University of Maryland, Baltimore

Radiation Safety Procedure

Procedure Number: 1.5

Title: Radiation Safety Audit Program

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Technical Review and Approval:

_____Date:_____

Radiation Safety Officer

Radiation Safety Committee Approval:

_____Date:_____

Chair, Radiation Safety Committee

PROCEDURE 1.5 – RADIATION SAFETY AUDIT PROGRAM

1.0 Purpose:

This procedure outlines the requirements for the audit program established at UMB as an internal means of assuring an adequate level of radiation safety and compliance with applicable regulatory and licensing requirements.

2.0 Scope:

This procedure is applicable to all formal (e.g., monthly, quarterly, and annual) EHS audits of the radiation safety program. The requirements of this procedure are not intended to constrain the routine oversight responsibilities of the EHS staff.

3.0 Procedure:

3.1. Scheduling of Audits

3.1.1. The RSO shall establish a schedule to ensure all required radiation safety program audits are performed. This schedule shall include, at a minimum:

- A quarterly review by the Radiation Safety Committee, with the assistance of the RSO, of occupational radiation exposure records of all individuals who work with radioactive material [G.8(b)(6)];
- A quarterly review by the Radiation Safety Committee, with the assistance of the RSO, of all incidents and misadministrations involving radioactive material, including incident causes and corrective actions [G.8(b)(7)];
- An annual review of the ALARA Program by the Radiation Safety Committee to ensure that individuals make every effort to maintain occupational doses, doses to members of the public, and radioactive releases ALARA [G.6(a)(3)];
- An annual review by the Radiation Safety Committee of the radioactive material program and the radiation protection program (referred to collectively as the radiation safety program) [D.101(c), G.8(b)(8)];
- An annual review of the Quality Management Program [G.6(c)(2)(i)]

3.1.2. The entire annual review of the radiation safety program need not be performed by one individual at the end of the year. The RSO may, at his discretion, separate the annual review into component parts for performance on a periodic (e.g., monthly or quarterly) basis. The component parts should be compiled into an integrated report at the end of the year.

3.2. Scope and Content of Audits

3.2.1. The quarterly audit of occupational radiation exposure records should include:

- A review of all exposure records, with special attention to any records that indicate prescribed action levels have been approached or exceeded;
- A review of any corrective actions taken in response to individuals exceeding prescribed action levels;
- Analysis of collective occupational doses for each quarter, segregated as may be effective (e.g., by activity, work group, type of material, etc.) to identify possible positive or adverse trends;
- Development of a summary report, including trends and corrective actions for approval by the RSC.

3.2.2. The quarterly review of all incidents and misadministrations involving radioactive material, should include, at a minimum:

- A review of all misadministrations reported in accordance with COMAR Sections D.1208 and D.1209;
- A verification that each report addresses the regulatory requirements for those reports;
- Incident causes and corrective actions;
- Analysis of reported misadministrations over a representative period of time, segregated as may be effective (e.g., by type of procedure, department, type of material) to identify possible positive or adverse trends;
- Development of a summary report, including trends and corrective actions for approval by the RSC.

3.2.3. The annual review of the ALARA Program shall include, at a minimum:

- A review of summaries of the types and amounts of radioactive materials used [G.6(a)(3)];
- A review of occupational dose reports [G.6(a)(3)];

- A review of the continuing education and training for all occupationally exposed individuals [G.6(a)(3)];
- Analysis of the information listed above, to detect possible positive or adverse trends; and
- Development of a summary report, including trends and corrective actions for approval by the RSC.

3.2.4. The annual review of the Quality Management Program shall include an evaluation of:

- A representative sample of patient and research subject administrations [G.6(c)(2)(i)(a)];
- All recordable events [G.6(c)(2)(i)(b)]; and
- All misadministrations [G.6(c)(2)(i)(c)].

3.2.5. UMB shall evaluate each of these reviews to determine the effectiveness of the Quality Management Program. Based on this evaluation, UMB shall make modifications to the Quality Management Program as necessary to meet the program objectives [G.6(c)(2)(ii)].

3.2.6. The annual review of the radiation safety program should include, at a minimum, a review of each functional element of the radiation safety program to determine the extent of compliance with applicable regulatory and license requirements, UMB policies, programs and procedures, and other commitments (e.g., responses to previously issued Notices of Violation), and current industry standards. The RSO may identify the functional elements of the radiation safety program as necessary to facilitate conduct of the audit. In general, the functional elements of the radiation safety program include:

- Radiation Safety Program Organization and Administration;
- ALARA Program;
- Fetal Protection Program;
- Radiation Safety Training Program;
- Radioactive Material Procurement, Receipt, and Use;
- Radioactive material Control/Access Control Program;
- Area Monitoring and Instrument Calibration Program;
- Contamination Control Program;
- Individual Monitoring Program;
- Sealed Radioactive Source Program;
- Posting and Labeling Program;
- Medical Use Programs;
- Radiation Safety Recordkeeping and Reporting; and
- Radioactive Material Transportation Program.

3.2.7. The individual performing the audit shall prepare appropriate checklists or use checklists prepared or approved by the RSO. The checklists should be used to guide, but not to limit, the scope of the auditor's activities.

4.0 Records and Reports:

4.1. Records

4.1.1. Records of radiation safety audits shall include:

- The name and signature of the individual(s) performing the audits;
- Date(s) on which the audit was conducted;
- Completed audit procedures or checklists, as appropriate;
- Audit findings, including any strengths or weaknesses [G.6(2)(c)(iii)].

4.1.2 Radiation safety records shall be created and maintained consistent with the requirements of Procedure 1.2, *Radiation Safety Records*.

4.2. Reports

There are no specific reports associated with the Radiation Safety Audit Program. However, a Radiation Safety Program audit could reveal a reportable event. See Procedure 1.3, *Radiation Safety Reports*, for information on reportable events.

5.0 References:

COMAR Part D, Section 101(c)
COMAR Part G, Section 6(a)(3), 6(c)(2), 8(b)(6) - (8)
UMB Radiation Safety Program