implement, and maintain written procedures that establish individual duties and responsibilities with respect to the ALARA Program. At a minimum, these written procedures will reflect the duties and responsibilities established in applicable sections of COMAR and in the licenses issued to UMB by COMAR. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the duties and responsibilities are effectively discharged as required by the applicable procedures, regulations, and license conditions.

CHAPTER 3 - PROGRAMMATIC MANAGEMENT CONTROLS

3.1 General

UMB's State of Maryland License (License Number MD-07-014-01) is a Type A Broad Scope materials license. Under a Broad Scope License, the regulatory agency (MDE/RHP) gives the licensee broad discretion to approve users, authorize new use applications provided such uses are within the scope of the license, and approve procedures for such uses. To support this authority to exercise management discretion, the licensee must develop and implement a sophisticated and comprehensive management control structure to ensure that an appropriate level of safety is achieved and maintained. UMB has developed a Management Control Program to ensure that all uses of radioisotopes and radiation authorized under the license will comply with the applicable regulatory requirements and the provisions of the UMB license. The Management Control Program ensures ongoing compliance with the applicable regulatory requirements and the provisions of the UMB license.

The UMB Radiation Safety Program (RSP), submitted under License Number MD-07-014-01, is intended to ensure that all UMB operations comply with the State of Maryland RHP/MDE requirements. The Management Control Program ensures that UMB's facilities, equipment, and implementing procedures comply with the Radiation Safety Program (RSP). Any proposed change to the RSP requires an amendment request to MDE. Prior approval is not needed for changes to UMB's implementing procedures provided such changes are consistent with the commitments made in the RSP.

The Management Control Program consists of implementing procedure control, approval process for use applications to the Radiation Safety Committee (RSC), review of ALARA engineering/facility designs, and training on the implementing procedures. The Radiation Safety Committee (RSC) is responsible for overseeing the Management Control Program.

3.2 Action/Method to Comply with Management Control Commitments

New implementing procedures and proposed changes to facilities or equipment that may affect radiation safety are reviewed for adequacy and approved prior to issuance according to established procedures.

3.2.1 The Chairman of the RSC or his/her designee and the Radiation Safety Officer (RSO) or his/her designee shall review and approve all Radiation Safety Procedures and proposed changes to facilities and equipment that may affect radiation safety.

3.2 Action/Method to Comply with Management Control Commitments

3.2.2 Upon approval, training copies are distributed along with a training record form, as needed, to designated departments. Procedures are controlled in such a manner that unauthorized changes cannot be made.

3.2.3 When procedures or design documents are changed, they are reviewed and approved by the same functions or organizations that performed the original review and approval.

3.2.4 The Radiation Safety Office/EHS maintains a copy of each obsolete procedure or design document, with its original change record, in an archive file for a period of 3 years. Subsequent disposition of said procedures will be determined at a later date.

3.3 Management Controls

UMB will develop, implement, and maintain written procedures that establish requirements for making modifications to facilities, equipment, and procedures. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the program is effective in establishing and maintaining effective control over changes to facilities, equipment, and procedures.

CHAPTER 4 - QUALITY CONTROL AND MANAGEMENT PROGRAMS

4.1 General

As required by Section G.6(b) and G.6(c) of COMAR, UMB has developed both a Quality Control (QC) Program and a Quality Management (QM) Program. The UMB Quality Control Program contains written implementing procedures for equipment used to obtain images from radionuclide studies. At a minimum, the implementing procedures include quality control procedures recommended by equipment manufacturers or procedures that have been approved by the Radiation Safety Committee.

The UMB Quality Management Program is established to provide high confidence that Nuclear Medicine and Radiation Oncology treatments will be administered as directed by the Authorized User. UMB will meet the requirements of G.6(c) through the written Quality Management Programs of the Nuclear Medicine and Radiation Oncology Divisions and the associated implementing procedures. The Radiation Safety Office/EHS of the EHS also has developed procedures to assist the training and implementation of UMB's Quality Management Program.

4.2 Action/Method to Meet QM/QC Requirements

4.2.1 Nuclear Medicine and Radiation Oncology will develop written implementing procedures in accordance with Sections G.6(b), G.6(c), D1208, and D1209 of COMAR, and be approved by the Radiation Safety Committee, in the area of QC and QM.

4.2.2 Nuclear Medicine and Radiation Oncology will develop a written Quality Management Program in accordance to Section G6(c) of COMAR

4.2.3 The Radiation Safety Office/EHS, EHS will develop supporting safety procedures for QM.

4.2.4 A review of the QM Program shall be conducted annually. Since the previous annual review, the following will be evaluated:

- A representative sample of patient administrations (no less than 10%);
- All recordable events; and
- All misadminstrations.

4.2.5 Each review will determine the effectiveness of the QM Program and, if required, make modifications to meet the QM Program. A copy of the annual review will be provided to the RSO.

4.2.6 Records of each annual review will include the evaluations and findings of the review.

4.3 Recordable Events

4.3.1 Within 7 days after the discovery of a recordable event, the QM Team will document and notify the Radiation Safety Officer.

4.3.2 Within 30 days after the discovery of a recordable event, the QM Team and the Radiation Safety Officer will evaluate and respond to the event by:

- Assembling the relevant facts, including the cause;
- Identifying what, if any, corrective action is required to prevent recurrence;
- Maintaining a record, for no less than 3 years, of the relevant facts and any corrective action.

4.4 Management Controls

UMB will develop, maintain, and implement procedures addressing misadministration and recordable events that comply with Sections D.1208 and D.1209 of COMAR. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the duties and responsibilities are effectively discharged as required by the applicable procedures, regulations, and license conditions.

CHAPTER 5 - CONTROL OF RADIATION EXPOSURE

5.1 Individual Radiation Monitoring Program

5.1.1 Monitoring Program Description

Current regulations establish stringent requirements for limiting individual radiation doses within specified values during a calendar year. UMB has established a program of individual dose monitoring to ensure compliance with these limits, to provide information to individuals concerning their radiation dose, and to provide data that facilitate implementation of the ALARA program. Depending on the hazards associated with the individual's work activities, the dose monitoring may include external dose monitoring, both internal and external dose monitoring, or no individual monitoring. Historically, UMB's radiation safety program has been effective in controlling individual doses to only a small fraction of the regulatory limits.

Once assigned to the appropriate level of individual monitoring, assigned individuals are responsible for wearing any assigned dosimeters properly, returning the dosimeters as scheduled, reporting for bioassays as scheduled, and reviewing any reports arising out of their participation in the program. Elements of the individual monitoring program are:

- Identification of individuals requiring individual monitoring in accordance with Section D.502 of COMAR and license requirement;
- Determination of prior and allowable individual doses (Section D.205 of COMAR);
- Determination of individual allowable dose (Section D.205 of COMAR);
- Issuance, use Section D.501(d), and return of personnel dosimeters;
- Collection of bioassay samples/analyses;
- Determination of individual dose equivalents.

5.1.2 Management Controls

UMB will develop, maintain, and implement written procedures that provide details on the implementation of each step of the individual monitoring program. At a minimum, these written procedures will address the applicable requirements of COMAR and UMB's radioactive material licenses. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the individual monitoring program is effectively implemented in accordance with the applicable procedures, regulations, and license conditions.

5.2 Restricted and Unrestricted Areas

5.2.1 General

Areas within UMB and other facilities operating under UMB's Radiation Safety Program are designated as either restricted or unrestricted areas for the purpose of radiation protection.

5.2.2 Restricted Areas

UMB has designated all areas in which radiation doses could routinely exceed 2 millirem in any one hour or 100 millirem in one year as restricted areas. Other areas may be designated temporarily or permanently as restricted areas because of the use of radiation producing devices or radioactive material.

By definition, access to restricted areas is controlled. Unless otherwise excepted, restricted areas must always be locked unless attended by trained users who have been instructed to limit access.

Areas posted with radiological warning signs (e.g., Radiation, High Radiation, Very High Radiation Area, airborne Radioactivity, and Radioactive Material Areas) are considered restricted areas unless the radiation source has been removed or the radiation-producing device cannot be energized.

5.2.3 Unrestricted Areas

Most areas of the UMB are designated as unrestricted areas and access is not controlled because of radiation. Areas may be controlled for other purposes but be considered unrestricted for purposes of complying with radiation protection regulations and programs.

Radiation doses do not have to be zero in an unrestricted area. Doses must be low enough that a member of the public or an employee not trained for the purpose of radiation protection would not exceed 100 millirem in one year.

Occasional exposures to patients administered radioactive material for diagnostic purposes do not need to have area to be posted or restricted.

5.2.4 Management Controls

UMB will develop, maintain, and implement written procedures that provide details on requirements for posting and control of restricted areas. At a minimum, these written procedures will address the applicable requirements of COMAR and UMB's radioactive material licenses. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the access control program is effectively implemented in accordance with the applicable procedures, regulations, and license conditions.

5.3 Security for Radioactive Material

5.3.1 Program Description

Radioactive materials that are stored in unrestricted areas must be secure from unauthorized removal or access (locked in an enclosure or otherwise prevented from being removed). Employees must control and maintain constant surveillance of licensed material that is in an unrestricted area and that is not in storage.

5.3.2 Management Controls

UMB will develop, maintain, and implement administrative procedures that establish requirements for radioactive material security. At a minimum, these written procedures will address the applicable requirements of COMAR and UMB's radioactive material licenses. UMB will conduct routine audits and implement corrective actions as necessary to ensure that radioactive material security is maintained in accordance with the applicable procedures, regulations, and license conditions.

5.4 Radiological Hazard Posting and Labeling

5.4.1 Radiological Hazard Posting

UMB implements a system of warning signs and labels to call attention to radiological hazards. The signs and labels provide information that facilitate the implementation of appropriate protection actions by trained radiation workers and also provide warning so that untrained individuals are alerted and remain unaffected by the radiological hazard. The warning signs and labels utilize the familiar three-bladed radiation-warning emblem (trefoil) imposed in black or magenta on a yellow background.

Postings (signs) are displayed at the entry points to areas where radiological hazards require specific protective actions. In addition, there can be specific entry and emergency instructions.

5.4.2 Radioactive Material Labeling

Labels are applied to radioactive devices, items, and containers of radioactive material. Labels use the radiation warning trefoil and the words "Caution" or "Danger" and "Radioactive Material." Additional information may be provided to ensure safe handling of the material.

5.4.3 Management Controls

UMB will develop, maintain, and implement detailed written procedures that establish requirements for posting and labeling of radiological hazards. These procedures will, at a minimum, be sufficient to ensure compliance with the posting and labeling established in COMAR and any additional requirements established in UMB's radioactive materials licenses. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the radiological hazard posting and labeling program is effectively implemented in accordance with the applicable procedures, regulations, and license conditions.

5.5 Fetal Protection Program

5.5.1 Purpose and Elements of the Fetal Protection Program

Because of the increased radio-sensitivity of the developing embryo/fetus (relative to that of an adult), special measures are warranted to provide an adequate level of protection. UMB has implemented a system of voluntary pregnancy declaration, enhanced monitoring, and enhanced protective measures (possibly including cessation of work involved radiation exposure). The salient features of the fetal protection program include employee training, voluntary pregnancy declaration, assessment of relative hazards, implementation of controls, and assessment of fetal dose.

5.5.2 Management Controls

UMB will develop, maintain, and implement detailed written procedures that establish requirements for protection of the embryo/fetus. These procedures will, at a minimum, be sufficient to ensure compliance with the fetal protection requirements established in COMAR and any additional requirements established in UMB's radioactive materials licenses. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the fetal protection program is effectively implemented in accordance with the applicable procedures, regulations, and license conditions.

CHAPTER 6 - CONTROL OF RADIOACTIVE MATERIALS

6.1 Radioactive Material Authorizations

Under UMB's broad scope license (MD-07-014-01), no person, can produce, acquire, receive, possess, use, or transfer radioactive material except in accordance with a specific authorization issued by the Radiation Safety Committee and the Radiation Safety Office/EHS.

6.1.1 Application for New Uses

Any individual who wishes to become an Authorized User of radioactive materials must submit an application to the Radiation Safety Office/EHS. The application must contain the following information:

- The proposed use;
- The radionuclides and possession limits needed;
- The facilities where radioactive material will be used or stored;
- A list of the radiation measuring equipment available to the applicant;
- A statement of the applicant's training and experience;
- The availability of any special safety devices;
- Commitment to comply with applicable sections of UMB's RSP; and
- Proposed waste disposal methods.

6.1.2 Application for an Amendment

Proposed changes to an Authorization must be requested in the form of an application to the Radiation Safety Office/EHS.

6.1.3 Application for Renewal

The Authorized User prior to the assigned expiration date must initiate application for renewal of an Authorization.

6.1.4 Approval

Upon approval, the Radiation Safety Officer will issue an authorization. The Radiation Safety Office/EHS will provide the application forms.

6.1.5 Management Controls

UMB will develop, maintain, and implement detailed written procedures that establish requirements for authorizing usage of radioactive materials. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the radioactive materials authorization program is effectively implemented in accordance with the applicable procedures, regulations, and license conditions.

6.2 Radioactive Material Procurement, Receipt, and Distribution

The acquisition of radioactive materials by purchase, transfer, or as a gift requires prior approval of the Radiation Safety Office/EHS. Unless otherwise approved by the Radiation Safety Committee, all radioactive materials destined for UMB are received by the Radiation Safety Office/EHS. All arriving and departing radioactive materials need to be entered into a campus-wide inventory database.

6.2.1 Procurement of Radioactive Material

Unless otherwise approved by the Radiation Safety Committee, requisitions prepared by Authorized Users must be submitted to the Radiation Safety Officer for review and approval. Approved requisitions will be processed as appropriate.

6.2.2 Receipt of Radioactive Material

All arriving materials will be evaluated for contamination and radiation readings in accordance with applicable procedures. The Radiation Safety Officer will be notified immediately if either contamination or radiation readings of the transport package exceed regulatory limits.

6.2.3 Transfer of Radioactive Material from UMB to Other Recipients

The shipper of radioactive material must notify the Radiation Safety Officer of the proposed transfer and provide evidence that the recipient is authorized to receive the radioactive material. The radioactive material must be delivered to the Radiation Safety Office/EHS along with a description of the article, such as the nature of radionuclide, the chemical form, the quantity (activity), the name, address, license number and phone number of the addressee.

6.2.4 Transfer of Radioactive Materials Between Authorized Users

Radioactive materials can be transferred between Authorized Users with prior written approval from the Radiation Safety Officer.

6.2.5 Management Controls

UMB will develop, maintain, and implement detailed written procedures that establish requirements for acquisition, use and disposition of radioactive materials. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the radioactive materials acquisition and disposition program is effectively implemented in accordance with the applicable procedures, regulations, and license conditions.

6.3 Sealed Radioactive Source Control

UMB has been licensed by the State of Maryland to possess and use certain sealed radioactive sources. These radioactive sources are used for a variety of activities, including research, patient diagnosis and treatment, and operational checks of instruments, depending on the activity of the source and the nature of its installation and use. The hazards associated with these sources vary widely, from minimal to extremely hazardous. To ensure continuing control over the storage and use of these sources, UMB implements a system of control and periodic inventories and leak tests. The source control system assigns responsibility for certain sources to certain individuals. The inventory system provides a periodic check to ensure the source remains in the location and use specified by the control system. The leak test, performed by the Radiation Safety Office/EHS, provides warning of any significant failure of the radioactive material capsule or other container, consistent with its design parameters. Certain exceptions are provided based on source activity. UMB has developed implementing procedure(s) to support its sealed sources inventory control program.

6.3.1 Registration of Sources

All sources of radioactive material sealed or encapsulated, regardless of the activity must be registered with the Radiation Safety Office/EHS. This requirement applies to sources such as low activity check sources that are incorporated into machines or devices.

6.3.2 Leak Testing of Sealed Sources

All sealed sources containing 100 μCi or more of beta (β) or gamma (γ) emitting radionuclides or 10 μCi or more of alpha (α) emitting material in any form other than gas will be tested for leakage and contamination by the Radiation Safety Office/EHS at intervals not to exceed six months. Exceptions are as follows:

- Sources containing exclusively hydrogen-3;
- Sources containing radionuclides with a half-life less than 30 days;
- Iridium-192 seeds in nylon ribbons; and
- Sealed sources that are no longer in use.

6.3.3 Inventory Control

A physical inventory of all sealed sources must be conducted at least annually. The inventory will confirm the model, serial number (if any), location (room, building) of the source, and initials of the individual conducting the inventory. The Radiation Safety Office/EHS conducts an annual physical inventory of sealed sources in its storage and a semi-annual inventory of sources requiring leak tests.

6.3 Sealed Radioactive Source Control

6.3.4 Management Controls

UMB will develop, maintain, and implement detailed written procedures that establish requirements for inventory, control, and leak testing of sealed radioactive sources. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the sealed radioactive source control program is effectively implemented in accordance with the applicable procedures, regulations, and license conditions.

6.4 Patient Release and Clearance of Materials

As part of its ALARA and Radioactive Material Control Programs, UMB is committed to ensuring that both patients and materials released from UMB's restricted areas will minimize public exposure.

6.4.1 Patient Release

Patients or human research subjects containing radiopharmaceuticals or permanent implants will not be released from confinement for medical care until it has been determined that the patient meets regulatory release requirements.

Patients or human research subject treated with temporary implants will not be released from confinement for medical care until:

- Immediately after removing the last temporary implant source from a patient or human research subject, a radiation survey of the patient or human research subject with a hand held radiation survey instrument has been performed to confirm that all sources have been removed; and
- A record of the patient or human research subject surveys has been made.

Each record will include the date of the survey, the name of the patient or human research subject, the dose rate from the patient or human research subject expressed as millirem (microsieverts) per hour and measured within 1 meter from the patient or human research subject, and the initials of the individual who performed the survey.

6.4.2 Clearance of Materials

It is important that the RSP maintain the ability to release specified areas, materials, and equipment from ongoing radiological controls. Such releases (referred to as "clearance") increase the efficiency of the program by:

- Saving resources that might otherwise be spent on maintaining controls where not needed;
- Eliminating the need to purchase new equipment to replace equipment that may have been exposed to radioactive contamination; and
- Reducing the volume of radioactive waste to be processed and disposed of by segregating non-radioactive from radioactive waste.

Clearance of areas, materials, and equipment is achieved by careful monitoring of affected surfaces, decontamination as necessary, and, if the radiological conditions meet defined criteria, release of the area or object. Any markings or labels identifying the area or object as radioactive must also be removed or defaced to eliminate the possibility of falsely alarming affected individuals.

6.4 Patient Release and Clearance of Materials

6.4.3 Management Controls

UMB will develop, maintain, and implement written procedure(s) that establish requirements for release of patients and clearance of areas, materials, equipment, and personnel. The release criteria provided in these procedures will be consistent with the requirements provided in COMAR and guidance provided in USNRC Regulatory Guide 10.8 (based on the guidance provided in Regulatory Guide 1.86). UMB will conduct routine audits and implement corrective actions as necessary to ensure that the patient release and material clearance programs are effectively implemented in accordance with the applicable procedures, regulations, and license conditions.

CHAPTER 7 - AREA MONITORING PROGRAM

7.1 General

Knowledge of area radiological conditions is required to properly plan and execute radiological work activities, ensure the continued proper operation and integrity of devices and facilities that contain radioactive material or generate radiation, and ensure compliance with various regulatory requirements, including requirements for hazard posting and labeling, access control, individual monitoring, radiation safety training, and ALARA. This knowledge is acquired through a program of routine and special monitoring of areas and items using specialized monitoring (survey) instruments.

7.2 Types of Monitoring Equipment

The monitoring equipment used at facilities operating under UMB's Radiation Safety Program includes:

- Portable radiation monitoring instruments that provide indication in dose or exposure per unit time;
- Fixed radiation monitoring instruments that activate alarms and/or protective features;
- Contamination monitoring instruments that provide indication in count rate, (convertible to disintegrations per unit time); and
- Air sampling instruments, which collect samples for subsequent analysis.

7.3 Calibration and Use of Portable Radiation Survey Instruments

UMB's radiological monitoring program requires that surveys be performed by knowledgeable individuals using properly selected and calibrated instruments. The instrument(s) used must be appropriate for the type(s), level(s), and energy(ies) of the radiation(s) encountered in the affected area. The instruments must be calibrated properly and operated in accordance with approved implementing procedure(s) to ensure consistent, accurate results.

7.4 Performance of Area Monitoring

7.4.1 To ensure that radioactive materials are confined to their designated use and storage areas and to ensure that radiation levels in both restricted areas and unrestricted areas are within regulatory limits, the Authorized User or his/her designee and the Radiation Safety Office/EHS will perform periodic radiological surveys.

7.4.2 The following elements apply to implementing procedures for surveys:

- Use of the proper survey instrument for the type of radionuclide being surveyed;
- Frequency of surveys commensurate with the hazards involved;
- Special survey requirements, if applicable;
- Documentation of survey results;
- Action levels for radiological conditions;
- Corrective action as necessary based on survey results;
- Review of survey results by the Radiation Safety Office/EHS.

7.5 Contamination Action Levels

UMB has established within its restricted areas a removable contamination action level of 200 dpm/100 cm^2 for beta/gamma-emitting radionuclides. Areas having removable contamination in excess of the UMB action level will be decontaminated as soon as practicable and resurveyed until removable contamination levels are below the action level. The individual performing the survey shall notify the Radiation Safety Office/EHS immediately upon discovery of contamination levels exceeding 1000 dpm/100 cm^2.

7.6 Confirmatory Surveys

In support of the UMB internal audit program, the Radiation Safety Office/EHS will perform periodic confirmatory surveys to ensure that Authorized Users or their designees have performed their required radiological surveys properly and that such survey results are documented. The type, frequency, and areas of survey will be determined by the Radiation Safety Office/EHS and will consist of both announced and unannounced surveys. All surveys will be documented and are available to Authorized Users and the Radiation Safety Committee for review.

In addition to the above independent confirmatory surveys, staff of the Radiation Safety Office/EHS will also perform additional surveys to meet commitments under the RSP of the license. These surveys will be documented and are available to Authorized Users and the Radiation Safety Committee for review.

7.7 Management Controls

UMB will develop, maintain, and implement written procedure(s) that establish requirements for monitoring of areas in and around UMB facilities. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the area-monitoring program is effectively implemented in accordance with the applicable procedures, regulations, and license conditions.

CHAPTER 8 - RADIATION SAFETY TRAINING

8.1 Program Scope and Content

UMB has established a Radiation Safety Training Program to ensure affected individuals are knowledgeable of:

- Any means that might be used to inform individuals of the storage, transfer, or use of radiation or radioactive material;
- The health protection problems associated with exposure to radiation or radioactive material;
- The precautions or procedures to minimize exposure;
- The purposes and functions of protective devices used at UMB;
- Applicable provisions of COMAR regulations and UMB's radioactive material licenses addressing protection of personnel from radiation exposure, and their responsibility to comply with these requirements;
- Individual responsibilities for promptly reporting to UMB any condition that may constitute, lead to, or cause a violation of the Atomic Energy Act, COMAR regulations, or UMB's radioactive material licenses or that may result in unnecessary exposure to radiation or radioactive material;
- Appropriate responses to warnings (e.g., lights, alarms, verbal warnings) that may result from any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and
- Radiation exposure reports that individuals may request.

8.2 Program Scope

The Radiation Safety Training Program has been established in a manner that allows for provision of training that is consistent with the hazards to which individuals will be exposed, the protective measures they will be required to implement, and their previous education, training, and experience. The major components of the Radiation Safety Training Program are the Radiation Worker Registry, which identifies affected individuals, and lesson plans and agendas, schedules, and facilities.

8.3 Radiation Worker Registry

Applicable regulations require that those who may work with radioactive materials or x-ray producing machines be provided training and be monitored for potential radiation exposure. Certain exceptions are provided for individuals who are likely to receive only incidental radiation doses. In order to assure compliance with these regulations, the Radiation Safety Office/EHS maintains a Radiation Worker Registry. This registry includes all individuals who are enrolled in the Radiation Dosimetry Program. Failure to register in the Radiation Worker Registry is considered an infraction of the terms and conditions of the authorization.

8.4 General Training

8.4.1 Consistent with MDE regulations, UMB requires that all radioactive material users (except those who may be excepted due to the incidental nature of their expected exposures) successfully complete a radiation safety-training course.

8.4.2 All occupationally exposed individuals are expected to schedule attendance in the general radiation safety-training course within sixty days of registering with Radiation Safety Office/EHS.

8.4.3 Upon completion of the required training, each student shall successfully complete appropriate written examinations. UMB may implement other arrangements (e.g., oral examinations) for individuals having special needs, such as language deficiencies.

8.4.4 Refresher training shall be provided as necessary to ensure that radiation workers are provided the latest site specific and other updated radiation protection information.

8.4.5 UMB will develop, maintain, and implement written procedures to establish the minimum content of the Radiation Safety Training Program in accordance with the applicable requirements of COMAR and UMB's radioactive materials licenses. In addition to the minimum content required by COMAR and UMB's radioactive material licenses, UMB will enhance the training as necessary to address issues related to implementation of UMB's Radiation Safety Program, any applicable incidents or events, results of audits or other program reviews, and other issues deemed pertinent by the RSC.

8.5 Specific Training

8.5.1 Training on Implementing Procedures

The Authorized User is responsible for ensuring that all individuals following the appropriate implementing procedures be trained with respect to those procedures. Such training will be documented. Radiation Safety Office/EHS will provide support as needed.

8.5.2 Training on Emergency Procedures

Emergency procedures will be posted in each radioactive materials use and storage area. The management of the Authorized User or the Authorized User or his/her designee is responsible for ensuring that all individuals that may need to follow the emergency procedures be trained with respect to those procedures. Training on emergency procedures is also included in the Radiation Safety Training course. Such training will be documented. Radiation Safety Office/EHS will provide support as needed.

8.5.3 Training for Authorized Users

The Radiation Safety Committee is responsible for reviewing and approving the training of Authorized User applicants in accordance with COMAR and the conditions of the applicable license. The Radiation Safety Officer is responsible for ensuring that all pertinent documentation for Authorized Users is filed in the Radiation Safety Office/EHS.

8.6 Management Controls

UMB will develop, maintain, and implement written procedure(s) that establish requirements for conduct of the Radiation Safety Training Program. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the Radiation Safety Training Program is effectively implemented in accordance with the applicable procedures, regulations, and license conditions.

CHAPTER 9 - RADIOACTIVE WASTE DISPOSAL

9.1 General

The nature of the activities performed at facilities operating under UMB's Radiation Safety Program unavoidably results in the generation of material that must be handled as radioactive waste. Because of the hazards and expense associated with handling and disposal of radioactive waste, every reasonable effort should be made to reduce the volume and activity of radioactive waste generated during work activities. Radioactive waste that is generated is handled by one of five methods as appropriate.

9.2 Types of Waste

9.2.1 Patient excreta

Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are exempt under COMAR Section D.1003b.

9.2.2 Decay-In-Storage

Waste that contains only radioactive material having a short half life (90 days or less) may be stored for decay. After the radioactive material has decayed below acceptable values (i.e., at background), the waste maybe disposed of as non-radioactive waste.

9.2.3 Disposal Into Sanitary Sewer

Authorized users can apply to EHS for a permit to dispose of radioactive waste into the sanitary sewer, provided all the requirements of COMAR Section D.1003a are met. EHS will ensure, through its permits, that all UMB Authorized Users with EHS permits will not exceed the limits of Section D.1003a(iv), that is, annual discharge of 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials combined.

9.2.4 Exempt Quantities

COMAR Section D.1006 authorizes UMB to dispose of 0.05 μCi (1.85 kBq) or less of hydrogen-3, or carbon-14 per gram of medium used for liquid scintillation counting and animal tissue if certain conditions are met. These types of waste can be incinerated under UMB's incinerator license issued by MDE/RHP. Careful monitoring is performed to ensure effluents and ash, from the incinerator, fall with acceptable values.

9.2.5 Disposal to an Authorized Radioactive Burial Facility

The remaining waste products must be processed into an acceptable waste form, packaged, and transported to a licensed burial facility.

9.3 EHS Requirements for Waste Disposal and Pickup

9.3.1 Authorized Exceptions

In accordance with federal and state requirements, all radioactive waste generated under licenses issued to UMB must be consigned to the Radiation Safety Office/EHS for disposal. The exceptions are:

- Certain aqueous radioactive liquids may be discharged to the sanitary sewer, but only after a permit has been obtained from EHS;

- Short lived nuclides (nuclides with a half-life of less than 90 days) may be held for decay-in-storage at the point of generation. Holding material for a period equivalent to ten half lives and survey to ensure the radioactivity is at background is required prior to disposal; and

- Release to the atmosphere may be necessary in certain circumstances, but this type of release as a result of use may not be used without specific written approval from the Radiation Safety Officer.

9.3.2 Waste Generator (Authorized User) Responsibilities

It is the responsibility of the waste generator to properly identify and prepare radioactive waste, in accordance with implementing procedure(s), for disposal by EHS. EHS will not accept the waste until it is properly identified, quantified, segregated, packaged, and documented.

9.4 Management Controls

UMB will develop, maintain, and implement written procedures as necessary to ensure that radioactive waste is handled, stored, packaged, and disposed of as required by applicable COMAR and license requirements. UMB will conduct routine audits and implement corrective actions as necessary to ensure radioactive waste procedures are effectively implemented in accordance with the applicable procedures, regulations, and license conditions.

CHAPTER 10 - RADIATION SAFETY RECORDS AND REPORTS

10.1 Radiation Safety Program Records

10.1.1 Purpose and Scope of Records Program

It is necessary to develop, process, distribute, and retain a variety of written and electronic records to demonstrate and assess the adequacy of the Radiation Safety Program. These records are necessary to demonstrate to affected managers and regulatory officials that the program has been implemented in a manner that meets applicable procedures and verbal and written commitments made by UMB. These records may also be necessary in the event that UMB must provide a defense in any litigation arising out of its activities involving radiation and radioactive materials. Radioactive material users and other affected individuals are responsible for creating high quality records that are suitable for reproduction, distribution, and retention.

10.1.2 Management Controls

UMB will develop, maintain, and implement written procedures as necessary to ensure that radiation safety records are created, reviewed, and retained as required by applicable COMAR and license requirements. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the radiation safety records are sufficient to document the implementation of the Radiation Safety Program in accordance with the applicable procedures, regulations, and license conditions.

10.2 Radiation Safety Program Reports

10.2.1 Purpose and Scope of Reports Program

To demonstrate compliance with regulatory and license requirements, allow for assessment of program effectiveness, and provide information regarding unplanned events, UMB is required to provide a variety of reports to RHP/MDE, other agencies, and affected individuals. Pertinent reports include notifications of incidents (e.g., overexposures), reports of loss of radioactive material, and reports of routine individual doses. While supporting information from other Departments is often necessary, generation and routing of these reports are generally the responsibilities of the Radiation Safety Office/EHS.

10.2.2 Management Controls

UMB will develop, maintain, and implement written procedures as necessary to ensure that radiation safety reports are created, reviewed, submitted, and retained as required by applicable COMAR and license requirements. UMB will conduct routine audits and implement corrective actions as necessary to ensure that the radiation safety reports are developed, submitted and retained in accordance with the applicable procedures, regulations, and license conditions.

CHAPTER 11 – RADIATION SAFETY AUDIT PROGRAM

11.1 Purpose of Radiation Safety Audits

A properly managed radiation safety program requires a comprehensive audit program to assess its effectiveness and user compliance. Types and frequencies of these audits depend on many factors such as the nature, quantity, and use of radioactive materials. UMB implements internal audits to assist Authorized Users in maintaining a safe environment. UMB will utilize external audits as necessary to provide an independent overview of its radiation safety program.

11.2 Nature of Internal Audits

Internal audits will address radiological safety issues applicable to the specific authorization and may include:

- A review of the authorization file to ascertain that all requirements are observed and completed;
- A review of inventory of radioactive materials to ensure that only authorized radionuclides are present in quantities equal to or less than the authorization limits;
- An examination of posting and labeling in applicable locations;
- Availability of proper instrumentation to conduct authorized activities;
- A review of contamination survey records to ensure that surveys are conducted in accordance with UMB RSP and implementing procedures;
- An observation of laboratory practices/procedures to determine compliance with UMB RSP and pertinent regulatory requirements;
- A review of radioactive waste disposal practices/procedures and records to determine compliance with UMB RSP and pertinent regulatory requirements;
- A review of acquisition and use of personnel monitoring equipment in accordance with UMB RSP and implementing procedures;
- Assurance that using radioactive material are properly instructed consistent with UMB RSP and implementing procedures;
- Assessment of any potential contamination; and
- A review of methods for ensuring security of radioactive materials.

11.3 Types of Audits

11.3.1 Routine Audits

Each authorization for the possession and use of radioactive material will be routinely inspected by EHS staff. Authorizations for the use of radioactive material in medical diagnosis or therapy will be audited at approximately monthly intervals. All other authorizations will be audited at a frequency determine by the Radiation Safety Office/EHS. However, these audits will be conducted no less frequently than once each year.

11.3.2 Special Audits

Special audits are performed for the resolution of any complaints, allegations, incidents, or as a follow-up of previous non-compliance issues. These audits will be conducted at the discretion of the Radiation Safety Office/EHS in consultation with the Radiation Safety Committee.

11.3.3 Annual Program Reviews

COMAR requires that UMB conduct reviews of the Radiation Protection, ALARA, and Radioactive Material Programs no less frequently than once each year. These reviews are also considered audits for the purposes of this document.

11.4 Audit Findings and Enforcement

The Radiation Safety Office shall review the audit findings and, if applicable, send a report to the Authorized User responsible for the audited activity. The Radiation Safety Committee and the Director, EHS will be provided all items of noncompliance that cannot be resolved between the Authorized User and the Radiation Safety Office/EHS.

11.5 Management Controls

UMB will develop, maintain, and implement written procedures as necessary to ensure that radiation safety audits are performed and corrective actions implemented as required by applicable COMAR and license requirements. UMB's audit program will include a self-audit to ensure the program satisfies the applicable regulations, and license conditions.